The hinge design of the two products is the same with slight modifications in the implant stem shape to accommodate differences in the anatomy of the phalanges. Drawing is included in Appendix D.

The new Sutter PIP prosthesis is constructed of silicone, the material was originally approved for use in 1981 under the Material Identification of PEHT 400 series. The material has twelve years of proven clinical performance. Material properties and independent laboratory testing of the material is included in Appendix E.

Material testing performed includes:

- Hemolysis test
- Physico Chemical
- MEM Elution
- Inhibition of Cell Growth
- Limulus Inhibition test
- USP Toxicity Class VI-121 deg C
  - Systemic Injection
  - Type B, Intracutaneous::Saline
  - Type B, Intracutaneous::EtOH
  - Type B, Intracutaneous::Oil
  - Type B, Intracutaneous::PEG
- Implantation test USP XX
  - Gross and Macroscopic
- Flex testing
- Abrasion testing
- Shear testing

7. SAFETY AND EFFECTIVENESS SUMMARY:

Materials used in the Sutter finger implant are the same materials and manufacturing processed currently used in many Sutter implants including the Sutter MCP finger joint implant. The implants are made of Bulk Silicone Elastomer. GMP controls are in place and adhered to for current manufacturing of all Sutter Products.

We believe the proximal interphalangeal joint implant to be safe and effective. No new technologies are employed in the design or manufacture of the device. We believe that the device is substantially equivalent to other Sutter implants as well as the referenced competitors' product already in commercial distribution. We request clearance to introduce the device for distribution in ninety days.

Sincerely,

Louise M. Focht

Louise M. Focht
Director Quality Assurance
Sutter Corporation
619-569-8148 x 2213

Enclosures:

Appendix A	Proposed Labeling
Appendix B	Surgical Technique
Appendix C	Equivalent Product Literature
Appendix D	Drawing
Appendix E	Material properties, testing, previously approved under 510k submission

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 2/8/05

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K9315-88/A2

To: Division Director: OR/DCRND

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____Additional information requires a new 510(k); however, the information submitted is incomplete; (Noitify company to submit a new 510(k);[Prepare the K30 Letter on the LAN]

_____No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

____Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: _____

Date: QUD. CCON - 2/25/05

Draft #2 : 9/8/99
Draft #3: 1/3/00
Draft #4: 3/7/03

POS

DMC 2/28

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2005

Mr. Mike Simpson
President
Small Bone Innovations
505 Park Avenue, 14th Floor
New York, NY 10022

Re: k812691 – Silicone Implants
k870200 – Sutter Finger Joint Prosthesis
k931588 – Sutter Proximal Interphalangeal Joint
k943853 – Distal Radius Fracture Fixation Plate System
k943873 – Orthomet Anatomcially Guided Carpal Tunnel Release System
k964359 – Avanta Orthopaedics Tendon Spacer
k965204 – Avanta Orthopaedics Trapezium Implant
k974911 – External Fixator
k981715 – Distal Radius Fracture Fixation Plate System
k981716 – External Fixator
k982268 – Ulnar Head Implant
k982288 – Radial Head Implant
k990596 – Distal Radius Fracture Fixation Plate System
k002644 – Avanta Radial Head Implant
k003033 – SCAPHIX Staple
k010786 – Ulnar Head Implant
k010847 – K-fix pin cap
k011819 – Radial Head Implant
k013629 – Finger Joint Prosthesis
k021859 – Wrist Implant
k023604 – Radial Head Implant
k030881 – Avanta Carpal Fusion Plating System

Dear Mr. Simpson:

We have reviewed your letter, dated January 31, 2005, stating that the rights to the above referenced premarket notifications (510(k)) have been transferred. Transfer of 510(k) rights alone does not require submission of new 510(k)s under 21 CFR 807.81(a)(3). Consequently, we cannot change the name of the original 510(k) submitters in our database. We suggest that information showing the transfer of the 510(k)s and their current ownership should be maintained in the company's files for review by an FDA investigator. You may contact the Center for Devices and Radiological Health's Office of Compliance at (240) 276-0100 if you have any questions on what information we expect to be maintained in your files.

2

If you have any other questions regarding this letter, please contact the 510(k) Staff at (301) 594-1190.

Sincerely yours,

Heather S Rosecrans

Heather S. Rosecrans
Director, Premarket Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: Don Guthner
Vice President
Musculoskeletal Clinical Regulatory Advisers, LLC
505 Park Avenue, 14th Floor
New York, NY 10022

Avanta Ortopaedics
9369A Carroll Park Drive
San Diego, CA 92121

Orthomet, Inc.
6301 Cecilia Circle
Minneapolis, MN 55439

H.Doug Plunkett
Avanta Orthopaedics, Inc.
9369 Carroll Park Drive, Suite A
San Diego, CA 92121

Sutter Corporation
9425 Chesapeake Drive
San Diego, CA 92123

Wright Medical Technology
5677 Airline Road
Arlington, TN 38002

Stuart, Julie

From: Garcia, Diane
Sent: Thursday, February 17, 2005 1:23 PM
To: Stuart, Julie
Subject: FW:

Diane Garcia
ODE/Program Operations Staff
HFZ-404
301-594-1190 ext. 157

-----Original Message-----
From:
Sent: None
Subject:

Dear Ms. Garcia,

In response to your telephone inquiry this morning, we are providing the following information:

In 1997, The Cretex Companies, Inc. acquired Avanta Orthopaedics Corp. as exhibited by the attached .pdf file of a copy of the 1998 Annual Registration Change. Since that time each annual registration up to 2004 has reflected the owner/operator as The Cretex Companies.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

Don Guthner

Donald W. Guthner

Vice President
Musculoskeletal Clinical and Regulatory Advisors, LLC
505 Park Ave., 14th Floor
New York, New York 10022
(212) 583-0250 x148
(212) 750-2112

K931588/A2

SBi
SMALL BONE INNOVATIONS

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

January 31st, 2005

RE: Transfer of Ownership, Avanta Inc. product line.

Dear Sir/Madam:

1. Ownership of the referenced product line in attachment #1 is transferred from The Cretex Companies, Inc., effective 12-31-2004, to Small Bone Innovations, LLC.

2. A new FDA Form 3514 signed by an authorized agent of Small Bone Innovations, LLC is provided in attachment #2.

3. Evidence for new ownership of the Avanta Inc. product line is provided in attachment #3.

4. A complete copy of all product regulatory files has been provided to Small Bone Innovations, LLC by Avanta LLC.

5. Revised draft labeling changes is provided as attachment #4. The revised labeling will be implemented in the first quarter of 2005, or to the exhaustion of the present labeling supplies, whichever comes first.

6. Small Bone Innovations, LLC understands that all changes in approved products from those described by the original applicant will require an approved supplement before enacting unless specifically exempt from prior FDA approval.

If there are any questions about this transfer please contact:

Don Guthner,
Vice President
Musculoskeletal Clinical Regulatory Advisers, LLC
505 Park Avenue, 14th Floor
New York, NY 10022
(212) 583-0250 ext. 148
dguthner@mcrallc.com

Sincerely,

Mike Simpson
President
Small Bone Innovations

505 Park Avenue, 14th Floor, New York, NY 10022
Phone (212) 583. 9700 Fax (212) 826. 9509

5

Attachment #1

Avanta Orthopedics, LLC.
FDA Approval Status

Product	Device Name	FDA Approval Type	FDA Approval #
Silicone MCP	Metacarpophalangeal Prosthesis	510K	K812691
Silicone Pre-Flex MCP	Metacarpophalangeal Prosthesis	510K	K870200
Silicone PIP	Finger Joint Prosthesis	510K	K013629
Silicone TRL Trap. Implant	Trapezial Implant	510K	K931588
Silicone TR Trap. Implant	Trapezial Implant	510K	K965204
[redacted]			
Braun-Cutter CMC (Avanta CMC)	Total Trapezio-Metacarpal Pros.	PMA	P960053
uHead	Ulnar Head Implant	510K	K982268
	Ulnar Head Implant	510K	K010786
rHead	Radial Head Implant	510K	K982288
	Radial Head Implant	510K	K002644
	Radial Head Implant	510K	K011819
rHead Recon	Modification to Radial Head Implant	510K	K023604
Wrist	Wrist Implant	510K	K021589
SCS Dorsal Plate	Distal Radius Fracture Fixation Plate	510K	K943853
Dorsal Buttress	Distal Radius Fracture Fixation Plate	510K	K990596
SCS Volar Plate	Distal Radius Fracture Fixation Plate	510K	K981715
Scaphix, Staple	Scaphix, Staple, Fixation, Bone	510K	K003033
K'Fix	K'Fix	510K	K010847
Tendon Spacer	Prosthesis, Tendon, Passive	510K	K964359
External Fixator	External Fixator	510K	K974911
	External Fixator	510K	K981716
GRS Carpal Tunnel	Anatomically Guided CT Release	510K	K943873
Carpal Fusion	Carpal Fusion Plating System	510K	K030881

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: September 30, 2004.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/31/2005		

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (120 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☑ Other *(specify):* Transfer of Ownership
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
Amendment	Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
Supplement	Supplement			
	Report			
	Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☑ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Small Bone Innovations, LLC			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(212) 583-9700		
Street Address	**FAX Number *(including area code)***		
505 Park Avenue, 14th Floor	(212) 826-9509		
City	**State / Province**	**ZIP/Postal Code**	**Country**
New York	NY	10022	USA
Contact Name			
Michael Simpson			
Contact Title	**Contact E-mail Address**		
President	msimpson@vbllc.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Musculoskeletal Clinical Regulatory Advisers, LLC.			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(212) 583-0250 ext.148		
Street Address	**FAX Number *(including area code)***		
505 Park Avenue, 14th Floor	(212) 826-9509		
City	**State / Province**	**ZIP/Postal Code**	**Country**
New York	NY	10022	USA
Contact Name			
Donald W. Guthner			
Contact Title	**Contact E-mail Address**		
Vice President	dguthner@mcrallc.com		

PSC Media Arts (301) 443-1090 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - Manufacturing
  - Sterilization
  - Packaging
  - Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - Software / Hardware
  - Color Additive
  - Material
  - Specifications
  - Other *(specify below)*

- ☐ Labeling change:
  - Indications
  - Instructions
  - Performance
  - Shelf Life
  - Trade Name
  - Other *(specify below)*

- ☐ Location change:
  - Manufacturer
  - Sterilizer
  - Packager

- ☐ Report Submission:
  - Annual or Periodic
  - Post-approval Study
  - Adverse Reaction
  - Device Defect
  - Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - Correspondent / Applicant
  - Design / Device
  - Informed Consent
  - Manufacturer
  - Manufacturing Process
  - Protocol - Feasibility
  - Protocol - Other
  - Sponsor

- ☐ Report submission:
  - Current Investigator
  - Annual Progress Report
  - Site Waiver Report
  - Final

- ☐ Repose to FDA Letter Concerning:
  - Conditional Approval
  - Deemed Approved
  - Deficient Final Report
  - Deficient Progress Report
  - Deficient Investigator Report
  - Disapproval
  - Request Extension of Time to Respond to FDA
  - Request Meeting
  - Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1		2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1		1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- ☐ Laboratory Testing
- ☐ Animal Trials
- ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
		☐ Class I ☐ Class II
Classification Panel		☐ Class III ☐ Unclassified

Indications *(from labeling)*

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

AVANTA
ORTHOPAEDICS

Attachment #3

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

January 20th, 2005

I HEREBY transfer all rights and ownership to the following PMA, HDE, and 510K's to Small Bone Innovations, Inc. 505 Park Avenue, 14th Floor New York, NY 10022 effective.

Silicone MCP	Metacarpophalangeal Prosthesis	510K	K812691
Silicone Pre-Flex MCP	Metacarpophalangeal Prosthesis	510K	K870200
Silicone PIP	Finger Joint Prosthesis	510K	K013629
Silicone TRL Trap. Implant	Trapezial Implant	510K	K931588
Silicone TR Trap. Implant	Trapezial Implant	510K	K965204
	(b)(4)		
Braun-Cutter CMC (Avanta CMC)	Total Trapezio-Metacarpal Pros.	PMA	P960053
uHead	Ulnar Head Implant	510K	K982268
	Ulnar Head Implant	510K	K010786
rHead	Radial Head Implant	510K	K982288
	Radial Head Implant	510K	K002644
	Radial Head Implant	510K	K011819
rHead Recon	Modification to Radial Head Implant	510K	K023604
Wrist	Wrist Implant	510K	K021589
SCS Dorsal Plate	Distal Radius Fracture Fixation Plate	510K	K943853
Dorsal Buttress	Distal Radius Fracture Fixation Plate	510K	K990596
SCS Volar Plate	Distal Radius Fracture Fixation Plate	510K	K981715
Scaphix, Staple	Scaphix, Staple, Fixation, Bone	510K	K003033
K'Fix	K'Fix	510K	K010847
Tendon Spacer	Prosthesis, Tendon, Passive	510K	K964359
External Fixator	External Fixator	510K	K974911
	External Fixator	510K	K981716
GRS Carpal Tunnel	Anatomically Guided CT Release	510K	K943873
Carpal Fusion	Carpal Fusion Plating System	510K	K030881

H. Doug Plunkett
Director
Avanta, Inc.

A. 9369A Carroll Park Drive · San Diego, California 92121 · (800)778-8837 · (858)452-8580 · (858)452-9945 facsimile

AVANTA
ORTHOPAEDICS
9369A Carroll Park Drive, San Diego, CA 92121 USA
(858) 452-8580 / (800) 778-8837 / (858) 452-9945 (fax)

MADE IN USA

WARNING: CLEAN, NOT STERILE

CE 0123

PRODUCT INSERT
INSTRUMENTS AND SIZERS

CAUTION: United States Federal Law restricts this device to sale by or on the order of a physician.

APPLICATION
Specialty instrumentation and sizers are designed to aid the surgeon in installation, assembly, and/or removal of a surgical device. The surgical techniques for implantation of the device describe the proper application of specialty instrumentation and should be read and understood by the surgeon prior to use.

WARNINGS
- Clean, not sterile, instruments and sizers must be sterilized prior to each use.
- Sizers are designed to aid in implant site preparation only. They must never be used as implants.
- The most common cause of instrument breakage is misuse. Specialty instrumentation should never be used for tasks it was not specifically designed to perform. Misuse of an instrument may result not only in damage to the instrument, but also trauma to the patient and operating room personnel.
- If not handled properly, instruments with cutting edges or sharp corners may compromise sterility by tearing surgical gloves.
- If an instrument tip becomes bent, chipped, or otherwise damaged the instrument should be replaced or repaired before further use. Attempts to straighten bends are not advised as the metallurgical integrity of the metal may be compromised in the process, and the instrument may subsequently break during use.

LIM 'ARRANTY
Av opaedics Corporation warrants that this product meets the manufacturer's specifications and is free from ma ring defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

CLEANING INSTRUCTIONS
- New instruments are packaged clean, not sterile and should be assumed to be contaminated. Instruments must be cleaned and sterilized before each use.
- For your safety, be familiar with the procedures for handling contaminated materials at your facility before following these instructions.
- Clean instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, use damp towels or sponges with deionized or distilled water to keep soiled instruments moist prior to cleaning.
- Manually scrub with a clean, soft-bristled brush or soft cloth in mild detergent following the detergent manufacturers instructions for use. Avoid using extreme detergent concentration levels. Detergents with enzyme cleaners or separate enzyme solutions may be used, but their effectivity has not been evaluated. Warm or hot water (300°F/149°C maximum) should be used to aid in cleaning. Ultrasonic cleaning is recommended for instruments with internal surfaces or crevices which may be hard to clean manually.
- pH neutral cleaners (pH 6.0-8.0) are recommended for longer life of the instruments. If acidic or alkaline solutions are used follow the manufacturers recommendations for neutralizing the pH by rinsing with water or neutralizing agent. Highly alkaline or acidic cleaners (used in some mechanical washers) are not recommended as they will reduce the life of the instruments and may effect instrument performance. Avoid prolonged exposure to acidic or alkaline solutions and solutions containing chlorides, bromides or iodine.
- Use of water soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.
- Rinse thoroughly with deionized water or distilled water.
- Dry completely before sterilizing.
- Inspect each instrument thoroughly for cleanliness, especially in broach teeth, internal surfaces and crevices. Instruments should be re-washed if there are any signs of foreign matter or residue. Check instruments thoroughly for damage. Do not use damaged instruments as they may compromise the surgical outcome, replace damaged instruments before next use.
- Silicone elastomer sizers may develop a static charge which attracts particulate matter. Sizers may be kept in sterile saline solution to minimize particulate pickup.
- Use of mechanical washers have not been evaluated by the manufacturer. Qualification of specific wash cycles and equipment should be completed by the user.

STERILIZATION
The recommended sterilization method is steam sterilization. EtO sterilization is not recommended for silicone sizers due to the lengthy airation time required for this material. The following sterilization cycles have been shown to produce a sterility assurance level of 10^{-6} when parts have been cleaned to the instructions above. Other similar steam cyles and cleaning procedures may be used but have not been evaluated. Sterilization qualification was performed using specific equipment and procedures. Use of cycles, equipment and procedures other than those listed should be qualified by the user. Do not exceed 300°F/149°C.

Wrapped Gravity Steam Sterilization 20 minutes minimum @ 270-275°F (132-135°C)
Wrapped Prevacumm Steam Sterilization 6 minutes minimum @ 270-275°F (132-135°C)
Unwrapped Prevacumm Steam Sterilization 4 minutes minimum @ 270-275°F (132-135°C)

For further information on the above cleaning and sterilization recommendations please contact:
Av thopaedics, 9369A Carroll Park Dr., San Diego, CA 92121
(8 3837 / (619) 452-8580 / (619) 452-9945 (Fax)

EU Representative:Medical Products International, BV, Schutweg 13a,
5145 NP Waalwijk, The Netherlands 31 (0) 416 563754

19-0351 rev D

AVANTA
ORTHOPAEDICS
9369A Carroll Park Drive, San Diego, CA 92121 USA
(858) 452-8580 / (800) 778-8837 / (858) 452-9945 (fax)

MADE IN USA

WARNING: CLEAN, NOT STERILE

CE 0123

PRODUCT INSERT
INSTRUMENTS AND SIZERS

CAUTION: United States Federal Law restricts this device to sale by or on the order of a physician.

APPLICATION
Specialty instrumentation and sizers are designed to aid the surgeon in installation, assembly, and/or removal of a surg cal device. The surgical techniques for implantation of the device describe the proper application of specialty instrume tation and should be read and understood by the surgeon prior to use.

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- The most common cause of instrument breakage is misuse. Specialty instrumentation should never be used for tasks was not specifically designed to perform. Misuse of an instrument may result not only in damage to the instrument, b also trauma to the patient and operating room personnel.
- If not handled properly, instruments with cutting edges or sharp corners may compromise sterility by tearing surgi gloves.
- If an instrument tip becomes bent, chipped, or otherwise damaged the instrument should be replaced or repaired befo further use. Attempts to straighten bends are not advised as the metallurgical integrity of the metal may be compromis in the process, and the instrument may subsequently break during use.

LIMITED WARRANTY
Avanta Orthopaedics Corporation warrants that this product meets the manufacturer's specifications and is free fr manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abus or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant t outcome of the surgical procedure.

CLEANING INSTRUCTIONS
- New instruments are packaged clean, not sterile and should be assumed to be contaminated. Instruments must cleaned and sterilized before each use.
- For your safety, be familiar with the procedures for handling contaminated materials at your facility before follow these instructions.
- Clean instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, use damp to els or sponges with deionized or distilled water to keep soiled instruments moist prior to cleaning.
- Manually scrub with a clean, soft-bristled brush or soft cloth in mild detergent following the detergent manufactur instructions for use. Avoid using extreme detergent concentration levels. Detergents with enzyme cleaners or separ enzyme solutions may be used, but their effectivity has not been evaluated. Warm or hot water (300°F/149°C maximu should be used to aid in cleaning. Ultrasonic cleaning is recommended for instruments with internal surfaces or crevi which may be hard to clean manually.
- pH neutral cleaners (pH 6.0-8.0) are recommended for longer life of the instruments. If acidic or alkaline solutions used follow the manufacturers recommendations for neutralizing the pH by rinsing with water or neutralizing age Highly alkaline or acidic cleaners (used in some mechanical washers) are not recommended as they will reduce the life the instruments and may effect instrument performance. Avoid prolonged exposure to acidic or alkaline solutions a solutions containing chlorides, bromides or iodine.
- Use of water soluble lubricants is recommended for instruments with moving parts or those intended to be assemb intraoperatively to another instrument.
- Rinse thoroughly with deionized water or distilled water.
- Dry completely before sterilizing.
- Inspect each instrument thoroughly for cleanliness, especially in broach teeth, internal surfaces and crevic Instruments should be re-washed if there are any signs of foreign matter or residue. Check instruments thoroughly damage. Do not use damaged instruments as they may compromise the surgical outcome, replace damaged instrume before next use.
- Silicone elastomer sizers may develop a static charge which attracts particulate matter. Sizers may be kept in ste saline solution to minimize particulate pickup.
- Use of mechanical washers have not been evaluated by the manufacturer. Qualification of specific wash cycles equipment should be completed by the user.

STERILIZATION
The recommended sterilization method is steam sterilization. EtO sterilization is not recommended for silicone sizers to the lengthy airation time required for this material. The following sterilization cycles have been shown to produ sterility assurance level of 10^{-6} when parts have been cleaned to the instructions above. Other similar steam cyles cleaning procedures may be used but have not been evaluated. Sterilization qualification was performed using spe equipment and procedures. Use of cycles, equipment and procedures other than those listed should be qualified by user. Do not exceed 300°F/149°C.

Wrapped Gravity Steam Sterilization 20 minutes minimum @ 270-275°F (132-135°C)
Wrapped Prevacumm Steam Sterilization 6 minutes minimum @ 270-275°F (132-135°C)
Unwrapped Prevacumm Steam Sterilization 4 minutes minimum @ 270-275°F (132-135°C)

For further information on the above cleaning and sterilization recommendations please contact:
Avanta Orthopaedics, 9369A Carroll Park Dr., San Diego, CA 92121
(800) 778-8837 / (619) 452-8580 / (619) 452-9945 (Fax)

EU Representative:Medical Products International, BV, Schutweg 13a,
5145 NP Waalwijk, The Netherlands 31 (0) 416 563754

19-0351

AVANTA
ORTHOPAEDICS
9617 Carroll Park Drive, San Diego, CA 92121 USA
(858)452-8580 / (800)776-8837 / (858)452-9945 (fax)

PRODUCT INSERT

METALLIC BONE FIXATION APPLIANCES AND ACCESSORIES

ENGLISH

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
The device consists of plates and screws for the treatment of the distal radius.

Materials:
- Stainless Steel 316 L, ASTM F 138, ASTM F 139
- 22-13-5 ASTM F-1314

INDICATIONS FOR USE
The intended use of the distal radius fracture fixation plate system is internal fixation of fractures and osteotomies of the distal radius. This may include:

- Displaced or non-displaced fracture which may or may not involve angulation or fragmentation of bone,
- Failed fracture fixation with or without bone graft,
- Osteotomy and repair of distal radius malunion with or without bone graft.

CONTRAINDICATIONS
- Active or latent infection
- Osteoporosis, insufficient quantity or quality of bone/soft tissue
- Material sensitivity – if suspected perform tests prior to surgery
- Sepsis
- Patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions

WARNINGS (See also the Patient Counseling Information Section)

- This device is intended for the use as described in this product insert only.
- Careful patient selection, education and counseling by the surgeon and rehabilitation care provided is important.
- Strenuous loading, excessive mobility, may lead to failure of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
- Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing.
- Improper insertion of the device during implantation can increase the possibility of loosening and migration.
- A poor result may be obtained if the fracture is not properly reduced or the device is not properly assembled.
- Explantation of this device may be necessary.
- Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

PRECAUTIONS
- An implant should never be reused. Previous stresses may have created imperfections which may lead to device failure.
- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. This is a single use device it is not intended for re-use. Re-sterilization is not recommended for the implant. Re-sterilization of the surgical instruments provided may be performed by following the instructions for use.
- Caution should be taken as to avoid nicking, scratching or other damage during handling of this device.
- Meticulous preparation of the implant site and selection of the proper size increase the potential for a successful outcome.
- The sterile products should be removed from its sterile package only after it is determined that the implant will be used on the patient.

ADVERSE EVENTS
- Adverse events published in the literature should be reviewed prior to using this device.
- Metal sensitivity reaction have been reported following metal implantation.
- Additional possible adverse events may include fracture of the bone, infection, pain and soft tissue irritation.

SURGICAL PROCEDURES
A manual is available describing detailed surgical procedure for use of this device. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings)
In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

- While the expected life of this device is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential fracture healing. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

STERILIZATION
- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. This is a single use device.

LIMITED WARRANTY
Avanta Orthopaedics Corporation warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU Representative:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

19-0361 rev D

DEUTSCH

PACKUNGSBEILAGE
Metallene Knochenfixierungsvorrichtungen und Zubehör

ACHTUNG
Nach dem Bundesgesetz (Vereinigte Staaten) ist dieses Medizinprodukt auf Verkauf, Vertrieb sowie Anwendung durch einen Arzt oder in dessen Auftrag beschränkt.

BESCHREIBUNG
Das Medizinprodukt besteht aus einer Platte und Schrauben zur Behandlung des distalen Radius.

Material:
- Rostfreier Stahl 316 L, entspricht ASTM F-138 oder ASTM F-139
- Rostfreier Stahl 22-13-5, entspricht ASTM F-1314

ANWENDUNGSGEBIETE
Das Fixierungsplattensystem für distale Radiusfraktur dient der internen Fixierung von Frakturen und Osteotomien des distalen Radius. Dazu gehören:
- Dislozierte und nicht-dislozierte Fraktur, die mit oder ohne Abwinkelung bzw. Fragmentierung des Knochens einhergehen kann
- Fehlgeschlagene Frakturfixierung mit oder ohne Knochentransplantat
- Osteotomie und Reparatur der Fehlheilung des distalen Radius mit oder ohne Knochentransplantat

GEGENANZEIGEN
- Aktive oder latente Infektion
- Osteoporose, unzureichende Menge oder Qualität des Knochens/Weichgewebes
- Empfindlichkeit gegenüber dem Material - wenn ein diesbezüglicher Verdacht besteht, sind vor dem chirurgischen Eingriff entsprechende Tests durchzuführen
- Sepsis
- Patienten mit mentalen oder neurologischen Erkrankungen, die nicht gewillt oder nicht fähig sind, die postoperativen Behandlungsanweisungen zu befolgen

WARNHINWEISE (Siehe auch den Abschnitt Informationen zur Patientenberatung)
- Dieses Medizinprodukt ist für den in dieser Packungsbeilage beschriebenen Verwendungszweck bestimmt.
- Sorgfältige Patientenauswahl, Edukation sowie Beratung durch den Chirurgen und den Leistungsanbieter für Rehabilitation sind besonders wichtig.
- Starke Belastung und übermäßige Mobilität können zum Ausfall des Medizinproduktes (Implantatversagen) führen. Die Patienten sind darauf hinzuweisen, dass sich das Ausfallrisiko des Medizinproduktes bei übermäßiger Beanspruchung erhöht.
- Bruch oder Beschädigung des Medizinproduktes können eintreten, wenn das Implantat bei verzögerter Frakturheilung, Pseudarthrose oder unvollständiger Heilung einer erhöhten Belastung ausgesetzt wird.
- Unsachgemäße Insertion des Medizinproduktes während der Implantation kann das Lockerungs- oder Migrationsrisiko des Implantats erhöhen.
- Ein schlechtes Ergebnis kann erzielt werden, wenn die Fraktur nicht korrekt eingerichtet oder das Medizinprodukt nicht ordnungsgemäß zusammengesetzt wird.
- Es kann erforderlich sein, dieses Implantat zu entfernen.
- Warnhinweis: Dieses Medizingerät ist nicht zur Verschraubung oder Fixierung an posterioren Elementen (Pedikel) der Halswirbel-, Brustwirbel- oder Lendenwirbelsäule zugelassen.
- Mitteilung gemäß dem Gesetz für sauberes Trinkwasser und zur Bekämpfung toxischer Stoffe des Bundesstaates Kalifornien (California Safe Drinking Water and Toxic Enforcement Act) von 1986 (Proposition 65): Dieses Produkt enthält eine Chemikalie/Chemikalien, von der/denen dem Bundesstaat von Kalifornien bekannt ist, dass sie Krebs und/oder Geburtsschäden und andere Reproduktionstoxizität erzeugt/erzeugen.

VORSICHTSMASSNAHMEN FÜR DIE ANWENDUNG
- Das Implantat darf nie wiederverwendet werden. Durch frühere Beanspruchungen können Störungen und Defekte entstanden sein, die zum Ausfall des Medizinproduktes führen können.
- Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn eine Beschädigung des Implantates oder der Verpackung vorzuliegen scheint, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden. Bei diesem Implantat handelt es sich um ein Medizinprodukt für einmaligen Gebrauch; es ist nicht zur Wiederverwendung bestimmt. Die Resterilisation des Implantates wird nicht empfohlen.
- Bei dem Umgang mit diesem Medizinprodukt ist darauf zu achten, dass Einkerbungen, Kratzer oder sonstige Beschädigungen vermieden werden.
- Sorgfältige Vorbereitung der Implantationsstelle und die Wahl der richtigen Größe des Implantates erhöhen die Erfolgsaussichten der Implantation.
- Das sterile Produkt ist erst aus seiner sterilen Verpackung zu entnehmen, wenn entschieden ist, dass das Implantat bei dem Patienten eingesetzt wird.

NEBENWIRKUNGEN
- Die in der Literatur veröffentlichten Nebenwirkungen sind vor Anwendung dieses Medizinproduktes zu beachten.
- Es wurde über Empfindlichkeitsreaktionen auf Metall nach Metallimplantation berichtet.
- Als weitere Nebenwirkungen können Knochenfrakturen, Infektionen, Schmerzen und Weichteilirritation auftreten.

CHIRURGISCHE VERFAHREN
Ein Handbuch mit einer genauen Beschreibung des chirurgischen Verfahrens zur Anwendung dieses Medizinproduktes ist verfügbar. Der Chirurg ist dafür verantwortlich, sich vor Anwendung dieses Medizinproduktes mit dem Verfahren vertraut zu machen. Der Chirurg ist weiterhin dafür verantwortlich, die einschlägigen Publikationen sorgfältig zu lesen und sich mit Berufskollegen zu beraten, die Erfahrung in der Anwendung dieser Vorrichtungen gesammelt haben.

INFORMATIONEN ZUR PATIENTENBERATUNG (Siehe auch Warnhinweise)
Neben den Patienteninformationen in den Abschnitten Warnhinweise und Nebenwirkungen sind dem Patienten die nachfolgenden Informationen zu vermitteln:

- Die erwartete Lebensdauer dieses Medizinproduktes ist zwar schwer zu bestimmen, aber sie ist begrenzt. Die Bestandteile sind aus Fremdstoffen gefertigt, die zur Erleichterung der Heilung einer potenziellen Fraktur in den Körper implantiert werden. Auf Grund einer Vielzahl biologischer, mechanischer und physikalisch-chemischer Faktoren, die diese Medizinprodukte beeinträchtigen, kann jedoch nicht erwartet werden, dass diese Bestandteile auf unbegrenzte Zeitdauer derselben Aktivitätsstufe und Belastung wie der normale gesunde Knochen standhalten.

STERILISATION
- Dieses Produkt wird mit Ethylenoxid (EO) sterilisiert.
- Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn das Implantat oder die Verpackung beschädigt zu sein scheinen, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden. Dies ist ein Medizinprodukt für einmaligen Gebrauch.

EINGESCHRÄNKTE GARANTIE
Avanta Orthopaedics Corporation gewährleistet, dass dieses Produkt die Spezifikationen des Herstellers erfüllt und bei der Lieferung keine Herstellungsfehler aufweist. Ausgeschlossen von dieser Garantie sind speziell Fehler, die auf nicht-bestimmungsgemäßen Gebrauch, Abusus oder unsachgemäße Handhabung des Medizinproduktes nach Eingang bei dem Käufer zurückzuführen sind. Für das Ergebnis des chirurgischen Verfahrens übernimmt Avanta Orthopaedics keine Garantie.

EU-Vertreter:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Niederlande
31 (0) 416 563754

FRANÇAIS

ENCART PUBLICITAIRE
Dispositifs et accessoires métalliques de fixation osseuse

ATTENTION
Les lois fédérales des États-Unis d'Amérique exigent que la vente, la distribution et l'utilisation de cet appareil soient assurées ou prescrites par un médecin.

DESCRIPTION
Ce dispositif comprend une plaque et des vis pour le traitement du radius distal.

Matériaux:
- Acier inoxydable 316 L conforme à la norme ASTM F-138 ou ASTM F-139
- Acier inoxydable 22-13-5 conforme à la norme ASTM F-1314

INDICATIONS
L'usage prévu de ce système de plaque pour fixation de fracture du radius distal est la fixation interne des fractures et ostéotomies du radius distal. Cela comprend notamment :

- fracture avec ou sans déplacement, comportant ou non une angulation ou une fragmentation de l'os,
- échec de fixation de fracture avec ou sans greffe osseuse,
- ostéotomie et réparation d'un cal vicieux du radius distal avec ou sans greffe osseuse.

CONTRE-INDICATIONS
- Infection active ou latente
- Ostéoporose, quantité ou qualité insuffisante d'os/de tissu osseux
- Allergie au matériau - en cas de suspicion d'allergie, faire des tests avant la chirurgie
- Sepsis
- Patients qui, du fait de leur état mental ou neurologique, n'ont pas la volonté suffisante ou sont incapables de suivre les instructions relatives aux soins post-opératoires.

AVERTISSEMENTS (voir aussi la section Conseils donnés au patient)
- Ce dispositif est uniquement prévu pour l'utilisation décrite dans cet encart.
- La sélection rigoureuse des patients, l'information et les conseils donnés au patient par le chirurgien et le prestataire de soins de réhabilitation sont importants.
- De fortes charges et une mobilité excessive peuvent entraîner l'échec du dispositif. Il faut informer le patient de l'augmentation du risque d'échec du dispositif en cas de sollicitations excessives.
- Une rupture ou un dommage du dispositif peut se produire si l'implant est soumis à une augmentation de charge associée à un retard de consolidation, une pseudarthrose ou une guérison incomplète.
- L'insertion incorrecte du dispositif pendant l'implantation peut augmenter la possibilité de relâchement et de migration.
- Le résultat obtenu peut être insatisfaisant en cas de réduction de fracture incorrecte ou d'assemblage incorrect du dispositif.
- Il peut être nécessaire d'explanter le dispositif.
- Avertissement : ce dispositif n'a pas reçu d'approbation pour l'attachement par vis ou la fixation aux éléments postérieurs (pédicules) de la colonne vertébrale (cervicale, thoracique ou lombaire).
- Notification conforme à la Proposition 65 de Californie (California Safe Drinking Water and Toxic Enforcement Act, acte exécutoire de la protection de l'eau potable contre les produits toxiques, approuvé en 1986) : ce produit contient un agent chimique connu dans l'État de Californie pour causer le cancer et/ou des malformations néonatales et autre toxicité liée à la reproduction.

PRÉCAUTIONS
- Il ne faut jamais réutiliser un implant. Les tensions précédentes peuvent avoir créé des imperfections risquant d'entraîner l'échec du dispositif.
- L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant. C'est un dispositif à usage unique ; il n'est pas prévu pour la réutilisation. Il n'est pas recommandé de restériliser l'implant.
- Il convient d'agir avec précaution pour éviter d'entailler, de rayer ou de causer un quelconque dommage à ce dispositif en le manipulant.
- Une préparation méticuleuse du site de l'implant et la sélection de la taille d'implant appropriée augmentent le potentiel de réussite.
- Les produits stériles ne doivent être enlevés de leur emballage stérile que si la décision d'implantation a été prise.

EFFETS INDÉSIRABLES
- Les effets indésirables publiés dans la littérature doivent être revus avant l'utilisation du dispositif.
- Des réactions d'allergie au métal ont été rapportées suite à l'implantation du dispositif.
- Les éventuels effets indésirables supplémentaires sont notamment : fracture osseuse, infection, douleur et irritation des tissus mous.

PROCÉDURES CHIRURGICALES
Un manuel est disponible ; il décrit en détail la procédure chirurgicale permettant d'utiliser l'implant. La connaissance de cette procédure est de la responsabilité du chirurgien. Il incombe également au chirurgien de se tenir au courant des publications pertinentes et de consulter des confrères expérimentés au sujet de la procédure à utiliser.

CONSEILS DONNES AU PATIENT (voir aussi Avertissements)
Outre l'information relative au patient qui est contenue dans les sections Avertissements et Effets indésirables, le patient doit recevoir l'information suivante :

- Il est difficile d'estimer la durée de vie prévue de ce dispositif, mais elle n'est pas illimitée. Ces composants sont en effet fabriqués dans des matériaux étrangers au corps humain et implantés pour leur potentiel de guérison des fractures. Toutefois, en raison des nombreux facteurs biologiques, mécaniques et physico-chimiques qui affectent ces dispositifs, les composants ne peuvent pas supporter le même niveau d'activité et les mêmes charges qu'un os sain pendant une période illimitée.

STÉRILISATION
- Ce composant est stérilisé par oxyde d'éthylène.
- L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant. C'est un dispositif à usage unique.

GARANTIE LIMITÉE
Avanta Orthopaedics Corporation garantit que ce produit est conforme aux spécifications du fabricant et qu'il est livré sans défaut de fabrication. Cette garantie exclut spécifiquement les défauts résultant d'une utilisation incorrecte ou abusive, ou d'une manipulation incorrecte du produit postérieure à la réception par l'acheteur. Avanta Orthopaedics ne garantit pas l'issue de la chirurgie.

Représentant en Europe :
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Pays-Bas
31 (0) 416 563754

ESPAÑOL

PROSPECTO DEL PRODUCTO
Aparatos y accesorios metálicos para la fijación ósea.

ATENCIÓN
Según la legislación federal estadounidense, este producto sólo puede ser vendido, distribuido y utilizado por un médico o por orden de un médico.

DESCRIPCIÓN
[illegible] dispositivo se compone de una placa y de tornillos para el tratamiento del radio distal.

Materiales:
- 316 L Acero inoxidable ASTM F-138 o a ASTM F-139;
- 22-13-5 Acero inoxidable ASTM F-1314.

INDICACIONES
El sistema de placa para la fijación de fracturas distales del radio se utiliza para la fijación interna de fracturas y osteotomías del radio distal. Esto puede incluir:

- Fractura dislocada o no dislocada, con o sin angulación o fragmentación del hueso;
- Fracaso de la fijación de una fractura, con o sin injerto óseo;
- Osteotomía y reparación - con o sin injerto óseo - de una consolidación deficiente del radio distal.

CONTRAINDICACIONES
- Infección activa o latente;
- Osteoporosis, cantidad o calidad insuficiente del hueso / del tejido blando;
- Hipersensibilidad al material - en caso de sospecha, efectuar las pruebas correspondientes antes de la cirugía;
- Sepsis.
- Pacientes con afecciones mentales o neurológicas que no están dispuestos a seguir las instrucciones para el cuidado postoperatorio, o que no sean capaces de hacerlo.

ADVERTENCIAS (Véase también el apartado "Información para el paciente")
- Este dispositivo está previsto para los usos descritos en el presente prospecto.
- Es importante una selección cuidadosa de los pacientes, así como una apropiada información y asesoramiento por parte del cirujano y del responsable de la rehabilitación.
- Los esfuerzos intensos o la movilidad excesiva pueden provocar el fracaso del dispositivo. Debe informarse a los pacientes de que las probabilidades de fracaso del dispositivo aumentan si se somete a sobrecargas mecánicas excesivas.
- El dispositivo puede romperse o dañarse si el implante se somete a un esfuerzo adicional, asociado a una consolidación retardada, a una seudoartrosis o a una consolidación incompleta.
- La inserción inadecuada del dispositivo durante la implantación puede aumentar la posibilidad de su aflojamiento y migración.
- Puede obtenerse un resultado insatisfactorio si la fractura no se reduce correctamente o si el dispositivo no se monta correctamente.
- Puede ser necesaria la explantación de este dispositivo.
- Advertencia: Este producto no está autorizado para su fijación o unión mediante tornillos a los elementos posteriores (pediculos) de la columna cervical, dorsal o lumbar.
- Notificación de acuerdo con los establecido en la California Safe Drinking Water and Toxic Enforcement Act of 1986 [Ley sobre Seguridad del Agua Potable y Agentes Tóxicos del Estado de California, conocida también como Proposition 65]: Este producto contiene una o más productos químicos de los que el Estado de California sabe que provocan cáncer y/o defectos congénitos, y otros efectos de toxicidad reproductiva.

PRECAUCIONES
- Nunca debe reutilizarse un implante. Los esfuerzos anteriores pueden haber provocado imperfecciones que podrían llevar a un fracaso del dispositivo.
- El implante se suministra estéril en un envase intacto. Si el implante o el envase aparecen dañados, si ha transcurrido la fecha de caducidad o si por cualquier motivo existen dudas sobre su esterilidad, el implante no debe utilizarse. Se trata de un producto desechable no previsto para su reutilización. No se recomienda reesterilizar el implante.
- [illegible] deberá tenerse buen cuidado para evitar las melladuras, las rayaduras y otros daños durante la manipulación de este dispositivo.
  La preparación meticulosa de la zona de implantación y la elección de un implante del tamaño correcto aumentan las posibilidades de éxito.
- Los productos estériles sólo deben extraerse de su envase una vez que se determine que el implante va a utilizarse en el paciente.

EFECTOS ADVERSOS
- Antes de utilizar este dispositivo deben estudiarse los efectos adversos descritos en la literatura.
- Se han descrito reacciones de hipersensibilidad al metal tras la implantación de materiales metálicos.
- Entre otros posibles efectos adversos figuran la fractura del hueso, la infección, el dolor y la irritación de los tejidos blandos.

TÉCNICAS QUIRÚRGICAS
Existe un manual donde se describe detalladamente la técnica quirúrgica para el uso de este dispositivo. Es responsabilidad del cirujano familiarizarse con la técnica antes de utilizar estos productos. También es responsabilidad del cirujano estar familiarizado con las publicaciones relevantes y consultar sobre la técnica con colegas experimentados antes del empleo de estos productos.

INFORMACIÓN PARA EL PACIENTE (Véase también el apartado "Advertencias")
Además de la información relacionada con los pacientes que figura en los apartados "Advertencias" y "Efectos adversos", debe transmitirse al paciente la siguiente información:

- Si bien resulta difícil de estimar la expectativa de vida de este dispositivo, ésta no es ilimitada. Sus componentes están fabricados con materiales ajenos al organismo que se introducen en el mismo para facilitar el proceso de consolidación ósea. Sin embargo, debido a los numerosos factores biológicos, mecánicos y fisicoquímicos que afectan a estos dispositivos, no es posible esperar que sus componentes resistan durante un periodo ilimitado el nivel de actividad y los esfuerzos a los que está sometido un hueso normal sano.

ESTERILIZACIÓN
- Este producto está esterilizado por óxido de etileno (EO).
- El implante se suministra estéril en un envase intacto. Si el implante o el envase aparecen dañados, si ha transcurrido la fecha de caducidad o si por cualquier motivo existen dudas sobre su esterilidad, el implante no debe utilizarse. Este producto es de un solo uso.

GARANTÍA LIMITADA
Avanta Orthopaedics Corporation garantiza que este producto cumple las especificaciones del fabricante y que no presenta defectos de fabricación en el momento de su entrega. Esta garantía excluye específicamente los defectos derivados del uso incorrecto, abuso o manejo inadecuado del producto tras su recepción por el comprador. Avanta Orthopaedics no garantiza el resultado de la intervención quirúrgica.

Representante en la UE:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Países Bajos
31 (0) 416 563754

NEDERLANDS

BIJSLUITER
Metaalhoudende botfixatiesystemen met toebehoren

LET OP
Krachtens de federale wetgeving (Verenigde Staten) mag dit product uitsluitend door of op voorschrift van een arts worden verkocht, gedistribueerd en gebruikt.

BESCHRIJVING
Dit product bestaat uit een plaat met schroeven voor behandeling van de distale radius.

Materiaal:
- 316 L roestvrij staal volgens ASTM F-138 of ASTM F-139
- 22-13-5 roestvrij staal volgens ASTM F-1314

INDICATIES
Het fixatieplaatsysteem voor fracturen van de distale radius dient voor de inwendige fixatie van fracturen en osteotomieën van de distale radius. Dit kan het volgende omvatten:

- Al of niet verschoven fractuur die al of niet gepaard is gegaan met angulatie of fragmentatie van het bot,
- Gefaalde fractuurfixatie, al of niet met een bottransplantaat,
- Osteotomie en herstel van een slechte consolidatie van de distale radius al of niet met een bottransplantaat.

CONTRA-INDICATIES
- Actieve of latente infectie
- Osteoporose, een onvoldoende hoeveelheid of inferieure kwaliteit bot/zacht weefsel
- Gevoeligheid voor het materiaal - voer bij een vermoeden hiervan voorafgaand aan chirurgie tests uit
- Sepsis
- Patiënten met mentale of neurologische aandoeningen die niet bereid of in staat zijn om de aanwijzingen voor postoperatieve verzorging op te volgen

WAARSCHUWINGEN (zie tevens de rubriek Informatie betreffende counseling van de patiënt)
- Dit systeem dient uitsluitend voor gebruik zoals beschreven in deze bijsluiter.
- Een zorgvuldige patiëntenselectie, voorlichting en counseling door de chirurg en de verlener van revalidatiezorg zijn belangrijk.
- Zware belasting en overmatige mobiliteit kunnen ertoe leiden dat het product faalt. Patiënten dienen erop te worden geattendeerd dat er een verhoogde kans bestaat dat het product faalt als er te veel van wordt gevergd.
- Wanneer het implantaat wordt blootgesteld aan een verhoogde belasting veroorzaakt door vertraagde consolidatie, geen consolidatie of onvolledige genezing, kan het product falen of beschadigd raken,.
- Onjuist inbrengen van het product gedurende de implantatie kan de kans op losraken en migratie vergroten.
- Als de fractuur niet goed wordt gezet of het product niet goed wordt samengesteld, kan dit een slecht resultaat tot gevolg hebben.
- Explantatie van dit product kan noodzakelijk zijn.
- Waarschuwing: Dit product is niet goedgekeurd voor aanhechting of fixatie met behulp van schroeven aan de achterelementen (pediculi) van de cervicale, thoracale of lumbale wervelkolom.
- Verklaring conform de wet van de Amerikaanse deelstaat Californië inzake veilig drinkwater en toxiciteit van 1986 (Proposition 65): Dit product bevat een of meer chemische stoffen waarvan het de staat Californië bekend is dat deze kanker en/of geboortegebreken en andere reproductieve toxiciteit veroorzaken.

VOORZORGSMAATREGELEN
- Een implantaat mag nooit opnieuw worden gebruikt. Eerdere belastingen kunnen gebreken hebben veroorzaakt die ertoe kunnen leiden dat het product faalt.
- Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien het implantaat of de verpakking beschadigd blijkt te zijn, de vervaldatum is verlopen of om welke reden dan ook wordt getwijfeld aan de steriliteit, dan mag het implantaat niet worden gebruikt. Dit is een product voor eenmalig gebruik en dient niet voor hergebruik. Opnieuw steriliseren van het implantaat wordt afgeraden.
- Zorgvuldigheid is vereist ter voorkoming van kerven, krassen en andere beschadigingen gedurende de hantering van het product.
- Een nauwkeurige voorbereiding van de implantatieplaats en keuze van de correcte afmetingen voor het implantaat vergroten de kans op een succesvol resultaat.
- De steriele producten mogen pas uit de steriele verpakking worden genomen als vaststaat dat het implantaat bij de patiënt zal worden gebruikt.

COMPLICATIES
- In de literatuur gepubliceerde complicaties moeten worden bestudeerd voordat dit product wordt gebruikt.
- Er zijn gevoeligheidsreacties op metaal na metaalimplantatie beschreven.
- Mogelijke bijkomende complicaties kunnen botfractuur, infectie, pijn en irritatie van zacht weefsel omvatten.

CHIRURGISCHE PROCEDURES
Er is een handleiding verkrijgbaar, waarin de chirurgische procedure voor het gebruik van dit product gedetailleerd wordt beschreven. Het is de eigen verantwoordelijkheid van de chirurg om vóór gebruik van deze producten vertrouwd te zijn met de procedure. Daarnaast is het de verantwoordelijkheid van de chirurg om vóór gebruik vertrouwd te zijn met de relevante publicaties en om het advies in te winnen van ervaren collega's met betrekking tot de procedure.

INFORMATIE BETREFFENDE COUNSELING VAN DE PATIËNT (zie tevens onder Waarschuwingen)
Naast de patiëntgerelateerde informatie onder Waarschuwingen en Complicaties moet de volgende informatie aan de patiënt worden verstrekt:

- Hoewel de verwachte levensduur van dit product moeilijk te schatten is, is deze beperkt. Deze componenten zijn gemaakt van lichaamsvreemde materialen, die in het lichaam worden geplaatst om het genezingsproces te bevorderen. Vanwege de vele biologische, mechanische en fysiochemische factoren die deze producten beïnvloeden, kan echter niet van de componenten worden verwacht dat ze voor onbeperkte tijd bestand zijn tegen het activiteitsniveau en de belasting van normaal gezond bot.

STERILISATIE
- Dit product is gesteriliseerd met ethyleenoxide (EO).
- Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien het implantaat of de verpakking beschadigd blijkt te zijn, de vervaldatum is verlopen, of om welke reden dan ook wordt getwijfeld aan de steriliteit, dan mag het implantaat niet worden gebruikt. Dit is een product voor eenmalig gebruik.

BEPERKTE GARANTIE
Avanta Orthopaedics Corporation garandeert dat dit product op het moment van levering voldoet aan de specificaties van de fabrikant en vrij is van fabricagefouten. Van deze garantie zijn defecten die een gevolg zijn van verkeerd gebruik, misbruik of een onjuiste hantering van het product na ontvangst door de koper specifiek uitgesloten. Avanta Orthopaedics biedt geen garantie op de uitkomst van de chirurgische ingreep.

Vertegenwoordiger binnen de EU:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Nederland
0 416 563754

ITALIANO

FOGLIO ILLUSTRATIVO
Apparecchi e accessori in metallo per fissazione osso

ATTENZIONE
La legislazione federale (Stati Uniti) impone la vendita, la distribuzione e l'uso di questo presidio ai soli medici o su loro prescrizione.

DESCRIZIONE
Il presidio è costituito da una piastra e viti per il trattamento del radio distale

Materiali:
- 316 L acciaio inossidabile per ASTM F-138 o ASTM F-139
- 22-13-5 acciaio inossidabile per ASTM F-1314

INDICAZIONI
L'uso previsto di questo sistema di fissazione a piastra è la fissazione interna di fratture e osteotomie del radio distale, tra le quali:

- frattura scomposta o non scomposta con possibile angolazione o frammentazione dell'osso,
- fissazione fallita di fratture, con o senza innesto osseo,
- osteotomia e riparazione di malunione del radio distale con o senza innesto osseo.

CONTROINDICAZIONI
- Infezione in atto o latente
- Osteoporosi, tessuto osseo/molle insufficiente per quantità o qualità
- Ipersensibilità al materiale - In caso di sospetta ipersensibilità, eseguire un test prima dell'intervento
- Sepsi
- Pazienti che per condizioni mentali o neurologiche non vogliono o possono seguire le istruzioni per le cure postoperatorie

AVVERTENZE (Si veda anche la Sezione relativa alle Informazioni per la Consulenza al Paziente)
- Il presidio è destinato unicamente all'uso descritto nel presente foglio illustrativo.
- È importante che il chirurgo e l'équipe di riabilitazione provvedano a selezionare attentamente i pazienti, educarli e consigliarli.
- Un accesso di carico o di mobilità possono comportare il fallimento del presidio. I pazienti devono essere avvertiti del maggiore potenziale di fallimento del presidio se sottoposto a sollecitazioni eccessive.
- Il presidio può rompersi o rimanere danneggiato se l'impianto viene assoggettato a carichi crescenti in associazione con unione ritardata, mancata unione o guarigione incompleta.
- L'inserimento non corretto del presidio durante d'impianto può aumentare la possibilità di distacco e spostamento dello stesso.
- Si può ottenere un risultato insoddisfacente se la frattura non viene ridotta correttamente o il presidio non è correttamente assemblato.
- In tali casi potrebbe rendersi necessario l'espianto del presidio.
- Avvertenza importante: Il presente presidio non è approvato per l'attacco o fissazione con viti degli elementi posteriori (peduncoli) delle vertebre cervicali, toraciche o lombari.
- Notifica in conformità con la Legge del 1986 dello Stato della California sulla sicurezza dell'acqua potabile e sulle sostanze tossiche (dichiarazione 65): Questo prodotto contiene uno o più sostanze chimiche note allo Stato della California come possibili cause di cancro e/o difetti neonatali e di altri effetti tossici sull'attività riproduttiva.

PRECAUZIONI
- Un impianto non deve mai essere riutilizzato. Le sollecitazioni subite in precedenza possono aver dato origine ad imperfezioni che determinerebbero il fallimento del presidio.
- L'impianto fornito è sterile se in confezione integra. Non utilizzare l'impianto se lo stesso o la confezione appaiono danneggiati, se la data di scadenza è stata superata o se per qualsiasi motivo si è indotti a dubitare della sua sterilità. Il presente presidio è monouso e non deve essere riutilizzato. Si sconsiglia la risterilizzazione dell'impianto.
- Manipolare il presidio con precauzione per evitare incisioni, graffi o altri danni.
- Una preparazione meticolosa del sito d'impianto e la selezione delle corrette dimensioni aumentano le probabilità di esito positivo dell'intervento.
- I prodotti sterili devono essere prelevati dalla confezione sterile solo dopo aver accertato l'uso effettivo dell'impianto sul paziente.

EVENTI INDESIDERATI
- Prima di usare il presidio, eseguire una ricerca degli eventi indesiderati pubblicati dalla letteratura.
- Sono stati riferiti casi di reazioni di sensibilizzazione ai metalli in seguito all'impianto.
- Altri possibili effetti indesiderati: fratture ossee, infezioni, dolore e irritazione dei tessuti molli.

PROCEDURE CHIRURGICHE
È disponibile un manuale che descrive nei dettagli la procedura chirurgica da applicare a questo presidio. È responsabilità del chirurgo acquisire familiarità con la procedura prima dell'uso di questi prodotti. È inoltre responsabilità del chirurgo anche acquisire familiarità con le pubblicazioni relative e consultarsi con colleghi esperti in merito alla procedura prima dell'uso.

INFORMAZIONI PER LA CONSULENZA AL PAZIENTE (Si vedano anche le Avvertenze)
Oltre alle informazioni relative al paziente contenute nelle sezioni Avvertenze ed Effetti indesiderati, devono essere trasmesse al paziente le seguenti informazioni:

- La durata prevista di questo presidio, sebbene sia difficile da valutare, è comunque limitata nel tempo. Si tratta infatti di elementi composti da materiali estranei all'organismo, inseriti per la potenziale guarigione della frattura. A causa dei molti fattori biologici, meccanici e fisiochimici che influiscono su questi dispositivi, non si può tuttavia pensare che essi possano resistere per un periodo di tempo illimitato a livelli di attività e carico uguali a quelli del normale osso sano.

STERILIZZAZIONE
- Questo prodotto è sterilizzato in ossido di etilene (EO).
- L'impianto fornito è sterile se in confezione integra. Non utilizzare l'impianto se lo stesso o la confezione appaiono danneggiati, se la data di scadenza è stata superata o se per qualsiasi motivo si è indotti a dubitare della sua sterilità. Il presidio è monouso.

GARANZIA LIMITATA
La Avanta Orthopaedics Corporation garantisce che il presente prodotto è conforme alle specifiche del produttore e che è esente da difetti di fabbricazione al momento della consegna. La presente garanzia esclude specificamente i difetti derivanti da uso improprio o non corretto o da errori di manipolazione del prodotto successivamente al ricevimento da parte dell'acquirente. La Avanta Orthopaedics non garantisce l'esito della procedura chirurgica.

Agente per l'UE:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Paesi Bassi
31 (0) 416 563754

CE 0123

AVANTA
ORTHOPAEDICS
9369 Carroll Park Drive, Suite A, San Diego, CA 92121 USA
(858)452-8580 / (858)452-9945 (fax)

PRODUCT INSERT

Avanta TMC Thumb Prosthesis
Trapezio-Metacarpal (TMC-) Daumenprothese von Avanta
Prothèse de pouce trapézo-métacarpienne Avanta
Prótesis carpometacarpiana del pulgar Avanta TMC
Protesi Avanta trapeziometacarpale dell'protese
Polegar Avanta TMC

ENGLISH

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
This semi constrained joint prosthesis consists of an ultra-high molecular weight polyethylene (UHMWPe) distal component which is cemented to the shaft of the prepared metacarpal bone, and a cobalt chromium proximal component which is cemented into the prepared trapezium bone. The cobalt chromium surface articulates with the UHMWPe component to form a semi-constrained prosthetic replacement of the TMC joint of the hand. The implant is available in several sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation. This device is for cemented use only.

Materials:
- ASTM F-75 cobalt chromium proximal component
- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) distal component

INDICATIONS
The implant is indicated for total joint replacement in skeletally mature patients with pain or instability of the joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

CONTRAINDICATIONS
- Active or latent infection
- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Skeletal immaturity.
- Known sensitivity to materials used in this device.

WARNINGS (See also the Patient Counseling Information and Adverse Events Section)
- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.

PRECAUTIONS
- Do *not* **resterilize.** The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
  The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
  Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance.

POTENTIAL ADVERSE EVENTS
General Surgery Related Risks
• bleeding • infection • loss of use of the hand • permanent disability • death

Joint Replacement Related Risks
- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- instability of the joint
- dislocation of the joint
- cement extrusion injury
- infection
- lengthening or shortening of the finger
- amputation
- bone weakening around the implant
- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional surgery may be required for reoperation, revision or fusion of the joint
- surgery may be started but a joint replacement cannot be done resulting in fusion of the joint
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

SURGICAL PROCEDURES
A manual is available describing detailed surgical procedure for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings and Adverse Events Section) A patient brochure is available for use in counseling the patient.
In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

- While the expected life of total joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.
- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION
- This component has been sterilized by ethylene oxide or gamma radiation.
- Do not resterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics, Inc. warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk
31 (0) 416563 754

DEUTSCH

ACHTUNG
Nach dem Bundesgesetz (Vereinigte Staaten) ist dieses Gerät auf Verkauf, Vertrieb sowie und Anwendung durch einen Arzt oder in dessen Auftrag beschränkt.

BESCHREIBUNG
Diese teilgekoppelte (semiconstrained) Gelenkprothese hat eine distale Komponente aus ultrahochmolekularem Polyethylen (UHMWPE), die in dem Schaft des präparierten Metacarpalknochens zementiert verankert ist, und eine proximale Kobaltchrom-Komponente, die in den präparierten Trapezknochen einzementiert ist. Zwischen Kobaltchromoberfläche und UHMWPE-Komponente besteht eine gelenkige Verbindung (Artikulation), um einen prothetischen Ersatz mit teilgekoppeltem (semi-constrained) System für das Trapezio-Metacarpal-(TMC-) Gelenk der Hand zu bilden. Das Implantat ist in mehreren Größen verfügbar, die alle an der rechten oder linken Hand eingesetzt werden können. Für jeden Implantattyp gibt es eine Palette von Probeprothesen, so genannte Sizer, die als Hilfsmittel für die Präparation des Knochens verwendet werden. Dieses Gerät ist nur zur zementierten Verankerung bestimmt.

Materialien
- Proximale Komponente aus Kobaltchrom gemäß ASTM F-75
- Distale Komponente aus ultrahochmolekularem Polyethylen (UHMWPE) gemäß ASTM F-648

ANWENDUNGSGEBIETE
Das Implantat ist indiziert als Totalgelenkersatz bei Patienten mit ausgereifter Skelettentwicklung, die infolge von Trauma, entzündlicher oder degenerativer Erkrankung oder Revision früherer Prothesen an Gelenkschmerzen oder Gelenkinstabilität leiden, und stellt eine Alternative zu Arthrodese oder rekonstruktiver Chirurgie dar.

GEGENANZEIGEN
- Durch Krankheit, Infektion oder frühere Implantation angegriffene Knochen, Muskulatur, Sehnen oder angrenzende Weichteile, die keine sichere Unterlage oder Fixierung für die Prothese bieten können.
- Unreife in der Skelettentwicklung.
- Bekannte Überempfindlichkeit gegenüber den in diesem Gerät verwendeten Materialien.

WARNHINWEISE (Siehe auch Abschnitt "Informationen zur Patientenberatung")
- Patienten sind auf das erhöhte Potenzial des Versagens der Prothese bei übermäßiger Belastung hinzuweisen. Starke Belastung, übermäßige Mobilität und Gelenkinstabilität können alle zu beschleunigtem Verschleiß und eventuellem Versagen durch Lockerung, Fraktur oder Dislokation der Prothese führen.

VORSICHTSMASSNAHMEN FÜR DIE ANWENDUNG
- Nicht resterilisieren. Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn eine Beschädigung des Implantates oder der Verpackung vorzuliegen scheint, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden.
- Sorgfältige Vorbereitung der Implantatlagers und die Wahl der richtigen Größe des Implantates erhöhen die Erfolgsaussichten der Implantation.
- Das Implantat ist erst aus seiner sterilen Verpackung zu entnehmen, wenn das Implantatlager vorbereitet und für die Größe des Implantats richtig dimensioniert ist.
- Bei der Handhabung des Implantats sind stumpfe Instrumente zu verwenden, um Kratzer, Schnitte oder Kerben auf dem Gerät und eine damit verbundene Beeinträchtigung der Implantatleistung zu vermeiden.

POTENZIELLE NEBENWIRKUNGEN
Allgemeine operationsbedingte Risiken
• Blutung • Infektion • Gebrauchsunfähigkeit der Hand • Arbeitsunfähigkeit • Tod

Durch Gelenkersatz bedingte Risiken
- Schmerzen
- Verletzung der umgebenden Nerven, Blutgefäße, Sehnen oder Weichteile
- Steifigkeit
- Nachtschmerz und wetterbedingte Schmerzen
- Bewegungsunfähigkeit
- Implantatfraktur
- Rotation des Implantats
- Beschleunigter Verschleiß der Komponenten des Gerätes
- Lockerung des Implantats in den Knochen
- Gelenkinstabilität
- Dislokation des Gelenks
- Verletzung infolge von Zementextrusion
- Infektion
- Verlängerung oder Verkürzung der Finger
- Amputation
- Schwächung der Knochen rund um das Implantat
- Verringerter Bewegungsradius
- Allergische oder andere Reaktionen auf die Metall- oder Plastematerialien
- Ein zusätzlicher chirurgischer Eingriff kann zur Reoperation, Revision oder Fusion des Gelenks erforderlich sein.
- Die Operation kann zwar begonnen werden, aber der Gelenkersatz ist nicht durchführbar, wodurch es zur Fusion des Gelenkes kommt.
- Mitteilung gemäß dem Gesetz für sauberes Trinkwasser und zur Bekämpfung toxischer Stoffe des Bundesstaates Kalifornien (California Safe Drinking Water and Toxic Enforcement Act) von 1986 (Proposition 65): Dieses Produkt enthält eine Chemikalie (), die nach Wissen des Bundesstaates Kalifornien Krebs und/oder Geburtsschäden sowie andere reproduktive Toxizität verursachen kann.

CHIRURGISCHE VERFAHREN
Ein Handbuch mit einer genauen Beschreibung des chirurgischen Verfahrens für den Einsatz dieser Implantatprothese ist verfügbar. Der Chirurg ist dafür verantwortlich, sich vor Anwendung dieses Medizinproduktes mit dem Verfahren vertraut zu machen. Der Chirurg ist weiterhin dafür verantwortlich, die einschlägigen Publikationen sorgfältig zu lesen und sich mit Berufskollegen zu beraten, die Erfahrung in der Anwendung dieses Verfahrens gesammelt haben.

INFORMATIONEN ZUR PATIENTENBERATUNG (Siehe auch Warnhinweise)
Eine Patientenbroschüre zur Verwendung bei der Beratung der Patienten ist verfügbar.

Neben den Patienteninformationen in den Abschnitten Warnhinweise und Nebenwirkungen sind dem Patienten die nachfolgenden Informationen zu vermitteln:

- Die erwartete Lebensdauer der Komponenten des Totalgelenkersatzes ist zwar schwer zu bestimmen, aber sie ist begrenzt. Diese Komponenten sind aus Fremdstoffen gefertigt, die zur potenziellen Wiederherstellung der Mobilität und zur Verringerung der Schmerzen in den Körper implantiert werden. Auf Grund einer Vielzahl biologischer, mechanischer und physikalisch-chemischer Faktoren, die diese Prothesen beeinflussen, kann jedoch nicht erwartet werden, dass die Komponenten auf unbegrenzte Zeitdauer demselben Aktivitätsgrad und derselben Belastung standhalten wie der normale gesunde Knochen.
- Unerwünschte Wirkungen dieser Prothese können möglicherweise Reoperation, Revision oder Fusion des betroffenen Gelenks erforderlich machen.

STERILISATION
- Diese Komponente wurde mit Ethylenoxid oder Gammabestrahlung sterilisiert.
- Nicht resterilisieren. Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn eine Beschädigung des Implantats oder der Verpackung vorzuliegen scheint, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden.
- Probeprothesen, so genannte Sizer, sind verfügbar, um zu vermeiden, dass die sterile Verpackung vor der Implantation der Prothese geöffnet werden muss. Das Implantat darf erst aus der sterilen Verpackung entnommen werden, wenn das Implantatlager vorbereitet und für die Größe des Implantats richtig dimensioniert ist.

EINGESCHRÄNKTE GEWÄHRLEISTUNG
Avanta Orthopaedics, Inc. gewährleistet, dass dieses Medizinprodukt die Spezifikationen des Herstellers erfüllt und bei der Lieferung keine Herstellungsfehler aufweist. Diese Gewährleistung schließt speziell Fehler aus, die auf nicht-bestimmungsgemäßen Gebrauch, Abusus oder unsachgemäße Handhabung des Medizinproduktes nach Eingang bei dem Käufer zurückzuführen sind. Avanta Orthopaedics übernimmt keine Gewährleistung für das Resultat der chirurgischen Methode.

EU-VERTRETER:
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk
31 (0) 416563 754

FRANÇAIS

ATTENTION
Les lois fédérales des États-Unis d'Amérique exigent que la vente, la distribution et l'utilisation de cet appareil soient assurées ou prescrites par un médecin.

DESCRIPTION
Cette prothèse articulaire semi-contrainte se compose d'une pièce distale en polyéthylène à poids moléculaire ultra élevé (UHMWPe) qui est cimentée à l'axe de l'os métacarpien préparé et d'une pièce proximale en cobalt-chrome qui est cimentée à l'os du trapèze préparé. La surface en cobalt-chrome s'articule sur la pièce en UHMWPe pour former un remplacement prothétique semi-constrictif de l'articulation trapézo-métacarpienne de la main. L'implant est disponible en plusieurs tailles, chacune d'elles étant utilisable à la main droite ou gauche. Une série de calibreurs d'essai est disponible pour chaque type d'implant, en tant qu'assistance à la préparation osseuse. Ce dispositif est prévu exclusivement pour la cimentation.

Matériaux
- pièce proximale cobalt-chrome ASTM F-75
- pièce distale en polyéthylène à poids moléculaire ultra élevé (UHMWPe) ASTM F-648

INDICATIONS
L'implant est indiqué pour le remplacement de l'articulation totale chez les patients dont la croissance est terminée et qui souffrent ou sont atteints d'instabilité articulaire due à un traumatisme, une maladie inflammatoire ou dégénérative ou une révision des procédures précédentes, en tant que solution de remplacement d'une arthrodèse ou d'une chirurgie reconstructive.

CONTRE-INDICATIONS
- Os, musculature, tendons ou tissu mou adjacent compromis par une maladie, une infection ou une implantation antérieure qui ne peuvent pas fournir un support adéquat ni permettre la fixation de la prothèse.
- Immaturité du squelette.
- Allergie avérée aux matériaux de ce dispositif.

AVERTISSEMENTS (voir aussi la section Conseils donnés au patient)
- Il faut informer le patient de l'augmentation du risque d'échec du dispositif en cas de sollicitations excessives. De fortes charges, une mobilité excessive et une instabilité articulaire peuvent accélérer l'usure du dispositif et entraîner un échec éventuel par relâchement, fracture ou dislocation.

PRÉCAUTIONS
- Ne pas restériliser. L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant.
- Une préparation méticuleuse du site de l'implant et la sélection de la taille d'implant appropriée augmentent le potentiel de réussite.
- Il faut enlever l'implant de son emballage stérile uniquement après la préparation et le dimensionnement correct du site de l'implant.
- Les implants doivent être manipulés avec des instruments à bout mousse pour ne pas rayer, couper ou entailler le dispositif et ne pas perturber les performances de l'implant.

EFFETS INDÉSIRABLES ÉVENTUELS
Risques généraux liés à la chirurgie
- saignements
- infection
- perte d'usage de la main
- incapacité de travail définitive
- décès

Risques liés au remplacement de l'articulation
- douleur
- lésion traumatique des nerfs, vaisseaux sanguins, tendons ou du tissu mou environnants
- raideur
- douleur nocturne et liée aux conditions météorologiques
- perte de mobilité
- fracture de l'implant
- rotation de l'implant
- usure accélérée des composants du dispositif
- relâchement de l'implant (détachement des os)
- instabilité de l'articulation
- luxation de l'articulation
- blessure par extrusion de ciment
- infection
- rallongement ou raccourcissement du doigt
- amputation
- affaiblissement osseux autour de l'implant
- diminution d'amplitude de mouvement
- réactions allergiques ou autres aux matériaux métalliques ou plastiques
- une chirurgie additionnelle peut être requise pour la réopération, la révision ou la fusion de l'articulation
- il se peut que l'on commence une chirurgie mais que l'on ne puisse pas remplacer l'articulation, ce qui entraîne une fusion de l'articulation
- Notification conforme à la Proposition 65 de Californie (California Safe Drinking Water and Toxic Enforcement Act, acte exécutoire de la protection de l'eau potable contre les produits toxiques, approuvé en 1986) : ce produit contient un agent chimique (;) connu dans l'État de Californie pour causer le cancer et/ou des malformations néonatales et autre toxicité liée à la reproduction.

PROCÉDURES CHIRURGICALES
Un manuel est disponible ; il décrit en détail la procédure chirurgicale permettant d'utiliser l'implant. La connaissance de cette procédure est de la responsabilité du chirurgien. Il incombe également au chirurgien de se tenir au courant des publications pertinentes et de consulter des confrères expérimentés au sujet de la procédure à utiliser.

CONSEILS DONNÉS AU PATIENT (voir aussi Avertissements)
Une brochure à l'attention du patient, contenant des conseils, a été réalisée.
Outre l'information relative au patient qui est contenue dans les sections Avertissements et Effets indésirables, le patient doit recevoir l'information suivante :

- Il est difficile d'estimer la durée de vie prévue des composants de remplacement d'articulation totale, mais ils ne sont pas inusables. Ces composants sont en effet fabriqués dans des matériaux étrangers au corps humain et implantés afin de restaurer la mobilité ou de réduire la douleur. Toutefois, en raison des nombreux facteurs biologiques, mécaniques et physio-chimiques qui affectent ces dispositifs, les composants ne peuvent pas supporter le même niveau d'activité et les mêmes charges qu'un os sain pendant une période illimitée.
- Des effets indésirables peuvent nécessiter la réopération, la révision ou la fusion de l'articulation concernée.

STÉRILISATION
- Ce composant a été stérilisé à l'oxyde d'éthylène ou aux rayons gamma.
- Ne pas restériliser. L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant.
- Des calibreurs d'essai sont disponibles ; ils évitent d'ouvrir l'emballage stérile avant l'implantation de la prothèse. Il faut enlever l'implant de son emballage stérile uniquement après la préparation et le dimensionnement correct du site de l'implant.

GARANTIE LIMITÉE
Avanta Orthopaedics, Inc. garantit que ce produit est conforme aux spécifications du fabricant et qu'il est livré sans défaut de fabrication. Cette garantie exclut spécifiquement les défauts résultant d'une utilisation incorrecte ou abusive, ou d'une manipulation incorrecte du produit postérieure à la réception par l'acheteur. Avanta Orthopaedics ne garantit pas l'issue de la chirurgie.

REPRÉSENTANT EN EUROPE :
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk
31 (0) 416563 754

ESPAÑOL

ATENCIÓN
Según la legislación federal estadounidense, este producto sólo puede ser vendido, distribuido y utilizado por un médico o por orden de un médico.

DESCRIPCIÓN
Esta prótesis articular semirrestrictiva está integrada por un componente distal, hecho de un polietileno de peso molecular ultra elevado (UHMWPe), el cual debe cementarse a la diáfisis del primer metacarpiano previamente preparada, y por un componente proximal de cobalto-cromo que debe cementarse al trapezoides carpiano debidamente preparado. La superficie de cobalto-cromo articula con el componente de UHMWPe, constituyendo un dispositivo de sustitución protésica semiconstrictiva para la articulación carpometacarpiana del pulgar. Este implante se suministra en varios tamaños, cada uno de los cuales puede utilizarse para manos derechas o izquierdas. Se dispone además de una gama de prótesis de prueba de distintos tamaños para cada tipo de implante, con el propósito de ayudar a la preparación del hueso. Este dispositivo ha sido construido solamente para usarse como prótesis cementada.

Materiales
- Componente proximal de cobalto-cromo, ASTM F-75,
- Componente distal de polietileno de peso molecular ultra elevado (UHMWPe), ASTM F-648.

INDICACIONES
Este implante está indicado para la sustitución total de la articulación en pacientes con esqueleto maduro, que presenten dolor o inestabilidad de la articulación, causados por traumatismo, inflamación o enfermedad degenerativa, como asimismo para la revisión quirúrgica de procedimientos previos, como una alternativa frente a la artrodesis o a la cirugía reconstructora.

CONTRAINDICACIONES
- Presencia de hueso, musculatura, tendones o tejidos blandos adyacentes comprometidos por enfermedad, infección o implantación previa, que no puedan proporcionar una sustentación o una fijación adecuada para la prótesis;
- Inmadurez del esqueleto;
- Hipersensibilidad conocida a los materiales que componen este dispositivo.

ADVERTENCIAS (Ver también el apartado "Información para el paciente")
- Se deberá advertir a los pacientes sobre el mayor riesgo potencial de fallo del dispositivo cuando éste es sometido a exigencias mecánicas excesivas. Los esfuerzos intensos, la movilidad excesiva y la inestabilidad articular pueden causar un desgaste acelerado y conducir al fracaso del implante por aflojamiento, fractura o dislocación del dispositivo.

PRECAUCIONES
- No resterilizar. El implante se suministra estéril en un envase intacto. Si el implante o el envase aparecen dañados, si ha transcurrido la fecha de caducidad o si por cualquier motivo existen dudas sobre su esterilidad, el implante no deberá utilizarse.
- La preparación meticulosa de la zona de implantación y la elección de un implante del tamaño correcto aumentan las posibilidades de éxito.
- El implante debe extraerse de su envase estéril sólo después de haber concluido la preparación de la zona de implantación y de haber determinado el tamaño correcto.
- Los implantes deben manipularse utilizando instrumentos romos para evitar rayaduras, cortes o acodaduras que puedan afectar el funcionamiento del implante.

POSIBLES EFECTOS ADVERSOS
Riesgos relacionados a la cirugía en general
• Sangramiento • Infección • Pérdida de la función de la mano • Discapacidad permanente • Muerte

Riesgos relacionados a la sustitución articular
- Dolor
- Daño a los nervios, vasos sanguíneos, tendones o a los tejidos blandos circundantes
- Rigidez
- Dolor nocturno o relacionado a los cambios climáticos
- Pérdida de la movilidad
- actura del implante
- otación del implante

  Desgaste acelerado de los componentes del dispositivo
- Aflojamiento del implante desde el hueso
- Inestabilidad de la articulación
- Dislocación de la articulación
- Lesión por la salida del cemento
- Infección
- Alargamiento o acortamiento del dedo
- Amputación
- Rarefacción ósea alrededor del implante
- Restricción del rango de movilidad
- Reacciones alérgicas u otro tipo de reacciones al metal o a los materiales plásticos
- Puede necesitarse la cirugía adicional para la reoperación, la revisión o la fusión de la articulación.
- Es posible que una vez iniciada la intervención, no pueda implantarse la prótesis, obligando a efectuar una fusión articular.
- Notificación de acuerdo con lo establecido en la California Safe Drinking Water and Toxic Enforcement Act of 1986 [Ley sobre Seguridad de Agua Potable y Agentes Tóxicos del Estado de California, conocida también como Proposición 65]: Este producto contiene una o más sustancias químicas de las que el Estado de California sabe que provocan cáncer y/o defectos congénitos y otros efectos de toxicidad reproductiva.

TÉCNICAS QUIRÚRGICAS
Existe un manual donde se describe detalladamente la técnica quirúrgica para el uso de este dispositivo. Es responsabilidad del cirujano familiarizarse con la técnica antes de utilizar estos productos. También es responsabilidad del cirujano estar familiarizado con las publicaciones relevantes y consultar sobre la técnica con colegas experimentados antes del empleo de estos productos.

INFORMACIÓN PARA EL PACIENTE (Véase también el apartado "Advertencias")
Además de la información relacionada con los pacientes que figura en los apartados "Advertencias" y "Efectos adversos", debe transmitirse al paciente la siguiente información:

- Si bien resulta difícil de estimar la expectativa de vida de este dispositivo, ésta no es ilimitada. Sus componentes están fabricados con materiales ajenos al organismo que se introducen en el mismo para facilitar el proceso de consolidación ósea. Sin embargo, debido a los numerosos factores biológicos, mecánicos y fisicoquímicos que afectan a estos dispositivos, no es posible esperar que sus componentes resistan durante un período ilimitado el nivel de actividad y los esfuerzos a los que está sometido un hueso normal sano.
- Los efectos adversos de este dispositivo pueden requerir reoperación, revisión o la fusión de la articulación comprometida.

ESTERILIZACIÓN
- Este producto ha sido esterilizado por óxido de etileno o por radiación gamma.
- No resterilizar. El implante se suministra estéril en un envase intacto. Si el implante o el envase aparecen dañados, si ha transcurrido la fecha de caducidad o si por cualquier motivo existen dudas sobre su esterilidad, el implante no deberá utilizarse.

Se suministra componentes de prueba en cantidad suficiente para que no sea necesario abrir el envase estéril antes de la implantación de la prótesis. El implante debe extraerse de su envase estéril sólo después de haber concluido la preparación de la zona de implantación y de haber determinado el tamaño correcto.

GARANTÍA LIMITADA
Wright Medical Technology, Inc. garantiza que este producto cumple las especificaciones del fabricante y que no presenta defectos de fabricación en el momento de entrega. Esta garantía excluye específicamente los defectos derivados del uso incorrecto, abuso o manejo inadecuado del producto tras su recepción por el comprador. Wright Medical Technology, Inc. no garantiza el resultado de la intervención quirúrgica.

REPRESENTANTE EN LA UE:
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk, Países Bajos
31 (0) 416563 754

NEDERLANDS

WAARSCHUWING
Volgens de federale wet (Verenigde Staten) mag verkoop, distributie en gebruik alleen plaatsvinden door of in opdracht van een arts.

BESCHRIJVING
Deze semi-constrained gewrichtsprothese bestaat uit een distale component van ultrahoog moleculair gewicht polyethyleen (UHMWP), welke aan de schacht van het voorbereide metacarpale bot wordt geïjmd, en een kobalt-chromen proximale component welke in het voorbereide handwortelbeentje wordt geïjmd. Het kobalt-chromen oppervlak is door een gewricht verbonden met de component van UHMWP om zo een semi-constrained prothetische vervanging van het duimzadelgewricht van de hand te vormen. Het implantaat is verkrijgbaar in verschillende maten, die allemaal kunnen worden gebruikt in de rechter- of linkerhand. Voor elk type implantaat is een serie proefmaten verkrijgbaar als hulp bij het voorbereiden van het bot. Dit instrument is uitsluitend voor geïjmd gebruik.

Materialen
- ASTM F-75 proximale component van kobalt-chroom
- ASTM F-648 distale component van ultrahoog molecular gewicht polyethyleen (UHMWP)

INDICATIES
Het implantaat is bestemd voor vervanging van het complete gewricht in patiënten met een volgroeid skelet met pijn of instabiliteit in het gewricht door trauma, inflammatoire of degeneratieve aandoeningen of voor revisie van eerdere ingrepen, als alternatief voor artrodese of reconstructieve chirurgie.

CONTRA-INDICATIES
- Door ziekte, infectie of eerdere implantatie aangetast bot, musculatuur, pezen, of omliggend zacht weefsel, welke niet genoeg steun of bevestiging voor de prothese kunnen bieden.
- Onvolgroidheid van het skelet.
- Bekende gevoeligheid voor de in dit instrument gebruikte materialen.

WAARSCHUWINGEN (zie ook het hoofdstuk Informatie voor patiëntvoorlichting)
- Patiënten dienen te worden gewezen op de verhoogde kans dat het instrument het begeeft wanneer er te hoge eisen aan worden gesteld. Zware belasting, overmatige beweeglijkheid en gewrichtsinstabiliteit kunnen allemaal leiden tot versnelde slijtage en uiteindelijk kan het instrument het begeven door losraken, breken of dislocatie.

VOORZORGSMAATREGELEN
- Niet hersteriliseren. Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien ofwel het implantaat ofwel de verpakking beschadigd blijkt te zijn, de vervaldatum is overschreden, of om welke reden dan ook aan de steriliteit wordt getwijfeld, mag het implantaat niet worden gebruikt.
- Een nauwkeurige voorbereiding van de implantatieplaats en de keuze van de juiste maat implantaat vergroten de kans op een succesvol resultaat.
- Het implantaat mag pas uit zijn steriele verpakking worden gehaald zodra de implantatieplaats is voorbereid en de juiste afmetingen heeft.
- Om te voorkomen dat er in het instrument wordt gekrast, gesneden of gekerfd moeten implantaten met stompe instrumenten worden geïnteerd, dit om de werking van het instrument niet nadelig te beïnvloeden

MOGELIJKE BIJWERKINGEN
Algemene risico's die bij chirurgie kunnen optreden
- bloedingen
- infecties
- verlies van gebruik van de hand
- blijvende invaliditeit
- overlijden

Risico's die bij het vervangen van een gewricht kunnen optreden
- pijn
- letsel aan omliggende zenuwen, bloedvaten, pezen of zacht weefsel
- stijfheid
- nachtelijke en weerafhankelijke pijn
- verlies van beweging
- breken van het implantaat
- rotatie van het implantaat
- versnelde slijtage van componenten van het instrument
- kans dat het implantaat losraakt van de botten
- instabiliteit van het gewricht
- dislocatie van het gewricht
- letsel door extrusie van het kleefmiddel
- infecties
- langer of korter worden van de vinger
- amputatie
- botverzwakking rondom het implantaat
- vermindering van het bewegingsbereik
- allergische of andere reacties op het metaal of op plastic materialen
- aanvullende chirurgie kan nodig zijn voor heroperatie, revisie of fusie van het gewricht
- wanneer u begint met chirurgie voor een gewrichtsvervanging, kan dit niet uitlopen op een fusie van het gewricht
- kennisgeving in overeenstemming met de California Safe Drinking Water and Toxic Enforcement Act (verordening van de Amerikaanse deelstaat Californië inzake veilig drinkwater en toxische handhaving) van 1986 (opmerking 65): Dit product bevat een chemische stof(fen) waarvan in de deelstaat Californië bekend is dat hij kanker veroorzaakt, en/of geboortebeperkingen en andere reproductieve toxiciteit.

CHIRURGISCHE PROCEDURES
Er is een handleiding verkrijgbaar waarin gedetailleerd de chirurgische procedure voor het gebruik van deze implantatie-instrumenten wordt beschreven. Het is de verantwoordelijkheid van de arts dat hij vertrouwd is met de procedure voordat hij deze producten gaat gebruiken. Daarnaast is het de verantwoordelijkheid van de chirurg dat hij voorafgaand aan het gebruik op de hoogte is van relevante publicaties en dat hij bij ervaren collega's advies inwint met betrekking tot de procedure.

INFORMATIE VOOR PATIËNTVOORLICHTING (zie ook Waarschuwingen)
Er is een patiëntenbrochure verkrijgbaar die kan worden gebruikt om de patiënt voor te lichten.

Naast de patiëntgerelateerde informatie in de hoofdstukken Waarschuwingen en Bijwerkingen dient de volgende informatie te worden medegedeeld aan de patiënt:

- Hoewel de verwachte levensduur van componenten voor een complete gewrichtsvervanging moeilijk te schatten is, is deze beperkt. Deze componenten zijn gemaakt van vreemde materialen, die in het lichaam worden geplaatst voor mogelijk herstel van de mobiliteit of vermindering van pijn. Vanwege de vele biologische, mechanische en fysiochemische factoren die invloed op deze instrumenten uitoefenen, kan echter niet van deze componenten worden verwacht dat zij gedurende onbeperkte tijd bestand zijn tegen het activiteitsniveau en de belasting van normaal gezond bot.
- Door nadelige effecten van dit instrument kan heroperatie, revisie of fusie van het betreffende gewricht nodig zijn.

STERILISATIE
- Deze component is gesteriliseerd door middel van ethyleenoxide of gammastraling.
- Niet hersteriliseren. Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien ofwel het implantaat ofwel de verpakking beschadigd blijkt te zijn, de vervaldatum is overschreden, of om welke reden dan ook aan de steriliteit wordt getwijfeld, mag het implantaat niet worden gebruikt.
- Proefmaatcomponenten zijn verkrijgbaar om te voorkomen dat de steriele verpakking vóór de implantatie van de prothese moet worden geopend. Het implantaat mag pas uit zijn steriele verpakking worden gehaald zodra de implantatieplaats is voorbereid en de juiste afmetingen heeft.

BEPERKTE GARANTIE
Avanta Orthopaedics, Inc. garandeert dat dit product beantwoordt aan de specificaties van de fabrikant en op het moment van levering geen productiefouten bevat. Uitgesloten van deze garantie zijn met name gebreken als gevolg van verkeerd gebruik, misbruik of een onjuiste bediening van het product nadat het door de koper is ontvangen. Avanta Orthopaedics geeft geen garantie op het resultaat van de chirurgische procedure.

EU-VERTEGENWOORDIGER:
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk
31 (0) 416563 754

ITALIANO

ATTENZIONE
La legislazione federale (Stati Uniti) impone la vendita, la distribuzione e l'uso di questo presidio ai soli medici o su loro prescrizione.

DESCRIZIONE
Questa protesi semi vincolata dell'articolazione è costituita da un componente distale in polietilene di peso molecolare ultraleggero (UHMWPe), cementato sul corpo dell'osso metacarpale preparato, e da un componente prossimale in cromo-cobalto cementato nell'osso trapezio preparato. La superficie in cromo-cobalto si articola con il componente in UHMWPe formando una sostituzione protesica semi vincolata dell'articolazione TMC della mano. L'impianto è disponibile in numerose misure, ognuna delle quali può essere utilizzata nella mano destra o sinistra. Per ogni tipo d'impianto è disponibile una vasta gamma di calibratori di prova, che rappresentano un valido ausilio nella preparazione dell'osso. Questo presidio è destinato unicamente all'uso cementato.

Materiali
- Componente prossimale in cromo-cobalto ASTM F-75
- Componente distale in polietilene di peso molecolare ultraleggero (UHMWPe) ASTM F-648

INDICAZIONI
L'impianto è indicato per la sostituzione totale in pazienti con sviluppo scheletrico completo con dolore o instabilità dell'articolazione in seguito a traumi, patologie infiammatorie o degenerative o per la revisione di procedure precedenti, in alternativa all'artrodesi o alla chirurgia ricostruttiva.

CONTROINDICAZIONI
- Ossa, muscolatura, tendini o tessuti molli adiacenti compromessi da patologie, infezioni o impianti precedenti che non sono in grado di fornire supporto o fissazione adeguati per la protesi.
- Immaturità scheletrica.
- Accertata ipersensibilità ai materiali utilizzati in questo presidio.

AVVERTENZE (vedere anche la sezione Informazioni per la consulenza ai pazienti)
- I pazienti devono essere avvertiti del maggiore potenziale di fallimento del presidio se sottoposto a sollecitazioni eccessive. Un eccesso di carico o di mobilità e l'instabilità articolare sono tutti fattori che possono accelerare l'usura e comportare il possibile fallimento del presidio per distacco, frattura o spostamento dello stesso.

PRECAUZIONI
- Non risterilizzare l'impianto. L'impianto fornito è sterile se in confezione integra. Non utilizzare l'impianto se lo stesso o la confezione appaiono danneggiati, se la data di scadenza è stata superata o se per qualsiasi motivo si è indotti a dubitare della sua sterilità.
- Una preparazione meticolosa del sito d'impianto e la scelta della misura corretta dell'impianto stesso aumentano le probabilità di esito positivo dell'intervento.
- L'impianto deve essere prelevato dalla confezione sterile solo dopo aver preparato e misurato correttamente il sito dell'impianto.
- Gli impianti devono essere maneggiati esclusivamente con l'ausilio di strumenti smussati per evitare di graffiare, tagliare o scalfire il presidio, in modo da non compromettere le prestazioni dell'impianto.

POTENZIALI EFFETTI INDESIDERATI
Rischi correlati alla chirurgia generale
- Emorragia
- Infezione
- Perdita dell'uso della mano
- Invalidità permanente
- Morte

Rischi correlati alla sostituzione dell'articolazione
- Dolore
- Lesioni dei nervi, vasi sanguigni, tendini o tessuti molli circostanti
- Rigidità
- Dolore notturno e correlato alle condizioni atmosferiche
- Perdita di motilità
- Frattura dell'impianto
- Rotazione dell'impianto
- Usura accelerata dei componenti del presidio
- Distacco dell'impianto dalle ossa
- Instabilità dell'articolazione
- Spostamento dell'articolazione
- Lesione dell'estrusione di cemento
- Infezione
- Allungamento o accorciamento del dito
- Amputazione
- Indebolimento dell'osso intorno all'impianto
- Diminuzione dell'ampiezza di movimento
- Reazioni allergiche o di altro tipo ai materiali metallici o plastici
- Può rendersi necessario un ulteriore intervento chirurgico per seconda operazione, revisione o fusione dell'articolazione.
- Può essere avviato un intervento chirurgico, senza però potere eseguire alcuna sostituzione dell'osso e con una conseguente fusione dell'articolazione.
- Notifica in conformità con la Legge del 1986 dello Stato della California sulla sicurezza dell'acqua potabile e sulle sostanze tossiche (dichiarazione 65): Questo prodotto contiene uno o più sostanze chimiche note allo Stato della California come possibili cause di cancro e/o difetti neonatali e di altri effetti tossici sull'attività riproduttiva.

PROCEDURE CHIRURGICHE
È disponibile un manuale che descrive nei dettagli la procedura chirurgica da applicare a questo presidio. È responsabilità del chirurgo acquisire familiarità con la procedura prima dell'uso di questi prodotti. È inoltre responsabilità del chirurgo anche acquisire familiarità con le pubblicazioni relative e consultarsi con colleghi esperti in merito alla procedura prima dell'uso.

INFORMAZIONI PER LA CONSULENZA AI PAZIENTI (vedere anche la sezione Avvertenze)
È disponibile un opuscolo per i pazienti da utilizzare per la relativa consulenza.

Oltre alle informazioni relative al paziente contenute nelle sezioni Avvertenze ed Effetti indesiderati, devono essere trasmesse al paziente le seguenti informazioni:

- La durata prevista di questo presidio, sebbene sia difficile da valutare, è comunque limitata nel tempo. Si tratta infatti di elementi composti da materiali estranei all'organismo, inseriti per facilitare il processo di guarigione. A causa dei molti fattori biologici, meccanici e fisiochimici che influiscono su questi dispositivi, non si può tuttavia pensare che essi possano resistere per un periodo di tempo illimitato a livelli di attività e carico uguali a quelli del normale osso sano.
- L'eventuale insorgenza di effetti indesiderati di questo presidio possono richiedere un secondo intervento, la revisione o la fusione dell'articolazione coinvolta.

STERILIZZAZIONE
- Il prodotto è sterilizzato in ossido di etilene o ai raggi gamma.
- Non risterilizzare l'impianto. L'impianto fornito è sterile se in confezione integra. Non utilizzare l'impianto se lo stesso o la confezione appaiono danneggiati, se la data di scadenza è stata superata o se per qualsiasi motivo si è indotti a dubitare della sua sterilità.
- Sono disponibili calibratori di prova per evitare di dover aprire la confezione sterile prima dell'impianto della protesi. L'impianto deve essere prelevato dalla confezione sterile solo dopo aver preparato e misurato correttamente il sito dell'impianto.

GARANZIA LIMITATA
Avanta Orthopaedics, Inc. garantisce che il presente prodotto è conforme alle specifiche del produttore e che è esente da difetti di fabbricazione al momento della consegna. La presente garanzia esclude specificamente i difetti derivanti da uso improprio o non corretto o da errori di manipolazione del prodotto successivamente al ricevimento da parte dell'acquirente. Avanta Orthopaedics non garantisce l'esito della procedura chirurgica.

AGENTE PER L'UE:
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk
31 (0) 416563 754

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AVANTA
ORTHOPAEDICS
9369 Carroll Park Drive, Suite A, San Diego, CA 92121 USA
P (858) 453-0505 F (858) 453-0515 (fax)

PRODUCT INSERT
SILICONE IMPLANTS
SILIKONIMPLANTATE
IMPLANTS DE SILICONE
IMPLANTES DE SILICONA
SILICONENIMPLANTATEN
PROTESI AL SILICONE

ENGLISH

CAUTION
United States Federal Law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
These devices are fabricated from medical grade silicone elastomer. In some implants, the material is internally reinforced with medical grade polyester mesh and/or fibers. Suture ties are provided in some implants for temporary stabilization. Polyester mesh or velour external surfaces, when present, promote long term stabilization through tissue ingrowth.

INDICATIONS
Silicone elastomer implants are designed to assist in joint arthroplasty. Clinical indications for use of these devices include:
1. Rheumatoid Arthritis
2. Osteoarthritis
3. Ankylosed joints, or those with limited range of motion which have not responded to conservative treatment
4. Non-functional joints due to inadequate bony alignment and joint space which cannot be restored by soft tissue reconstruction alone
5. Destroyed articular surfaces

CONTRAINDICATIONS
General contraindications for the use of these implants for joint reconstruction include:
1. A current with skin, bone, circulatory and/or neurological infection
2. Non-functioning and irreparable musculoskeletal system
3. Active sepsis
4. Inadequate bone stock

WARNINGS (See also the Patient Counseling Information Section)
Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
Implants are non-physiological devices that can be worn away, fractured or broken. An implant site may become infected (sepsis), necrotic, or inflamed. The status of the adjacent bone and soft tissue may be inadequate to support the implant, or may deteriorate in time as a result of metabolic disorders or both. The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time. Revision (including removal) surgery to replace the implant or to carry out alternative procedures. Range of surgeries with implants are not uncommon.

PRECAUTIONS
The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, unsterile, or has been previously opened or if sterility is questioned for any reason, the implant should not be used. Do not resterilize. Implants should be kept inventoried in sterile saline solution after removal from sterile wrapping prior to implantation. Implants should only be handled with blunt instruments to avoid scratching, cutting or etching the device.
Meticulous preparation of the implant site and selection of the proper size implant increase the potential for successful outcome. A complete range of trial sizes is available to aid in bone preparation. It is suggested that the proper size implant be removed from its sterile package only after the implant site has been prepared and properly sized.

ADVERSE EVENTS
Potential adverse events reported with joint prostheses include pain, loosening, fracture, dislocation, or infection. There have been some reports of material with silicone sensitivity reactions following joint replacement. Implantation of materials such as silicone may result in foreign body reaction adjacent to the implant site. Rarely the surrounding nerves, blood vessels, tissue, or soft tissue can occur as a consequence of implanting this device. In some persons, wear particles from silicone elastomer implants used in bone and joint reconstruction may particulate in, or exacerbate, synovitis or bone cyst complications in certain bone. Considerable factors have been reported to include the use of implants in physically invasive patients, associated pre-operative pathology such as mass and degenerative changes, intraoperative hemorrhagic stabilization with K-wires, subsequent anaphylaxis, implant over or undersizing and unopposed or reduced deltoid tone.

SURGICAL PROCEDURES
A surgical procedure for use of the implant device is available. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant published data and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings)
Prior to any patient scheduled for implant surgery with government accessory or essential specifications and alternatives, which they include non-implant procedures such as soft tissue reconstruction or arthrodesis, prior to surgery is necessary. In addition to the patient related information mentioned in the Warnings and following Precautions sections, the following information should be conveyed to the patient: 1) Active or latent infection may necessitate implantation, revision, or fusion of the involved joint. 2) While the extracted life of joint replacement cannot be difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain.

However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

STERILIZATION
This component has been sterilized by ethylene oxide or gamma radiation. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize. Trial size components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics, Inc. warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. The warranty is expressly excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE
Medical Products International Europe, BV
Schieweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563764

DEUTSCH

BESCHREIBUNG
Diese Prothesen werden aus medizinischem Silikonelastomer hergestellt. Bei einigen dieser Prothesen sind dieses Material intern mit einem netzgewebe und/oder Fasern aus medizinischem Polyester verstärkt. Einige Prothesen sind mit Nahtverbindungen zur temporären Stabilisierung versehen. Polyesternetzgewebe oder Velourstoberflächen unterstützen an manchen Prothesen die langfristige Stabilisierung, da sie ein Einwachsen des Gewebes ermöglichen.

INDIKATIONEN
Prothesen aus Silikonelastomeren werden für die Alloarthroplastik entwickelt. Klinische Indikationen für die Verwendung dieser Prothesen sind u.a.
1. Rheumatoide Arthritis
2. Osteoarthritis
3. Versteifte Gelenke oder Gelenke mit eingeschränkter Beweglichkeit, die auf traditionelle Behandlungen nicht angesprochen haben
4. Nichtfunktionelle Gelenke mit mangelhafter Knochenstellung und Gelenkspalte, deren Funktion durch Weichteil-Rekonstruktion allein nicht wiederhergestellt werden kann
5. Zerstörte Gelenkflächen

KONTRAINDIKATIONEN
Allgemeine Kontraindikationen für die Verwendung dieser Prothesen für die Gelenkrekonstruktion sind u.a.
1. Haut-, Knochen-, Kreislauf- und/oder neurologische Infektion
2. Funktionsunfähiger und irreparabler Muskel-Gerüst-Apparat
3. Akute Sepsis
4. Inadäquates Knochenmaterial

WARNHINWEISE (Siehe auch den Abschnitt „Patienteninformationen")
Extreme Belastungen, übermäßige Mobilität und artikuläre Instabilität können zu Verschleißerscheinungen, Versagen und schließlich Versagen der Prothese durch Lockerung, Brüche oder Verrutschen führen. Patienten sollten über das erhöhte Risiko eines Versagens der Prothese durch Überbeanspruchung aufgeklärt werden.
Prothesen sind körperfremde Hilfsmittel, die sich abnutzen, einbrechen oder brechen können. Eine Implantatinfektion kann zum Absterben, Entzündungen oder Nekrosen des Knochens und/oder Weichteilgewebes führen. Es ist bekannt, daß Silikonelastomere, z.B. die Prothese, nur unzureichend unterstützen oder sich mit der Zeit verschlechtern und zu Instabilität, Deformierung oder Brüchen führen. Die Vorteile einer Implantation durch Prothesen können die Einschränkungen des Patienten gut, nicht perfekt oder mit der Zeit abnehmen und neue Revisionseingriffe notwendig machen, damit die Prothese weiterhin oder alternative Verfahren durchgeführt werden können. Keine ausreichende Zusammenhang mit Prothesen sind nicht ungewöhnlich.

VORSICHTSMASSNAHMEN
Die Prothesen in einer unbeschädigten sterilisierten Verpackung und steril. Falls die Prothese oder die Verpackung beschädigt aussieht, das Verfallsdatum überschritten wurde oder die Sterilität aus irgendeinem Grund infrage gestellt wird, darf die Prothese nicht verwendet werden. Nicht resterilisieren. Nach dem Entfernen aus der sterilen Verpackung die Prothese bis zum Zeitpunkt der Implantation in einem Bad mit steriler Kochsalzlösung aufbewahren. Zur Vermeidung von Kratzern, Schnitten oder Kerben dürfen die Prothesen nur mit stumpfen Instrumenten gehandhabt werden.
Die gründliche Vorbereitung der Implantationsstelle und die Wahl der richtigen Prothesengröße erhöhen die Chance eines erfolgreichen Eingriffs. Eine komplette Auswahl an Größen zur Gelenkrekonstruktion steht für die Vorbereitung des Knochenbetts zur Verfügung. Es wird vorgeschlagen, daß die Prothese der entsprechender Größe erst dann aus der sterilen Verpackung genommen wird, wenn die Implantationsstelle vorbereitet und genau bemessen worden ist.

KOMPLIKATIONEN
Zu den möglichen Komplikationen, die bei Gelenkprothesen berichtet wurden, gehören Schmerzen, Lockerung, Frakter, Verrutschen und Infektionen. Es wurden Fälle berichtet, daß Gewebereaktionen eine Überempfindlichkeit gegen Silikon auf. Die Implantation von Materialien wie Silikon kann im Umfeld der Implantatstelle zu Abstoßungsreaktionen gegen Fremdkörper führen. Als Folge der Implantation können umgebende Nerven, Blutgefäße, Gewebe oder Muskelteile verletzt werden. Bei manchen Patienten können Verschleißpartikel der bei einer Knochen- und Gelenkrekonstruktion verwendeten Silikonelastomer-Prothese eine Synovitis oder Knochenzyst-komplikationen im angrenzenden Knochen hervorrufen oder begünstigen. Zu berücksichtigen Faktoren, die bekannt wurden, gehören die Verwendung der Prothese bei physisch übertrieben aktiven Patienten, präoperative pathologische Befunde wie Zysten und degenerative Veränderungen, intraoperative temporäre Kreislaufsenkung durch K-Drähte, nachfolgende Anaphylaxie, falsche Größenbestimmung der Prothese und zuviel komplette oder reduzierende Determinierung.

OPERATIONSVERFAHREN
Eine Operationstechnik für die Verwendung dieser Prothese ist erhältlich. Der Chirurg muß sich vor der Verwendung dieser Produkte mit der Operationstechnik vertraut machen. Außerdem gehört es zur Verantwortung des Chirurgen, sich durch Lesen der relevanten Publikationen und im Konsultation mit erfahrenen Kollegen die nötigen Verfahrensinformationen vor der Verwendung der Prothese einzuholen.

PATIENTENINFORMATIONEN (Siehe auch „Warnhinweise")
Patienten, die für die Implantation vorgesehen sind, müssen vor der Operation über die möglichen Komplikationen und Alternativen aufgeklärt werden und diese Aufklärung ist dokumentarisch nachzuweisen. Zu den Alternativen können Verfahren ohne Implantate, wie eine Rekonstruktion von Weichteilen oder Arthrodese zählen. Zusätzlich zu den patientenbezogenen Informationen in den Abschnitten „Warnhinweise" und „Komplikationen", müssen die Patienten über Folgendes informiert werden: 1) Krankheitsherden können eine erneute Operation, einen Revisionseingriff oder Fusion des betroffenen Gelenkes erforderlich machen. 2) Die zu erwartende Lebensdauer der Gelenkersatzkomponenten ist keine abzuschätzen, sie ist jedoch begrenzt. Diese Komponenten aus körperfremdem Material werden in den Körper eingesetzt, um die Beweglichkeit wenn möglich, wiederherzustellen oder Schmerzen zu verringern.

Aufgrund zahlreicher biologischer, mechanischer und physikochemischer Faktoren, die diese Prothesen beeinflussen, können die Komponenten jedoch nicht dauerhaft Aktivitätsniveau und der Belastung eines normalen gesunden Knochens über einen unbegrenzten Zeitraum standhalten.

STERILISATION
Dieses Produkt wurde mit Ethylenoxid oder Gammastrahlen sterilisiert. Die Prothese in einer unbeschädigt gelassenen Packung ist steril. Falls die Prothese oder die Verpackung beschädigt aussieht, das Verfallsdatum überschritten wurde oder die Sterilität aus irgendeinem Grund infrage gestellt wird darf die Prothese nicht verwendet werden. Nicht resterilisieren. Gestalte zur Größenbestimmung stehen zur Verfügung, damit die sterile Verpackung vor Implantation der Prothese nicht geöffnet werden muss. Die Prothese sind darin aus der sterilen Verpackung nehmen, wenn die Implantationsstelle vorbereitet und genau bemessen worden ist.

BESCHRÄNKTE GARANTIE
Avanta Orthopaedics, Inc. garantiert, daß dieses Produkt den Spezifikationen des Herstellers entspricht und beim Zeitpunkt der Lieferung keine Herstellungsfehler aufweist. Schäden, die auf unsachgemäße Behandlung, Mißbrauch oder falsche Verwendung des Produkts nach dem Empfang durch den Käufer hervorgerufen werden, sind von dieser Garantie ausdrücklich ausgeschlossen. Avanta Orthopaedics übernimmt keine Garantie für den Ausgang des chirurgischen Eingriffs.

EU-VERTRETER
Medical Products International Europe, BV
Schieweg 13a
5145 NP Waalwijk, Niederlande
31 (0) 416 563764

FRANÇAIS

DESCRIPTION
Ces appareils sont fabriqués en silicone-élastomère de qualité médicale. Dans certains implants, ce matériau est renforcé intérieurement d'un treillis de tissées et/ou de fibres polyester de qualité médicale. Les fibres de sutures sont prévues dans certains implants pour une stabilisation temporaire. Le treillis de maillage en polyester ou les surfaces extérieures en nature velours favorisent toujours favorisent la stabilisation à long terme d'un tissé à l'autre ou la croissance tissulaire interne.

INDICATIONS
Les implants de silicone-élastomère ont été conçus pour servir d'appuis à l'arthroplastie articulaire. Les indications cliniques de ces appareils comprennent :
1. Arthrite rhumatoïde
2. Ostéoarthrite
3. Articulations ankylosées ou celles dont l'amplitude du mouvement est limitée et qui n'ont pas répondu au traitement conservateur
4. Articulations non-fonctionnelles avec un mauvais alignement osseux et un espace articulaire qui ne peut pas être restauré par la seule reconstruction des tissus mous
5. Surfaces articulaires détruites

CONTRE-INDICATIONS
Les contre-indications générales de l'usage de ces implants pour la reconstitution articulaire sont les suivantes :
1. Patient présentant une défaillance interne, associée, actuelle ou virale
2. Septicémie
3. Système musculosquelettique non-fonctionnel ou irréparable
4. Septicémie active
5. Masseuse constitution osseuse

MISES EN GARDE (Voir aussi la partie Information et Conseils destinés au patient)
Contraintes importantes, modes excessifs et instabilité articulaire peuvent toutes accélérer l'usure et amener à une éventuelle défaillance par décollement, fracture ou dislocation de l'appareil. Les patients doivent être conscients de risque potentiel accru de défaillance de l'appareil si ne dernier subit des contraintes excessives.
Les implants sont des appareils mécaniques qui peuvent s'user, se briser ou se casser. Un site d'implant peut s'infecter, devenir septicémique, se nécroser ou s'enflammer. L'état de l'os adjacent et du tissu mou peut être inapproprié pour soutenir l'implant ou peut se détériorer avec le temps et associer à une instabilité à une difficulté ou aux deux. Les avantages de l'implantation chirurgicale peuvent ne pas répondre aux attentes du patient ou peuvent s'altérer avec le temps et nécessiter alors une chirurgie ré-opératoire pour remplacer l'implant ou traiter en utilisant de procédures alternatives. Les interventions chirurgicales comportant à l'aide d'implants ne sont pas exceptionnelles.

PRÉCAUTIONS
L'implant est fourni stérile dans un emballage intact. Si l'implant ou son emballage apparaît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en doute pour une raison quelconque, il faut prescrire l'emploi de cet implant. Ne pas restériliser. Les implants doivent être gardés dans une solution saline stérile après avoir été retirés de leur emballage stérile avant implantation. Il convient de manipuler les implants uniquement avec des instruments émoussés pour éviter de rayer, de couper ou d'entailler l'appareil.
Une préparation méticuleuse du site d'implantation et le choix de la taille appropriée de l'implant augmentent la chance de succès de l'implantation. Il existe une gamme complète de gabarits pour aider à la préparation de l'os. Il est recommandé de retirer l'implant de taille appropriée de son emballage stérile seulement après que le site d'implantation a été préparé et correctement dimensionné.

EFFETS INDÉSIRABLES
Parmi les effets indésirables potentiels des prothèses on a signalé la douleur le descellement, la fracture, la déformation ou l'infection. On a signalé parfois le cas de patients qui ont manifesté des réactions de sensibilité à la silicone après remplacement de l'articulation. L'implantation de matériaux comme le silicone peut en outre être une réaction allergique au voisinage du site de l'implantation. Le tissu des nerfs, vaisseaux sanguins, tissons ou tissus mous environnants peut survenir suite à l'implantation de cet appareil. Chez certains patients, les particules d'usure issues des implants de silicone-élastomères utilisés dans la reconstitution osseuse et articulaire peuvent entraîner ou accentuer une synovite ou des complications kystiques dans l'os spongy. Dans les facteurs contributifs ont été signalés pour inclure l'emploi d'implants chez des patients physiquement très actifs, une pathologie préopératoire associée, comme les tumeurs et les modifications dégénératives, la stabilité peropératoire consécutive avec des fils K, les anaphylaxies subséquentes, un implant surdimensionnement et sous-dimensionnement de l'implant et le traumatisme non corrigée du deltoïde.

PROCÉDURES CHIRURGICALES
Il existe une procédure chirurgicale à suivre dans le cadre de l'utilisation de cet appareil. Il est de la responsabilité du chirurgien de bien prendre connaissance de cette procédure avant d'utiliser ces produits. De plus, le chirurgien est tenu de s'informer sur les données publiées et de consulter des confrères expérimentés avant d'utiliser ces prothèses.

INFORMATION ET CONSEILS DESTINÉS AU PATIENT (Voir également la partie Mises en garde)
Il convient de fournir à tout patient programmé pour une implantation chirurgicale des informations détaillées sur les complications et alternatives possibles, qui peuvent comprendre des procédures non-entraînant une nouvelle reconstruction des tissus mous, à savoir l'arthrodèse. En plus de l'information relative au patient, contenue dans les parties ci-dessus et dans la partie « Mises en garde », il faudra en faire part au patient que : 1) Les effets indésirables peuvent nécessiter une nouvelle opération, une ablation ou une fusion de l'articulation concernée. 2) Comme la longévité des composants de remplacement de l'articulation est difficile à estimer, elle est limitée. Ces composants sont constitués de matériaux étrangers qui sont placés à l'intérieur de l'organisme en vue de la restauration potentielle de la mobilité ou de la réduction de la douleur.

Toutefois, en raison de nombreux facteurs biologiques, mécaniques et physicochimiques entourant à ces appareils, les composants ne peuvent pas pouvoir indéfiniment au niveau d'activité et aux contraintes d'un os sain normal pendant une durée illimitée.

STÉRILISATION
Ce composant a été stérilisé à l'oxyde d'éthylène ou aux rayons gamma. L'implant est fourni stérile dans un emballage intact. Si l'implant ou son emballage apparaît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en doute pour une raison quelconque, il faut prescrire l'emploi de cet implant. Ne pas re-stériliser. Il existe des gabarits d'essai pour vous éviter d'ouvrir un emballage stérile avant l'implantation de la prothèse. Il faut retirer l'implant de son emballage stérile seulement après que le site d'implantation a été préparé et correctement dimensionné.

GARANTIE LIMITÉE
Avanta Orthopaedics, Inc. garantit que ce produit présente aux spécifications du fabricant et qu'il est dénué de défauts de fabrication au moment de sa livraison. Cette garantie exclut expressément les défauts résultant d'une mauvaise utilisation, d'un usage abusif ou d'une manipulation incorrecte du produit après réception de celui-ci par l'acheteur. Avanta Orthopaedics n'assure toute responsabilité quant à l'issue de l'intervention chirurgicale.

REPRÉSENTANT UE
Medical Products International Europe, BV
Schieweg 13a
5145 NP Waalwijk, Pays-Bas
31 (0) 416 563764

CE

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ESPAÑOL

DESCRIPCIÓN

Estos dispositivos están fabricados con un elastómero de silicona de grado médico. En algunos implantes, este material se ha reforzado internamente con una malla y/o fibra de poliéster de grado médico. En algunos implantes se han incluido fibra de sutura para la estabilización temporal. Las superficies externas de malla de poliéster o de tereftalato de tipo liso, texturizado, flocado/poroso o tejido pueden presentar endurecimiento del tejido blando.

INDICACIONES

Los implantes de dispositivos de silicona están diseñados para asistir en la aplicación de antebrazos. Las indicaciones clínicas para el uso de estos dispositivos incluyen:

1. Artritis reumatoidea
2. Osteoartritis
3. Articulaciones anquilosadas o con un rango de movimiento limitado que no han respondido a tratamientos conservadores
4. Articulaciones disfuncionales debido a una alteración ósea traumática y un soporte artricular que no se puede recuperar suficiente por medio de reconstrucción del tejido blando
5. Superficiedad articular destruida/ausente

CONTRAINDICACIONES

Las contraindicaciones generales para el uso de estos implantes en reconstrucciones articulares incluyen:

1. Un paciente con portadores nutritivos, óseo, inadecuado y/o neurológico
2. Sistema musculoesquelético disfuncional o inestable
3. Tejidos activos
4. Vasos óseos inadecuados

ADVERTENCIAS

Las cargas pesadas, una movilidad excesiva y la inestabilidad articular pueden contribuir a un desgaste acelerado y al fallo mecánico del dispositivo al afojarse, fracturarse o deformarse. Los pacientes deben ser conscientes de que la posibilidad de fallo aumenta si se la misma exigencia de ejercicio.

Los materiales son dispositivos mecánicos que no pueden reparación fatiga o rompe. Si fuga de un implante puede irritaciones, dolor, tendinitis o inflamación. El estado del hueso adyacente y del tejido blando puede no ser adecuado para soportar el implante o puede deteriorarse con el tiempo causando inestabilidad, deformidad o artritis. Puede ser que los beneficios no se consigan las actividades del paciente o que se disminuyen con el tiempo, haciendo necesaria una cirugía de revisión para cambiar el implante o realizar procedimientos alternativos. En el caso de los implantes, las fuerzas de revisión no son seguras.

PRECAUCIONES

El implante se presenta estéril en un envase sellado. No se debe usar el implante si éste o el envase parecen estar dañados, si ha pasado la fecha de caducidad, o si han sucedido mal. Se pone en duda su esterilidad. No se esterilice de nuevo. Los implantes se deben manipular correctamente en todo momento usando guantes quirúrgicos estériles nuevos antes de tocar el implante. Para evitar que los materiales se rayen, agrien o mellen, retire suficiente se deben manipular con instrumentos suaves.

La compatibilidad de ambos componentes se debe seleccionar la forma del implante y el tamaño apropiado del mismo. Se dispone de una gama completa de medidas de prueba para facilitar la preparación del hueso. Se recomienda mantener el implante del tamaño apropiado en su envase estéril hasta que se haya preparado y medido adecuadamente la zona del implante.

EVENTOS ADVERSOS

Los eventos adversos potenciales comunes en cuanto de prótesis articulares incluyen dolor, ensanchamiento, fractura, calcificación o infección. Se conocen algunos casos de pacientes con reacciones de sensibilidad a la silicona tras el reemplazo de la articulación. La implantación de estos dispositivos como la silicona pueden ser lugar a una reacción adversa de la zona del implante debido a presencia de un cuerpo extraño. Como consecuencia de la implantación de este dispositivo se puede producir inflamación en los nervios vasos sanguíneos, tendones o tejidos blandos circundantes. En algunos pacientes, las partículas de desgaste de los implantes de elastómero de silicona utilizados en la reconstrucción de huesos y articulaciones pueden provocar o exacerbar la aparición o complicaciones de quistes óseos en el hueso receptor. Se sabe que ciertos factores que contribuyen con el uso de implantes en pacientes frecuentes demasiado activos, ciertas patologías preexistentes incluidas como diuretes y cambios degenerativos, la estabilización ser/pone atrapamiento con alambres-IC los implantes suficiente, el uso no implantes demasiado pequeños o pequeños y la deformación en cantidad o recurrente.

PROCEDIMIENTOS QUIRÚRGICOS

Se recomienda un procedimiento quirúrgico que permita el uso no tras implante. Tras recomendación del cirujano familiarizarse con el procedimiento antes de la base antes productos. Además, antes de utilizarlo el cirujano es responsable de estar familiarizado con la literatura relevante y consultar con colegas con experiencia en el procedimiento.

INFORMACIÓN SOBRE ASISTENCIA AL PACIENTE

Antes de la cirugía es necesario proporcionar a cada paciente un informe de una cirugía se implante información documentada sobre las posibles complicaciones y sobre las alternativas que pueden convenir en presentaciones alternativas, como la reconstrucción del tejido blando o la artrodesis. Además de la información relacionada con el paciente que se indique en las secciones Advertencias y Eventos Adversos, se debe informar al paciente de lo siguiente: 1) Los efectos adversos pueden hacer necesaria la repetición de la operación, lo cual/o a la toma de la articulación artificial. 2) Aunque no exista ninguna limitación de la duración de los componentes en la articulación de reemplazo, su vida/se que se limitada. Estos componentes están hechos de materiales extraños que se colocan dentro del cuerpo para la potencial oxidación de la movilidad o reducción del dolor.

Un embalaje debido a los numerosos factores biológicos, mecánicos y fisiológicos que afectan a estos procedimientos, no se puede asegurar que dichos componentes vayan a tener el nivel de actividad y las cargas de un hueso normal y sano durante un período de tiempo limitado.

ESTERILIZACIÓN

Este componente ha sido esterilizado mediante óxido de etileno o radiación gamma. El implante se presenta estéril en un envase estéril. No se debe usar el implante si este o el envase parecen estar dañados. Si ha pasado la fecha de caducidad o si ha sucedido nada. Se pone en duda su esterilidad. No lo esterilice de nuevo. Se deben manipular correctamente en todo momento usando guantes quirúrgicos estériles nuevos antes de tocar el implante. Para evitar que los materiales se rayen, agrien o mellen, retire suficiente se deben manipular con instrumentos suaves.

GARANTÍA LIMITADA

Avanta Orthopaedics, Inc. garantiza que este producto cumple con las especificaciones del fabricante y que en el momento de entrega está libre de defectos de fabricación. Esta garantía excluye específicamente los defectos percibidos por el usar incidental, abuso o mantenimiento inapropiado del producto después de que el comprador lo reciba. Avanta Orthopaedics no garantiza el resultado del procedimiento quirúrgico.

REPRESENTANTE EN LA UE

Medinet Products International Europe, BV
Schohweg 18a
5145 NP Waalwijk, Holanda
31 (0) 416 663764

NEDERLANDS

BESCHRIJVING

Deze implantaten zijn vervaardigd van medisch siliconenelastomeer. Bij sommige implantaten is dit materiaal aan de binnenzijde versterkt met medisch polyester mesh en/of vezel. Sommige implantaten zijn voorzien van hechtdraadbevestiging voor tijdelijke stabilisatie. Buitenoppervlakken van polyester mesh of weefsel kunnen/zijn verharding langdurige stijfheid/te vormen in het weefsel.

INDICATIES

Siliconenelastomeer implantaten zijn bestemd als ondersteuning bij de polsgewrichten. Dergelijk. De klinische indicaties voor het gebruik van deze implantaten zijn:

1. Reumatoïde artritis
2. Osteoartritis
3. Deze artrotische en/of gewrichten gewrichten of gewrichten met een beweginguitgebreid die niet op conservatieve behandeling gereageerd hebben
4. Niet functioneren van gewrichten als gevolg van onvoldoende botvorming en gewrichtsvorm die niet van voldoen herstelt door middel van reconstructie van het zachte weefsel alleen
5. Verwoeste gewrichtsoppervlak

CONTRA-INDICATIES

De algemene contra-indicaties voor het gebruik van deze implantaten voor gewrichtsvervangende zijn:

1. Matig- tot- zwakkere- en/of neurologische deficiëntie
2. Een niet functionerende en onvoldoende musculatuur
3. Actieve sepsis
4. Inadequate botvoorraad

WAARSCHUWINGEN

Zware belasting, overmatige mobiliteit en instabiele gewrichten kunnen een snelle/ het versnelde slijtage en uiteindelijk falen door loslating, breuken of vervorming van het implantaat. Patiënten moeten bewust gemaakt worden van de verhoogde kans op falen van het implantaat als hier gymnastiek voor het gewricht wordt.

Implantaten zijn mechanische prothesen en kunnen/ afbreken, of een mechanisme/ een reden als de kunnen breken. De plaats van het implantaat kan gekenmerkt/ op/in gevolgen of symptomen optreden. De status van het aangrenzende bot en zachte weefsel kan ontoereikend zijn voor de ondersteuning van het implantaat of kan in de loop van de tijd verslechteren met betrekking/ tot, inwonning of losse als gevolg. Het kan ten dat implantaatcomponenten niet de voordelen bieden die de patiënt verwacht/ dat of dat de patiënten in de loop van de tijd slechter/ waardoor revisiechirurgie noodzakelijk is om het implantaat te vervangen of alternatieve procedures te verrichten. Revisiechirurgie is niet ongecompliceerd.

VOORZORGSMAATREGELEN

Het implantaat wordt steriel geleverd in een steriele verpakking. Als het implantaat of de verpakking beschadigd lijken te zijn, als de vervaldatum overschreden is/verschreden of als om de een of andere reden twijfel bestaat over de steriliteit mag het implantaat niet gebruikt worden. Niet opnieuw steriliseren. Voor het hanteren van implantaten implantaten in steriele (bescherming ondersteunend) tijdens/ nauw bij uit de steriele verpakking gebeldt. Om materialen/ mogen valkuilstof weerga beschadigen gebruikt worden. Met gebruiker steriliseren. Voor het implantaat te voorbereiden.

Zeer nauwgezette voorbereiding van de plaats van het implantaat en de keuze van de juiste maat implantaat verhogen de kans op een succesvol resultaat. Een volledig assortiment proefinstrumenten is verkrijgbaar ter ondersteuning van de/voorbereiding. Deskundigheid moet van het implantaat met de juiste maat/ pas uit de steriele verpakking te halen nadat de plaats van het implantaat is voorbereid en de juiste maat heeft.

BEWERKINGEN

De mogelijke bijwerkingen die gemeld zijn bij het gebruik van vergelijkbare/dergelijke zijn pijn, zwelling, trauma, overgevoelige en infectie. Er is ook een zeldzaam meldingen van patiënten die na gewrichtsvervanging overgevoelig blijken te zijn voor siliconen. Het implanteren van implantaten zoals siliconen kan leiden tot ontstekingsreacties bij de plaats van het implantaat. Letsel van zenuwgroepe zenuwen, bloedvaten, zachte en zacht weefsel kunnen optreden als gevolg van het insteken van dit implantaat

Bij sommige patiënten kunnen deeltjes van siliconenelastomeerslijtage die bij bot- en gewrichtsvervangende gebruikt worden, zorgen tot de complicaties symptoms of verhogen in gevaarzaad het of deze verergeren. Van de volgende factoren is gemeld dat deze daartoe bijdragen: het gebruik van implantaten bij hoge/ overgewicht patiënten, bijkomende pathologische/ pre-existente/ degenerative veranderingen, misvormingen rondom/ omliggende weefsel, ongeschikte implantaat, het gebruik van een te groot of te klein implantaat en ongecompenseerde of herhaalde inwonning.

ITALIANO

DESCRIZIONE

Questi dispositivi sono realizzati in elastomero di silicone di grado medicale. In alcune protesi, questo materiale è rinforzato internamente con una maglia e/o fibra di poliestere di grado medicale. Alcune protesi sono provviste di suture di sutura in grado di fornire una stabilizzazione temporanea. La maglia di poliestere o di tereftalato liscia, testurizzata, flocata/porosa o tessuta può causare l'indurimento del tessuto molle circostante.

INDICAZIONI

Le protesi in elastomero di silicone sono indicate come supporto in interventi di artroplastica. Le indicazioni cliniche per l'uso di questi dispositivi includono:

1. Artrite reumatoide
2. Osteoartrite
3. Articolazioni anchilosate o caratterizzate da un'ampiezza limitata del movimento, nel caso che non abbiano risposto a trattamenti conservativi
4. Articolazioni affette da tessuto traumatico associato ad una scheletrici abnormità, tessuto a tal una appoggio articolare tale da/ integrità non può essere ripristinata con la sola ricostruzione del tessuto molle
5. Distruzione di una o più superfici articolari

CONTROINDICAZIONI

Le controindicazioni generali all'utilizzo di questo protesi per la maggioranza protesiche includono:

1. Presenza di deficit a livello cutaneo, osseo, circolatorio e/o neurologico nel paziente
2. Sistema muscoloscheletrico affettoso/ la cui funzionalità non è ripristinabile
3. Tessuti in corso
4. Massa ossea insufficiente

AVVERTENZE

Carichi e mobilità eccessivi e instabilità articolare contribuiscono/ fattori in grado di accelerare l'usura e l'eventuale guasto del dispositivo attraverso un processo di allentamento, frattura o deformazione. I pazienti devono essere pertanto/ di tale che il livello di grado del dispositivo aumenta in caso di sollecitazioni eccessive della stessa.

Le protesi sono dei dispositivi meccanici soggetti a usura, allentamento e rottura. Il tipo di impianto/ di una protesi è soggetto al rischio di irritazioni, dolore, edema o infiammazione. Le condizioni dell'osso e del tessuto molle adiacenti potrebbero essere inadeguate a sostenere la protesi oppure subire fratture o deterioramenti/ procedure, con conseguente instabilità o deformità. È possibile che i benefici/ desiderati della protesi non vengano/ più mantenuti nel tempo, in tal caso/ di peggiorare l'attività del paziente o peggiorare la loro qualità nel tempo. In tal caso/ di peggiorare indispensabile eseguire un intervento/ chirurgico di revisione/ altre o sostituire la protesi o ad eseguire delle procedure alternative. Gli interventi chirurgici di revisione di protesi non sono/ lievi.

RESPONSABILITÀ

Avanta Orthopaedics declina/ garantisce che questo prodotto soddisfa le specifiche della casa produttrice e non presenta difetti al momento della consegna. Questa garanzia esclude espressamente qualsiasi difetto derivante da utilizzo incidentale, abuso o mantenimento inadeguato del prodotto successivamente all'avvio della stessa. Inoltre il risultato dell'intervento. Avanta Orthopaedics non garantisce l'esito positivo della procedura chirurgica.

REAZIONI AVVERSE

Alcune potenziali reazioni avverse riportate in seguito all'impianto di protesi articolari includono: dolore, allentamento, frattura, dislocazione o infezione. Sono stati riportati i casi di pazienti che hanno manifestato delle reazioni di sensibilità al silicone in seguito alla sostituzione dell'articolazione. L'impianto di materiali quali il silicone possono dar luogo a reazione di corpo estraneo nelle adiacenze del sito di impianto.

PRECAUZIONI

La protesi è fornita in condizioni sterili, se all'interno di una confezione integra. Evitare di procedere all'utilizzo della protesi nel caso in cui si constati un danno alla stessa o alla confezione, scadute la data di scadenza o di qualsiasi altra/ anomalia. Non risterilizzare. Dopo la rimozione dall'involucro sterile e prima dell'inserimento di impianto, le protesi devono essere conservate in soluzione salina sterile. Le protesi vanno maneggiate esclusivamente con l'ausilio di strumenti avvalsati per evitare di graffiarle.

Una preparazione accurata del sito di impianto ed una corretta scelta delle dimensioni della protesi aumentano la probabilità di successo dell'intervento. Una gamma completa di discussi di prova è disponibile per la predisposizione dimensionale dell'osso. Si consiglia di estrarre la protesi dalla giusta dimensione dalla sua confezione sterile soltanto dopo aver predisposto e dimensionato adeguatamente il sito di impianto.

GARANZIA LIMITATA

Avanta Orthopaedics, Inc. garantisce che questo prodotto soddisfa le specifiche della casa produttrice e non presenta difetti al momento della consegna. Questa garanzia esclude espressamente qualsiasi difetto derivante da utilizzo incidentale, abuso o mantenimento inadeguato del prodotto successivamente all'avvio della stessa. Inoltre il risultato dell'intervento. Avanta Orthopaedics non garantisce l'esito positivo della procedura chirurgica.

RAPPRESENTANTE EU

Medinet Products International Europe, BV
Schohweg 18a
5145 NP Waalwijk, Paesi Bassi
+31 (0) 416 663764

AVANTA
ORTHOPAEDICS
9400 Carroll Park Drive, San Diego, CA 92121 USA
(858) 452-8580 / (800) 778-8837 / (858) 452-9945 (fax)

MADE IN USA

WARNING: CLEAN, NOT STERILE

PRODUCT INSERT

METALLIC BONE FIXATION APPLIANCES AND ACCESSORIES

SCS SYSTEM

CAUTION: United States Federal Law restricts this device to sale by or on the order of a physician.

CAUTION
United States Federal law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
The device system consists of plates, screws, accessories and instruments for the treatment of the distal radius.

Specialty instrumentation, trials and accessories are designed to aid the surgeon in installation, assembly, and/or removal of a surgical device. The surgical techniques for implantation of the device describe the proper application of specialty instrumentation and should be read and understood by the surgeon prior to use.

Materials
- Stainless Steel F 316 L, ASTM F 138, ASTM F 139
- ASTM A 564 Stainless Steel 17-4PH

INDICATIONS FOR USE
The intended use of the distal radius fracture fixation plate systems is internal fixation of fractures and osteotomies of the distal radius. This may include:
- Displaced or non-displaced fractures which may or may not involve angulation or fragmentation of bone.
- Failed fracture fixation with or without bone graft.
- Osteotomy and repair of distal radius malunion with or without bone graft.

CONTRAINDICATIONS
- Active or latent infection
- Osteoporosis, insufficient quantity or quality of bone/soft tissue
- Material sensitivity – if suspected perform tests prior to surgery
- Sepsis
- Patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions

WARNINGS (See also the Patient Counseling Information Section)
- The device is intended for the use as described in this product insert only.
- Careful patient selection, education and counseling by the surgeon and rehabilitation care provided is important.
- Strenuous loading, excessive mobility, may lead to failure of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
- Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing.
- Improper insertion of the device during implantation can increase the possibility of loosening and migration.
- A poor result may be obtained if the fracture is not properly reduced or the device is not properly assembled.
- Explantation of this device may be necessary.
- Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

PRECAUTIONS
- An implant should never be reused. Previous stresses may have created imperfections which may lead to device failure.
- Caution should be taken as to avoid nicking, scratching or other damage during handling of this device.
- Meticulous preparation of the implant site and selection of the proper size increase the potential for a successful outcome.
- The sterile products should be removed from its sterile package only after it is determined that the implant will be used on the patient.

ADVERSE EVENTS
- Adverse events published in the literature should be reviewed prior to using this device.
- Metal sensitivity reactions have been reported following metal implantation.
- Additional possible adverse events may include fracture of the bone, infection, pain and soft tissue irritation.

SURGICAL PROCEDURES
A manual is available describing a detailed surgical procedure for use of this device. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

LIMITED WARRANTY
Avanta Orthopaedics Corporation warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

CLEANING INSTRUCTIONS – WARNINGS
- Clean, not sterile, instruments, trials and accessories, which are not sterile must be sterilized prior to each use.
- The most common cause of instrument breakage is misuse. Specialty instrumentation should never be used for tasks it was not specifically designed to perform. Misuse of an instrument may result not only in damage to the instrument, but also trauma to the patient and operating room personnel.
- If not handled properly, instruments with cutting edges or sharp corners may compromise sterility by tearing surgical gloves.
- If an instrument tip becomes bent, chipped, or otherwise damaged the instrument should be replaced or repaired before further use. Attempts to straighten bends are not advised as the metallurgical integrity of the metal may be compromised in the process, and the instrument may subsequently break during use.
- New instruments are packaged clean, not sterile and should be assumed to be contaminated. Instruments must be cleaned and sterilized before each use.
- For your safety, be familiar with the procedures for handling contaminated materials at your facility before following these instructions.
- Clean instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, use damp towels or sponges with deionized or distilled water to keep soiled instruments moist prior to cleaning.
- Manually scrub with a clean, soft-bristled brush or soft cloth in mild detergent following the detergent manufacturers instructions for use. Avoid using extreme detergent concentration levels. Detergents with enzyme cleaners or separate enzyme solutions may be used, but their effectivity has not been evaluated. Warm or hot water (300ºF/149ºC maximum) should be used to aid in cleaning. Ultrasonic cleaning is recommended for instruments with internal surfaces or crevices which may be hard to clean manually.
- pH neutral cleaners (pH 6.0-8.0) are recommended for longer life of the instruments. If acidic or alkaline solutions are used follow the manufacturers recommendations for neutralizing the pH by rinsing with water or neutralizing agent. Highly alkaline or acidic cleaners (used in some mechanical washers) are not recommended as they will reduce the life of the instruments and may effect instrument performance. Avoid prolonged exposure to acidic or alkaline solutions and solutions containing chlorides, bromides or iodine.
- Use of water soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively in another instrument.
- Rinse thoroughly with deionized water or distilled water.
- Dry completely before sterilizing.
- Inspect each instrument thoroughly for cleanliness, especially in/each teeth, internal surfaces and crevices. Instruments should be re-washed if there are any signs of foreign matter or residue. Check instruments thoroughly for damage. Do not use damaged instruments as they may compromise the surgical porcome, replace damaged instruments before next use.
- Use of mechanical washers have not been evaluated by the manufacturer. Qualification of specific wash cycles and equipment should be completed by the user.

STERILIZATION
The recommended sterilization method is steam sterilization. The following sterilization cycles have been shown to produce a sterility assurance level of 10^{-6} when parts have been cleaned to the instructions above. Other similar steam cycles and cleaning procedures may be used but have not been evaluated. Sterilization qualification was performed using specific equipment and procedures. Use of cycles, equipment and procedures other than those listed should be qualified by the user. Do not exceed 300ºF/149ºC.

Wrapped Gravity Steam Sterilization 20 minutes minimum @ 270-275ºF (132-135ºC)
Wrapped Prevacumm Steam Sterilization 6 minutes minimum @ 270-275ºF (132-135ºC)
Unwrapped Prevacumm Steam Sterilization 6 minutes minimum @ 270-275ºF (132-135ºC)

For further information on the above cleaning and sterilization recommendations please contact:
Avanta Orthopaedics, 9400A Carroll Park Dr., San Diego, CA 92121
(800) 778-8837 / (858) 452-8580 / (858) 452-9945 (Fax)

EU Representative: Medical Products International Europe, BV, Schutweg 13a,
5145 NP Waalwijk, The Netherlands 31 (0) 416 563754

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AVANTA
ORTHOPAEDICS
9369 Carroll Park Drive, Suite A, San Diego, CA 92121 USA
(858) 452-8580 / (858) 452-9945 (fax)

PRODUCT INSERT

Avanta TMC Thumb Prosthesis
Daumen-Metacarpal-(TMC-)Gelenkprothese von Avanta
Prothèse de pouce trapézo-métacarpienne Avanta
Prótesis trapeciometacarpiana del pulgar, Avanta TMC
Protesi per trapezio metacarpale del pollice Avanta
Protesi del pollice Avanta TMC

ENGLISH

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
This semi constrained joint prosthesis consists of an ultra-high molecular weight polyethylene (UHMWPe) distal component which is cemented to the shaft of the prepared metacarpal bone, and a cobalt chromium proximal component which is cemented into the prepared trapezium bone. The cobalt chromium surface articulates with the UHMWPe component to form a semi-constrained prosthetic replacement of the TMC joint of the hand. The implant is available in several sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation. This device is for cemented use only.

Materials:
- ASTM F-75 cobalt chromium proximal component
- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) distal component

INDICATIONS
The implant is indicated for total joint replacement in skeletally mature patients with pain or instability of the joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

CONTRAINDICATIONS
- Active or latent infection.
- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Skeletal immaturity.
- Known sensitivity to materials used in this device.

WARNINGS (See also the Patient Counseling Information and Potential Adverse Events Section)
- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.

PRECAUTIONS
- **Do not resterilize.** The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
  The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
  Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance.

POTENTIAL ADVERSE EVENTS
General Surgery Related Risks
• bleeding • infection • loss of use of the hand • permanent disability • death

Joint Replacement Related Risks
- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- instability of the joint
- dislocation of the joint
- cement extrusion injury
- infection
- lengthening or shortening of the finger
- amputation
- bone weakening around the implant
- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional surgery may be required for reoperation, revision or fusion of the joint
- surgery may be started but a joint replacement cannot be done resulting in fusion of the joint
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

SURGICAL PROCEDURES
A manual is available describing detailed surgical procedure for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings and Potential Adverse Events Section) A patient brochure is available for use in counseling the patient.

In addition to the patient related information contained in the Warnings and Potential Adverse Events sections, the following information should be conveyed to the patient:

- While the expected life of total joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.
- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION
- This component has been sterilized by ethylene oxide or gamma radiation.
- Do not resterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics, Inc. warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk The Netherlands
31 (0) 416563 754

DEUTSCH

BESCHREIBUNG
Diese teilgekoppelte Gelenkprothese hat eine distale Komponente aus ultrahochmolekularem Polyethylen (UHMWPE), die in dem Schaft des präparierten Metacarpalknochens zementiert verankert ist, und eine proximale Kobaltchrom-Komponente, die in den präparierten Trapezknochen einzementiert ist. Zwischen Kobaltchromoberfläche und UHMWPE-Komponente besteht eine gelenkige Verbindung (Artikulation), um einen prothetischen Ersatz mit teilgekoppeltem System für das Trapezio-Metacarpal-(TMC-) Gelenk der Hand zu bilden. Das Implantat ist in mehreren Größen verfügbar, die alle an der rechten oder linken Hand eingesetzt werden können. Für jeden Implantattyp gibt es eine Palette von Probeprothesen, die als Hilfsmittel für die Präparation des Knochens verwendet werden. Dieses Gerät ist nur zur zementierten Verankerung bestimmt.

Materialien:
- Proximale Komponente aus Kobaltchrom gemäß ASTM F-75
- Distale Komponente aus ultrahochmolekularem Polyethylen (UHMWPE) gemäß ASTM F-648

ANWENDUNGSGEBIETE
Das Implantat ist indiziert als Totalgelenkersatz bei Patienten mit ausgereifter Skelettentwicklung, die infolge von Trauma, entzündlicher oder degenerativer Erkrankung oder Revision früherer Prothesen an Gelenkschmerzen oder Gelenkinstabilität leiden, und stellt eine Alternative zu Arthrodese oder rekonstruktiver Chirurgie dar.

GEGENANZEIGEN
- Aktive oder latente Infektion.
- Durch Krankheit, Infektion oder frühere Implantation angegriffene Knochen, Muskulatur, Sehnen oder angrenzende Weichteile, die keine sichere Unterlage oder Fixierung für die Prothese bieten können.
- Unreife in der Skelettentwicklung.
- Bekannte Überempfindlichkeit gegenüber den in diesem Gerät verwendeten Materialien.

WARNHINWEISE (Siehe auch Abschnitt "Informationen zur Patientenberatung" und "Potenzielle Nebenwirkungen")
- Patienten sind auf das erhöhte Potenzial des Versagens der Prothese bei übermäßiger Belastung hinzuweisen. Starke Belastung, übermäßige Mobilität und Gelenkinstabilität können alle zu beschleunigtem Verschleiß und eventuellem Versagen durch Lockerung, Fraktur oder Dislokation der Prothese führen.

VORSICHTSMAßNAHMEN
- **Nicht resterilisieren.** Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn eine Beschädigung des Implantates oder der Verpackung vorzuliegen scheint, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden.
- Sorgfältige Vorbereitung des Implantatlagers und die Wahl der richtigen Größe des Implantates erhöhen die Erfolgsaussichten der Implantation.
  Das Implantat ist erst aus seiner sterilen Verpackung zu entnehmen, wenn das Implantatlager vorbereitet und für die Größe des Implantats richtig dimensioniert ist.
- Bei der Handhabung des Implantats sind stumpfe Instrumente zu verwenden, um Kratzer, Schnitte oder Kerben auf dem Implantat und eine damit verbundene Beeinträchtigung der Implantatleistung zu vermeiden.

POTENZIELLE NEBENWIRKUNGEN
Allgemeine operationsbedingte Risiken
• Blutung • Infektion • Gebrauchsunfähigkeit der Hand • Arbeitsunfähigkeit • Tod

Durch Gelenkersatz bedingte Risiken
- Schmerzen
- Verletzung der umgebenden Nerven, Blutgefäße, Sehnen oder Weichteile
- Steifigkeit
- Nachtschmerz und wetterbedingte Schmerzen
- Bewegungsunfähigkeit
- Implantatfraktur
- Rotation des Implantats
- Beschleunigter Verschleiß der Komponenten des Implantats
- Lockerung des Implantats in den Knochen
- Gelenkinstabilität
- Dislokation des Gelenks
- Verletzung infolge von Zementextrusion
- Infektion
- Verlängerung oder Verkürzung der Finger
- Amputation
- Schwächung der Knochen rund um das Implantat
- Verringerter Bewegungsradius
- Allergische oder andere Reaktionen auf die Metall- oder Plastemateriallen
- Ein zusätzlicher chirurgischer Eingriff kann zur Reoperation, Revision oder Fusion des Gelenks erforderlich sein.
- Die Operation kann zwar begonnen werden, aber der Gelenkersatz ist nicht durchführbar, wodurch es zur Fusion des Gelenkes kommt.
- Mitteilung gemäß dem Gesetz für sauberes Trinkwasser und zur Bekämpfung toxischer Stoffe des Bundesstaates Kalifornien (California Safe Drinking Water and Toxic Enforcement Act) von 1986 (Proposition 65): Dieses Produkt enthält eine Chemikalie (i), die nach Wissen des Bundesstaates Kalifornien Krebs und/oder Geburtsschäden sowie andere reproduktive Toxizität verursachen kann.

CHIRURGISCHE VERFAHREN
Ein Handbuch mit einer genauen Beschreibung des chirurgischen Verfahrens für den Einsatz dieser Implantatprothese ist verfügbar. Der Chirurg ist dafür verantwortlich, sich vor Anwendung dieses Medizinproduktes mit dem Verfahren vertraut zu machen. Der Chirurg ist weiterhin dafür verantwortlich, die einschlägigen Publikationen sorgfältig zu lesen und sich mit Berufskollegen zu beraten, die Erfahrung in der Anwendung dieses Verfahrens gesammelt haben.

INFORMATIONEN ZUR PATIENTENBERATUNG (Siehe auch Warnhinweise und Potenzielle Nebenwirkungen)
Eine Patientenbrochüre zur Verwendung bei der Beratung der Patienten ist verfügbar.

Neben den Patienteninformationen in den Abschnitten Warnhinweise und Nebenwirkungen sind dem Patienten die nachfolgenden Informationen zu vermitteln:

- Die erwartete Lebensdauer der Komponenten des Totalgelenkersatzes ist zwar schwer zu bestimmen, aber sie ist begrenzt. Diese Komponenten sind aus Fremdstoffen gefertigt, die zur potenziellen Wiederherstellung der Mobilität und zur Verringerung der Schmerzen in den Körper implantiert werden. Auf Grund einer Vielzahl biologischer, mechanischer und physikalisch-chemischer Faktoren, die diese Prothesen beeinflussen, kann jedoch nicht erwartet werden, dass die Komponenten auf unbegrenzte Zeitdauer demselben Aktivitätsgrad und denselben Belastung standhalten wie der normale gesunde Knochen.
- Unerwünschte Wirkungen dieser Prothese können möglicherweise Reoperation, Revision oder Fusion des betroffenen Gelenks erforderlich machen.

STERILISATION
- Diese Komponente wurde mit Ethylenoxid oder Gammabestrahlung sterilisiert.
- Nicht resterilisieren. Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn eine Beschädigung des Implantats oder der Verpackung vorzuliegen scheint, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden.
- Probeprothesen sind verfügbar, um zu vermeiden, dass die sterile Verpackung vor der Implantation der Prothese geöffnet werden muss. Das Implantat darf erst aus der sterilen Verpackung entnommen werden, wenn das Implantatlager vorbereitet und für die Größe des Implantats richtig dimensioniert ist.

EINGESCHRÄNKTE GEWÄHRLEISTUNG
Avanta Orthopaedics, Inc. gewährleistet, dass dieses Medizinprodukt die Spezifikationen des Herstellers erfüllt und bei der Lieferung keine Herstellungsfehler aufweist. Diese Gewährleistung schließt speziell Fehler aus, die auf nicht-bestimmungsgemäßen Gebrauch, Abusus oder unsachgemäße Handhabung des Medizinproduktes nach Eingang bei dem Käufer zurückzuführen sind. Avanta Orthopaedics übernimmt keine Gewährleistung für das Resultat der chirurgischen Methode.

EU-VERTRETER:
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk, Die Niederlande
31 (0) 416563 754

FRANÇAIS

DESCRIPTION
Cette prothèse articulaire semi-contrainte se compose d'une pièce distale en polyéthylène à poids moléculaire ultra élevé (UHMWPe) qui est cimentée à l'axe de l'os métacarpien préparé et d'une pièce proximale en cobalt-chrome qui est cimentée à l'os du trapèze préparé. La surface en cobalt-chrome s'articule sur la pièce en UHMWPe pour former un remplacement prothétique semi-constrictif de l'articulation trapézo-métacarpienne de la main. L'implant est disponible en plusieurs tailles, chacune d'elles étant utilisable à la main droite ou gauche. Une série de calibreurs d'essai est disponible pour chaque type d'implant, en tant qu'assistance à la préparation osseuse. Ce dispositif est prévu exclusivement pour la cimentation.

Matériaux :
- pièce proximale cobalt-chrome ASTM F-75
- pièce distale en polyéthylène à poids moléculaire ultra élevé (UHMWPe) ASTM F-648

INDICATIONS
L'implant est indiqué pour le remplacement de l'articulation totale chez les patients dont la croissance est terminée et qui souffrent ou sont atteints d'instabilité articulaire due à un traumatisme, une maladie inflammatoire ou dégénérative ou une révision des procédures précédentes, en tant que solution de remplacement d'une arthrodèse ou d'une chirurgie reconstructive.

CONTRE-INDICATIONS
- Infection active ou latente.
- Os, musculature, tendons ou tissu mou adjacent compromis par une maladie, une infection ou une implantation antérieure qui ne peuvent pas fournir un support adéquat ni permettre la fixation de la prothèse.
- Immaturité du squelette.
- Allergie avérée aux matériaux de ce dispositif.

MISES EN GARDE (voir aussi les sections Conseils donnés au patient et Effets indésirables éventuels)
- Il faut informer le patient de l'augmentation du risque d'échec du dispositif en cas de sollicitations excessives. De fortes charges, une mobilité excessive et une instabilité articulaire peuvent accélérer l'usure du dispositif et entraîner un échec éventuel par relâchement, fracture ou dislocation.

PRÉCAUTIONS
- **Ne pas restériliser.** L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant.
- Une préparation méticuleuse du site de l'implant et la sélection de la taille d'implant appropriée augmentent le potentiel de réussite.
  Il faut enlever l'implant de son emballage stérile uniquement après la préparation et le dimensionnement correct du site de l'implant.
- Les implants doivent être manipulés avec des instruments à bout mousse pour ne pas rayer, couper ou entailler le dispositif et ne pas perturber les performances de l'implant.

EFFETS INDÉSIRABLES ÉVENTUELS
Risques généraux liés à la chirurgie
- saignements
- infection
- perte d'usage de la main
- incapacité de travail définitive
- décès

Risques liés au remplacement de l'articulation
- douleur
- lésion traumatique des nerfs, vaisseaux sanguins, tendons ou du tissu mou environnants
- raideur
- douleur nocturne et liée aux conditions météorologiques
- perte de mobilité
- fracture de l'implant
- rotation de l'implant
- usure accélérée des composants du dispositif
- relâchement de l'implant (détachement des os)
- instabilité de l'articulation
- luxation de l'articulation
- blessure par extrusion de ciment
- infection
- rallongement ou raccourcissement du doigt
- amputation
- affaiblissement osseux autour de l'implant
- diminution d'amplitude de mouvement
- réactions allergiques ou autres aux matériaux métalliques ou plastiques
- une chirurgie additionnelle peut être requise pour la reopération, la révision ou la fusion de l'articulation
- il se peut que l'on commence une chirurgie mais que l'on ne puisse pas remplacer l'articulation, ce qui entraîne une fusion de l'articulation
- Notification conforme à la Proposition 65 de Californie (California Safe Drinking Water and Toxic Enforcement Act, acte exécutoire de la protection de l'eau potable contre les produits toxiques, approuvé en 1986) : ce produit contient un agent chimique (;) connu dans l'État de Californie pour causer le cancer et/ou des malformations neonatales et autre toxicité liée à la reproduction.

PROCÉDURES CHIRURGICALES
Un manuel est disponible : il décrit en détail la procédure chirurgicale permettant d'utiliser l'implant. La connaissance de cette procédure est de la responsabilité du chirurgien. Il incombe également au chirurgien de se tenir au courant des publications pertinentes et de consulter des confrères expérimentés au sujet de la procédure à utiliser.

CONSEILS DONNÉS AU PATIENT (voir aussi Mises en garde et Effets indésirables éventuels)
Une brochure à l'attention du patient, contenant des conseils, a été réalisée.

Outre l'information relative au patient qui est contenue dans les sections Avertissements et Effets indésirables éventuels, le patient doit recevoir l'information suivante :

- Il est difficile d'estimer la durée de vie prévue des composants de remplacement d'articulation totale, mais ils ne sont pas inusables. Ces composants sont en effet fabriqués dans des matériaux étrangers au corps humain et implantés afin de restaurer la mobilité ou de réduire la douleur. Toutefois, en raison des nombreux facteurs biologiques, mécaniques et physio-chimiques qui affectent ces dispositifs, les composants ne peuvent pas supporter le même niveau d'activité et les mêmes charges qu'un os sain pendant une période illimitée.
- Des effets indésirables peuvent nécessiter la réopération, la révision ou la fusion de l'articulation concernée.

STÉRILISATION
- Ce composant a été stérilisé à l'oxyde d'éthylène ou aux rayons gamma.
- Ne pas restériliser. L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de peremption est dépassée ou si la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant.
- Des calibreurs d'essai sont disponibles : ils évitent d'ouvrir l'emballage stérile avant l'implantation de la prothèse. Il faut enlever l'implant de son emballage stérile uniquement après la préparation et le dimensionnement correct du site de l'implant.

GARANTIE LIMITÉE
Avanta Orthopaedics, Inc. garantit que ce produit est conforme aux spécifications du fabricant et qu'il est livré sans défaut de fabrication. Cette garantie exclut spécifiquement les défauts résultant d'une utilisation incorrecte ou abusive, ou d'une manipulation incorrecte du produit postérieure à la réception par l'acheteur. Avanta Orthopaedics ne garantit pas l'issue de la chirurgie.

REPRÉSENTANT POUR L'UE :
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk, Pays-Bas
31 (0) 416563 754

ESPAÑOL

DESCRIPCIÓN
Esta prótesis articular semirrestrictiva está integrada por un componente distal, hecho de un polietileno de peso molecular ultra elevado (UHMWPe), el cual debe cementarse a la diáfisis del primer metacarpo previamente preparada, y por un componente proximal de cobalto-cromo que debe cementarse al trapecio carpiano debidamente preparado. La superficie de cobalto-cromo articula con el componente de UHMWPe, constituyendo un dispositivo de sustitución protésica semirrestrictiva para la articulación trapeciometacarpiana del pulgar. Este implante se suministra en varios tamaños, cada uno de los cuales puede utilizarse para la mano derecha o la izquierda. Se dispone además de una gama de medidores de prueba de distintos tamaños para cada tipo de implante, con el propósito de ayudar a la preparación del hueso. Este dispositivo ha sido construido solamente para usarse como prótesis cementada.

Materiales:
- Componente proximal de cobalto-cromo, ASTM F-75;
- Componente distal de polietileno de peso molecular ultra elevado (UHMWPe), ASTM F-648.

INDICACIONES
Este implante está indicado para el reemplazo articular total en pacientes con estructura ósea madura, que presenten dolor o inestabilidad en la articulación, causados por traumatismo, enfermedades inflamatorias o degenerativas o revisión quirúrgica de procedimientos previos, como una alternativa frente a la artrodesis o a la cirugía reconstructora.

CONTRAINDICACIONES
- Infección activa o latente;
- Compromiso de los huesos, músculos, tendones o tejido blando adyacentes a causa de patologías, infección o implante previo, que ofrezcan una sustentación o una fijación adecuadas para la prótesis;
- Inmadurez ósea;
- Hipersensibilidad conocida a los materiales que componen este dispositivo.

ADVERTENCIAS (véase también las secciones Información para el paciente y Posibles efectos adversos)
- Se deberá advertir a los pacientes sobre el mayor riesgo potencial de fallo del dispositivo cuando éste es sometido a exigencias mecánicas excesivas. Los esfuerzos intensos, la movilidad excesiva y la inestabilidad articular pueden causar un desgaste acelerado y conducir al fracaso del implante por aflojamiento, fractura o dislocación del dispositivo.

PRECAUCIONES
- **No resterilizar.** El implante se presenta estéril en un envase intacto. Si el implante o el envase están dañados, si ha transcurrido la fecha de validez o si por cualquier motivo se duda de su esterilidad, el implante no deberá utilizarse.
- La preparación meticulosa de la zona de implantación y la elección de un implante del tamaño adecuado aumentan las posibilidades de éxito.
- El implante debe sacarse de su envase estéril sólo después de haber concluido la preparación de la zona de implantación y de haber determinado el tamaño correcto.
- Los implantes deben manipularse utilizando instrumentos romos para evitar rayaduras, cortes o marcas que puedan afectar el funcionamiento del implante.

POSIBLES EFECTOS ADVERSOS
Riesgos relacionados con la cirugía en general
• Sangramiento • Infección • Pérdida de la función de la mano • Discapacidad permanente • Muerte

Riesgos relacionados con la sustitución articular
- Dolor
- Daño a los nervios, vasos sanguíneos, tendones o al tejido blando circundantes
- Rigidez
- Dolor nocturno o relacionado a los cambios climáticos
- Pérdida de la movilidad
- Fractura del implante
- Rotación del implante
- Desgaste acelerado de los componentes del dispositivo
  Aflojamiento del implante desde el hueso
  Inestabilidad de la articulación
  Dislocación de la articulación
  Lesión por la extrusión del cemento
- Infección
- Alargamiento o acortamiento del dedo
- Amputación
- Debilitamiento óseo alrededor del implante
- Restricción del rango de movilidad
- Reacciones alérgicas u otro tipo de reacciones al metal o a los materiales plásticos
- Puede necesitarse cirugía adicional para la reoperación, la revisión o la fusión de la articulación.
- Es posible que una vez iniciada la intervención, no pueda implantarse la prótesis, obligando a efectuar una fusión articular.
- Notificación de acuerdo con la establecido por la California Safe Drinking Water and Toxic Enforcement Act of 1986 (Ley sobre Seguridad de Agua Potable y Agentes Tóxicos del Estado de California, conocida también como Proposición 65): Este producto contiene una o más sustancias químicas de las que el Estado de California sabe que provocan cáncer y/o defectos congénitos y otros efectos de toxicidad reproductiva.

PROCEDIMIENTOS QUIRÚRGICOS
Existe un manual que describe en detalle el procedimiento quirúrgico para el uso de estos implantes. Es responsabilidad del cirujano familiarizarse con el procedimiento antes de utilizar estos productos. También es responsabilidad del cirujano familiarizarse con las publicaciones relevantes y consultar con colegas experimentados acerca del procedimiento antes del empleo de estos implantes.

INFORMACIÓN PARA EL PACIENTE (véase también las secciones Advertencias y Posibles efectos adversos) Hay disponible un folleto que se usa para asesorar al paciente.

Además de la información relativa al paciente que figura en las secciones Advertencias y Posibles efectos adversos) se deberá transmitir al paciente la siguiente información:

- Si bien resulta difícil de estimar la duración prevista de este dispositivo, esta no es ilimitada. Sus componentes están fabricados con materiales ajenos al organismo que se introducen en el mismo para facilitar el proceso de consolidación ósea. Sin embargo, debido a los numerosos factores biológicos, mecánicos y fisicoquímicos que afectan a estos dispositivos, no es de esperar que sus componentes resistan durante un período ilimitado el nivel de actividad y los esfuerzos a los que está sometido un hueso normal sano.
- Los efectos adversos de este dispositivo pueden requerir una nueva operación, revisión o la fusión de la articulación afectada.

ESTERILIZACIÓN
- Este producto ha sido esterilizado por óxido de etileno o por radiación gamma.
- No resterilizar. El implante se presenta estéril en un envase intacto. Si el implante o el envase están dañados, si ha transcurrido la fecha de validez o si por cualquier motivo se duda de su esterilidad, el implante no deberá utilizarse.
- Se suministran componentes de prueba en cantidad suficiente para que no sea necesario abrir el envase estéril antes de la implantación de la prótesis. El implante debe extraerse de su envase estéril sólo después de haber concluido la preparación de la zona de implantación y de haber determinado el tamaño correcto.

GARANTÍA LIMITADA
Avanta Orthopaedics Corporation garantiza que este producto cumple las especificaciones del fabricante y que no presenta defectos de fabricación en el momento de su entrega. Esta garantía excluye específicamente los defectos derivados del uso erróneo, abuso o manipulación incorrecta del producto una vez recibido por el comprador. Avanta Orthopaedics no garantiza el resultado de la intervención quirúrgica.

REPRESENTANTE EN LA UE:
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk, Países Bajos
31 (0) 416563 754

NEDERLANDS

BESCHRIJVING
Deze semi-constrained gewrichtsprothese bestaat uit een distale component van ultrahoog molecuulair gewicht polyethyleen (UHMWPE), welke aan de achtzijde van het voorbereide metacarpale bot wordt gelijmd, en een kobalt-chromen proximale component welke in het voorbereide handwortelbeentje wordt gelijmd. Het kobalt-chromen oppervlak is door een gewricht verbonden met de component van UHMWP om zo een semi-constrained prothetische vervanging van het duimzadelgewricht van de hand te vormen. Het implantaat is verkrijgbaar in verschillende maten, die allemaal kunnen worden gebruikt in de rechter- of linkerhand. Voor elk type implantaat is een serie proefmaten verkrijgbaar als hulp bij het voorbereiden van het bot. Dit instrument is uitsluitend voor gelijmd gebruik.

Materialen:
- ASTM F-75 proximale component van kobalt-chroom
- ASTM F-648 distale component van ultrahoog molecuulair gewicht polyethyleen (UHMWP)

INDICATIES
Het implantaat is bestemd voor vervanging van het complete gewricht in patiënten met een volgroeid skelet met pijn of instabiliteit in het gewricht door trauma, inflammatoire of degeneratieve aandoeningen of voor revisie van eerdere ingrepen, als alternatief voor artrodese of reconstructieve chirurgie.

CONTRA-INDICATIES
- Actieve of latente infectie.
- Door ziekte, infectie of eerdere implantatie aangetast bot, musculatuur, pezen, of omliggend zacht weefsel, welke niet genoeg steun of bevestiging voor de prothese kunnen bieden.
- Onvolgroeidheid van het skelet.
- Bekende gevoeligheid voor de in dit instrument gebruikte materialen.

WAARSCHUWINGEN (zie ook het hoofdstuk Informatie voor patiëntvoorlichting en Mogelijke Bijwerkingen)
- Patiënten dienen te worden gewezen op de verhoogde kans dat het instrument het begeeft wanneer er te hoge eisen aan worden gesteld. Zware belasting, overmatige beweeglijkheid en gewrichtsinstabiliteit kunnen allemaal leiden tot vroegtijdige slijtage en uiteindelijk kan het instrument het begeven door loskraken, breken of dislocatie.

VOORZORGSMAATREGELEN
- **Niet hersteriliseren.** Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien oliwel het implantaat oliwel de verpakking beschadigd blijkt te zijn, de vervaldatum is overschreden, of om welke reden dan ook aan de sterriliteit wordt getwijfeld, mag het implantaat niet worden gebruikt.
- Een nauwkeurige voorbereiding van de implantatieplaats en de keuze van de juiste maat implantaat vergroten de kans op een succesvol resultaat.
- Het implantaat mag pas uit zijn steriele verpakking worden gehaald zodra de implantatieplaats is voorbereid en de juiste afmetingen heeft.
- Om te voorkomen dat er in het instrument wordt gekrast, gesneden of gekerfd moeten implantaten met stompe instrumenten worden gehanteerd, dit om de werking van het instrument niet nadelig te beïnvloeden.

MOGELIJKE BIJWERKINGEN
Algemene risico's die bij chirurgie kunnen optreden
- bloedingen
- infecties
- verlies van gebruik van de hand
- blijvende invaliditeit
- overlijden

Risico's die bij het vervangen van een gewricht kunnen optreden
- pijn
- letsel aan omliggende zenuwen, bloedvaten, pezen of zacht weefsel
- stijfheid
- nachtelijke en weersafhankelijke pijn
- verlies van beweging
- breken van het implantaat
- rotatie van het implantaat
- versnelde slijtage van componenten van het instrument
- kans dat het implantaat loskraakt van de botten
- instabiliteit van het gewricht
- dislocatie van het gewricht
- letsel door extrusie van het kleefmiddel
- infecties
- langer of korter worden van de vinger
- amputatie
- botverzwakking rondom het implantaat
- vermindering van het bewegingsbereik
- allergische of andere reacties op het metaal of op plastic materialen
- aanvullende chirurgie kan nodig zijn voor heroperatie, revisie of fusie van het gewricht
- wanneer u begint met chirurgie voor een gewrichtsvervanging, kan dit niet uitlopen op een fusie van het gewricht
- kennisgeving in overeenstemming met de California Safe Drinking Water and Toxic Enforcement Act (verordening van de Amerikaanse deelstaat Californië inzake veilig drinkwater en toxische handhaving) van 1986 (opmerking 65): Dit product bevat een chemische stof(fen) waarvan in de deelstaat Californië bekend is dat hij kanker veroorzaakt, en/of geboortebeperkingen en andere reproductieve toxiciteit.

CHIRURGISCHE PROCEDURES
Er is een handleiding verkrijgbaar waarin gedetailleerd de chirurgische procedure voor het gebruik van deze implantate-instrumenten wordt beschreven. Het is de verantwoordelijkheid van de arts dat hij vertrouwd is met de procedure voordat hij deze producten gaat gebruiken. Daarnaast is het de verantwoordelijkheid van de chirurg dat hij voorafgaand aan het gebruik op de hoogte is van relevante publicaties en dat hij bij ervaren collega's advies inwint met betrekking tot de procedure.

INFORMATIE VOOR PATIËNTVOORLICHTING (zie ook Waarschuwingen en Mogelijke Bijwerkingen)
Er is een patiëntenbrochure verkrijgbaar die kan worden gebruikt om de patient voor te lichten.

Naast de patiëntgerelateerde informatie in de hoofdstukken Waarschuwingen en Mogelijke Bijwerkingen dient de volgende informatie te worden medegedeeld aan de patient:

- Hoewel de verwachte levensduur van componenten voor een complete gewrichtsvervanging moeilijk te schatten is, is deze beperkt. Deze componenten zijn gemaakt van vreemde materialen, die in het lichaam worden geplaatst voor mogelijk herstel van de mobiliteit of vermindering van pijn. Vanwege de vele biologische, mechanische en fysiochemische factoren die invloed op deze instrumenten uitoefenen, kan echter niet van deze componenten worden verwacht dat zij gedurende onbepaalde tijd bestand zijn tegen het activiteitsniveau en de belasting van normaal gezond bot.
- Door nadelige effecten van dit instrument kan heroperatie, revisie of fusie van het betreffende gewricht nodig zijn.

STERILISATIE
- Deze component is gesteriliseerd door middel van ethyleenoxide of gammastraling.
- Niet hersteriliseren. Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien oliwel het implantaat oliwel de verpakking beschadigd blijkt te zijn, de vervaldatum is overschreden, of om welke reden dan ook aan de sterriliteit wordt getwijfeld, mag het implantaat niet worden gebruikt.
- Proefmaatcomponenten zijn verkrijgbaar om te voorkomen dat de steriele verpakking vóór de implantatie van de prothese moet worden geopend. Het implantaat mag pas uit zijn steriele verpakking worden gehaald zodra de implantatieplaats is voorbereid en de juiste afmetingen heeft.

BEPERKTE GARANTIE
Avanta Orthopaedics, Inc. garandeert dat dit product beantwoordt aan de specificaties van de fabrikant en op het moment van levering geen productiefouten bevat. Uitgesloten van deze garantie zijn met name gebreken als gevolg van verkeerd gebruik, misbruik of een onjuiste bediening van het product nadat het door de koper is ontvangen. Avanta Orthopaedics geeft geen garantie op het resultaat van de chirurgische procedure.

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Schutweg 13A
5145 NP Waalwijk, Nederland
31 (0) 416563 754

ITALIANO

DESCRIZIONE
Questa protesi articolare semivincolata è costituita da un componente distale in polietilene ad altissimo peso molecolare (UHMWPe), cementato sul corpo dell'osso metacarpale preparato, e da un componente prossimale in cromo-cobalto cementato nell'osso trapezio preparato. La superficie in cromo-cobalto si articola con il componente in UHMWPe formando una sostituzione protesica semivincolata dell'articolazione trapezio-metacarpale della mano. L'impianto è disponibile in numerose misure, ognuna delle quali può essere utilizzata nella mano destra o sinistra. Per ogni tipo d'impianto è disponibile una vasta gamma di calibratori di prova, che rappresentano un valido ausilio nella preparazione dell'osso. Questo presidio è destinato unicamente all'uso cementato.

Materiali:
- Componente prossimale in cromo-cobalto ASTM F-75
- Componente distale in polietilene ad altissimo peso molecolare (UHMWPe) ASTM F-648

INDICAZIONI
L'impianto è indicato per la sostituzione totale dell'articolazione in pazienti con sviluppo scheletrico completo, che accusano dolore o instabilità dell'articolazione in seguito a traumi, patologie infiammatorie o degenerative o per la revisione di procedure precedenti, in alternativa all'artrodesi o alla chirurgia ricostruttiva.

CONTROINDICAZIONI
- Infezione attiva o latente.
- Ossa, muscolatura, tendini o tessuti molli adiacenti compromessi da patologie, infezioni o impianti precedenti che non sono in grado di fornire supporto o fissazione adeguati per la protesi.
- Immaturità scheletrica.
- Accertata ipersensibilità ai materiali utilizzati in questo presidio.

AVVERTENZE (vedere anche le sezioni Informazioni per la consulenza ai pazienti e Potenziali eventi avversi)
- Si raccomanda di informare i pazienti sulla maggiore probabilità di insuccesso, se gli impianti vengono sottoposti a sollecitazioni eccessive. I carichi particolarmente pesanti, l'eccessiva mobilità e l'instabilità articolare possono accelerare l'usura e provocare eventuali danni alla protesi per distacco, frattura o lussazione.

PRECAUZIONI
- **Non risterilizzare l'impianto.** Non utilizzarlo se l'impianto stesso o la confezione sembrano danneggiati, se è trascorsa la data di scadenza o se si dubita della sterilità per qualsiasi motivo.
- Una preparazione meticolosa del sito d'impianto e la scelta della misura corretta dell'impianto stesso aumentano le probabilità di esito positivo dell'intervento.
- L'impianto deve essere prelevato dalla confezione sterile solo dopo aver preparato e misurato correttamente il sito dell'impianto.
- Gli impianti devono essere maneggiati esclusivamente con l'ausilio di strumenti smussati per evitare di graffiare, tagliare o scalfire il presidio, in modo da non compromettere le prestazioni dell'impianto.

POTENZIALI EFFETTI AVVERSI
Rischi correlati alla chirurgia in generale
- Emorragia
- Infezione
- Perdita dell'uso della mano
- Invalidità permanente
- Morte

Rischi correlati alla sostituzione dell'articolazione
- Dolore
- Lesioni dei nervi, vasi sanguigni, tendini o tessuti molli circostanti
- Rigidità
- Dolore notturno e correlato alle condizioni atmosferiche
- Perdita di motilità
- Frattura dell'impianto
- Rotazione dell'impianto
- Usura accelerata dei componenti del presidio
- Distacco dell'impianto dalle ossa
- Instabilità dell'articolazione
- Lussazione dell'articolazione
- Lesione per l'estrusione di cemento
- Infezione
- Allungamento o accorciamento del dito
- Amputazione
- Indebolimento dell'osso intorno all'impianto
- Diminuzione dell'ampiezza di movimento
- Reazioni allergiche o di altro tipo ai materiali metallici o plastici
- Può rendersi necessario un ulteriore intervento chirurgico per seconda operazione, revisione o fusione dell'articolazione.
- L'intervento chirurgico può avere inizio senza però potere eseguire alcuna sostituzione dell'osso e con una conseguente fusione dell'articolazione.
- Notifica in conformità con la Legge del 1986 dello Stato della California sulla sicurezza dell'acqua potabile e sulle sostanze tossiche (dichiarazione 65): Questo prodotto contiene uno o più sostanze chimiche note allo Stato della California come possibili cause di cancro e/o difetti neonatali e di altri effetti tossici sull'attività riproduttiva.

PROCEDURE CHIRURGICHE
È disponibile un manuale che descrive nei dettagli la procedura chirurgica da applicare a questo presidio. È responsabilità del chirurgo acquisire familiarità con la procedura prima dell'uso di questi prodotti. È inoltre responsabilità del chirurgo anche acquisire familiarità con le pubblicazioni relative e consultarsi con colleghi esperti in merito alla procedura prima dell'uso.

INFORMAZIONI PER LA CONSULENZA AI PAZIENTI (vedere anche le sezioni Avvertenze e Potenziali eventi avversi)
È disponibile un opuscolo per i pazienti da utilizzare per la relativa consulenza.

Oltre alle informazioni specifiche, riportate nelle sezioni Avvertenze ed Eventi avversi, si raccomanda di comunicare ai pazienti anche quanto segue:

- I componenti sostitutivi dell'articolazione hanno una durata limitata che, purtroppo, risulta difficile da stimare. Questi componenti sono realizzati con materiali estranei, che vengono inseriti nel corpo per ripristinare una potenziale mobilità o ridurre il dolore. Tuttavia, considerando i numerosi fattori biologici, meccanici e fisiochimici legati a questi dispositivi, non si può partire dal presupposto che siano in grado di sostenere il livello di attività e i carichi del normale osso sano per un periodo di tempo illimitato.
- L'eventuale insorgenza di effetti avversi potrebbe richiedere un secondo intervento, la revisione o la fusione dell'articolazione coinvolta.

STERILIZZAZIONE
- Il prodotto è stato sterilizzato con ossido di etilene o raggi gamma.
- Non risterilizzare l'impianto. L'impianto fornito è sterile se la confezione è integra. Non utilizzarlo se l'impianto stesso o la confezione sembrano danneggiati, se è trascorsa la data di scadenza o se si dubita della sterilità per qualsiasi motivo.
- Sono disponibili calibratori di prova per evitare di dover aprire la confezione sterile prima dell'impianto della protesi. L'impianto deve essere prelevato dalla confezione sterile solo dopo aver preparato e misurato correttamente il sito dell'impianto.

GARANZIA LIMITATA
Avanta Orthopaedics, Inc. garantisce che il presente prodotto è conforme alle specifiche del produttore e che è esente da difetti di fabbricazione al momento della consegna. La presente garanzia esclude specificamente i difetti derivanti da uso improprio o non corretto o da errori di manipolazione del prodotto successivamente al ricevimento da parte dell'acquirente. Avanta Orthopaedics non garantisce l'esito della procedura chirurgica.

RAPPRESENTANTE PER L'UE:
Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk, Paesi Bassi
31 (0) 416563 754

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AVANTA
ORTHOPAEDICS
9369 Carroll Park Drive, Suite A, San Diego, CA 92121 USA
(858)452-8580/(858)452-9945(fax)

PRODUCT INSERT

AVANTA PIP FINGER PROSTHESIS
AVANTA PIP-FINGERPROTHESE
PROTHÈSE DIGITALE AVANTA PIP
PRÓTESIS AVANTA PIP
AVANTA PIP-VINGERPROTHESE
PROTESI DEL DITO PIP AVANTA

ENGLISH

HUMANITARIAN DEVICE. The Avanta PIP Finger Prosthesis is authorized by Federal law for use in arthroplasty of the PIP joint when either the:

- patient is in need of a revision of failed PIP prosthesis(es); or
- patient expects to place his/her hands under loading situations, which preclude the use of an alternative implant in the painful osteo-arthritic and post traumatic arthritic PIP joint.

The effectiveness of this device for this use has not been demonstrated.

CAUTION

Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION

The Proximal-Interphalangeal Finger Prosthesis consists of an ultra-high molecular weight polyethylene (UHMWPe) component with a titanium alloy stem which may be cemented to the shaft of the prepared middle phalanx, and a cobalt chromium stem component which is inserted into the prepared proximal phalanx. The cobalt chromium surface articulates with the UHMWPe component to form a semi-constrained prosthetic replacement for the proximal interphalangeal joint. The implant is available in five sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation. This device is available with and without titanium plasma spray applied to the stems.

Materials:

- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) distal component
- ASTM F75 cobalt chromium proximal component
- ASTM F136 titanium alloy Ti-6Al-4V
- ASTM F1580 CPTi titanium coatings for surgical implants.

INDICATIONS

The Avanta PIP Finger Prosthesis is indicated for use in arthroplasty of the PIP joint when either the:

- patient is in need of a revision of failed PIP prosthesis(es); or
- patient expects to place his/her hands under loading situations which preclude the use of an alternative implant in the painful osteo-arthritic and post traumatic arthritic PIP joint.

CONTRAINDICATIONS

- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Skeletal immaturity.

WARNINGS (See also the Patient Counseling Information Section)

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.

PRECAUTIONS

- Do not resterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.

ADVERSE EVENTS

REPORTED ADVERSE EVENTS

There has been some clinical experience with this device. In the US, 18 patients have been implanted with the device with a maximum length of follow-up of 6 months. In addition, eight patients in Sweden have been implanted with the device. In the US patients, the most commonly reported adverse events were post operative pain and flexor tenolysis. In the Swedish patients, two revision surgeries have been performed.

- For more details see Table 5: Complications for US Patients in the Clinical Experience Section for reported adverse events associated with the device.

POTENTIAL ADVERSE EFFECTS

General Surgery Related Risks

- bleeding
- infection
- loss of use of the hand
- permanent disability
- death

Joint Replacement Related Risks

- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue (e.g., hematoma)
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- dislocation of the joint
- cement extrusion injury
- infection
- lengthening or shortening of the finger
- amputation
- bone weakening around the implant
- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional surgery may be required for reoperation, revision or fusion of the joint
- surgery may be started but a joint replacement cannot be done resulting in fusion of the joint
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

CLINICAL EXPERIENCE

There has been some clinical experience with this device. In the US, 18 patients have been implanted with the device with a maximum length of follow-up of 6 months. In addition, eight patients in Sweden have been implanted with the device since September 1996.

A prospective randomized clinical study being performed in the US, patients are randomized either into the experimental group which received the Avanta PIP Finger Prosthesis or into the control, which received a silicone elastomer implant. Thirty-one patients have been randomized into the study to date. However only 18 of these patients have had surgery performed to implant either the control device or the Avanta PIP Finger Prosthesis. Table 3 describes the patients randomized into the study, patients implanted with a device and the patient dropouts from the study. Thirteen of these patients have follow-up data, which is summarized in Tables 4-6. Tables 4-6 describe the patient demographics, reported complications and length of follow-up for this clinical study to date. There are currently no articles published from this clinical study.

Table 3: US Patients

Patient Category	Number of Patients
Total Randomized into Study	31
Total Who Have Had Surgery	18
Total Still Enrolled But No Surgery*	10
Withdrew Prior to Surgery	3
Withdrew After Surgery (3 months post-op)	2
With follow-up Data**	13

* 10 Patients have not withdrawn from the study, but no surgery date has been scheduled, 5/10 of these patients are control patients.
** Data report forms have been returned on only 13 patients. Tables 4-6 describe the clinical results for these 13 patients.

Table 4: Demographics for 13 US Patients with Follow-up

Category	Patients with Avanta PIP Implant*	Patients with Silicone Implant	Total
Male	6	1	7
Female	5	1	6
Mean Age**, SD	51.25*17.4 (n=8)	61 (n=1)	
Age Range (years)	34-71	61	
Osteo-arthritis	5	0	5
Post-traumatic arthritis	3	1	4
Rheumatoid Arthritis	2	1	3
Silicone Implant Revision	1	0	1

* Description of number of patients with more than one implant. There are 13 patients with 18 implants. One osteo-arthritic patient has 2 implants, one rheumatoid control patient has 3 implants; two post-traumatic patients have two implants.
** The sum of n not equal to 13 because of the failure to record the age of the patient in 4 instances (3 Avanta PIP Finger Joint and 1 silicone implant patients).

Table 5: Complications for US Patients

Complication	Avanta PIP Patients(n=11)	Silicone Patients(n=2)
pain (3 months post-op*)	4	0
Edema	1	0
ulnar deviation	1	0
extensor lag	1	0
limited range of motion	1	0
cracked bone	1	0
snapping over dorsum with composite flexion	1	0
flexor tenolysis	3	0
subluxation	0	0
rotation	0	0
revision	0	0

* 5 Avanta PIP patients experienced pain at 3 months post operative, and 5 Avanta PIP patients and 2 Silicone patients experienced pain 1-4 weeks postoperative.

Table 6: Number of US Patients (Implants) at Each follow-up Time Point*

Length of follow-up	Avanta PIP Implant Patients (# Implants)	Silicone Implant Patients (# Implants)
Post-op (1-4 weeks)	11 (14)	2 (4)
3 months	9 (8)	2 (4)
6 months	4 (6)	0
12 months	0	0
24 months	0	0
Post-op withdrawal	1(1)	1 (3)

* The Avanta implant patient refused to return for continued therapy or follow-up visits. The control implant patient withdrew after the 3 months post-op visit. The reason for withdraw is not documented. The 3 month visit is the last visit for these patients.

A case series by Dr. Sollerman[1] reports on eight of his patients who have been implanted with a total of 11 Avanta PIP Finger Prostheses since September 1996. These patients have a mean age of 51 (31-66) years. The indications Dr. Sollerman reported for surgery were pain and stiffness due to post-traumatic arthrosis (4), rheumatoid arthritis (3), osteoarthritis (3) and Ehlers-Danlos syndrome (1). Two revisions were performed, one due to extension lag caused by insufficient bone resection and, one due to a rotational deformity. Dr. Sollerman has reported his early results show excellent pain relief and in most cases a functional range of motion, on average 46 (30-65) degrees with an extension lag of 11 (-10-35) degrees. The intrinsic stability of the device has been excellent in all cases in spite of severance of the collateral ligaments in seven joints. No signs of radiographic loosening have been observed in this unspecified short follow-up period.

1. Sollerman, C. Möller, K. PIP Joint Arthroplasty with Noncemented Semiconstrained Implants. Department of Hand Surgery, Sahlgrenska University Hospital, Göteborg, Sweden. 7th Congress of the International Federation of Societies for Surgery of the Hand. Vancouver, Canada May 24-28, 1998.

SURGICAL PROCEDURES

A manual is available describing detailed surgical procedures for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the implant procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings)

A patient brochure is available for use in counseling the patient.

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

While the expected life of total joint replacement components is difficult to estimate it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION

- This component has been sterilized by ethylene oxide or gamma radiation.
- Do not resterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY

Avanta Orthopaedics Inc., warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

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Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

DEUTSCH

MEDIZINPRODUKT MIT SONDERZULASSUNG GEMÄß HUMANITARIAN DEVICE EXEMPTION (HDE). Die Avanta PIP-Fingerprothese ist gemäß Bundesgesetz der Vereinigten Staaten für die Anwendung bei der Arthroplastik des PIP-Gelenks zugelassen, wenn:

- der Patient nach Versagen einer oder mehrerer PIP-Prothesen einen Revisionseingriff benötigt, oder
- die Hände des Patienten voraussichtlich Belastungen ausgesetzt werden, die die Anwendung eines alternativen Implantats für das schmerzhafte osteoarthritische und posttraumatische arthritische PIP-Gelenk ausschließen.

Die Effektivität dieses Produktes für diese Anwendung ist nicht belegt.

ACHTUNG

Laut US-Bundesgesetz darf dieses Produkt nur von einem Arzt oder in dessen Auftrag verkauft, vertrieben und eingesetzt werden.

BESCHREIBUNG

[illegible]

Werkstoffe

- Distale Komponente aus ultrahochmolekularem Polyethylen (UHMW-PE) gemäß ASTM F-648
- Proximale Komponente aus Cobalt-Chrom gemäß ASTM F-75

INDIKATIONEN

[illegible]

KONTRAINDIKATIONEN

[illegible]

WARNUNGEN (Siehe auch den Abschnitt Patienteninformation)

[illegible]

ACHTUNG

[illegible]

KOMPLIKATIONEN

BERICHTETE UNERWÜNSCHTE EREIGNISSE

[illegible]

- In Tabelle 5, Komplikationen bei US-Patienten, im Abschnitt Klinische Erfahrungen sind die berichteten unerwünschten Ereignisse im Detail aufgeführt.

POTENTIELLE UNERWÜNSCHTE EREIGNISSE

Allgemeine Operationsrisiken

- Blutung
- Infektion
- Funktionsbeeinträchtigung der Hand
- Bleibende Behinderung
- Tod

Operationsrisiken bei Gelenkersatz

[illegible]

KLINISCHE ERFAHRUNGEN

[illegible]

Tabelle 3. US-Patienten

Patientenkategorie	Patienten
Randomisierte Patienten insgesamt	31
Operierte Patienten insgesamt	18
Aufgenommene, aber noch nicht operierte Patienten insgesamt	10
Dropouts vor der Operation	3
Dropouts nach der Operation	2
Mit Nachbeobachtungsdaten**	13

* 10 Patienten sind nicht aus der Studie ausgeschieden, aber noch ohne Operationstermin; 5/10 dieser Patienten sind Kontrollpatienten.
** Datenbögen sind nur für 13 Patienten zurückgekommen. Die Tabellen 4-6 zeigen die klinischen Ergebnisse für diese 13 Patienten.

Tabelle 4. Demographische Merkmale der 13 US-Patienten mit Verlaufsbeobachtung

Patientenkategorie	Patienten mit Avanta PIP-Implantat	Patienten mit Silikonimplantat	Insgesamt
Männlich	6	1	7
Weiblich	5	1	6
Mittleres Alter, SD	51,25*17,4 (n=8)	61 (n=1)	
Altersbereich (Jahre)	34-71	61	
Osteoarthritis	5	0	5
Posttraumatische Arthrose	3	1	4
Rheumatoide Arthritis	2	1	3
Silikonimplantat-Revision	1	0	1

* Beschreibung der Anzahl an Patienten mit mehr als einem Implantat. Es sind 13 Patienten mit 18 Implantaten: Ein Patient mit Osteoarthritis hat 2 Implantate, ein Kontrollpatient mit Polyarthritis hat 3 Implantate, zwei posttraumatische Patienten haben 2 Implantate.
** Die Summe n ist nicht 13, weil in 4 Fällen versäumt wurde, das Alter des Patienten zu dokumentieren (3 Patienten mit Avanta PIP-Fingerprothese und 1 Patient mit Silikonimplantat).

Tabelle 5. Komplikationen bei US-Patienten

Komplikation	Avanta MCP-Implantat (8 Patienten)	Prothese Silikonimplantat (2 Patienten)
Schmerzen (3 Monate nach der Operation*)	4	0
Ödeme	1	0
Ulnardeviation	1	0
Streckhemmung	1	0
Eingeschränkter Bewegungsbereich	1	0
Knochenbruch	1	0
Schnellender Finger mit composite Flexion	1	0
Flexor-Tenolyse	3	0
Subluxation	0	0
Rotation	0	0
Revision	0	0

* 5 Patienten mit Avanta PIP-Fingergelenk hatten 3 Monate nach der Implantation noch Schmerzen, und 5 Patienten mit Avanta PIP-Prothese sowie 2 Patienten mit Silikonimplantat hatten 1-4 Wochen nach der Operation Schmerzen.

Tabelle 6. Anzahl der US-Patienten (Implantate) bei jeder Verlaufskontrolle*

Dauer der Beobachtungszeit	Patienten mit Avanta PIP-Implantat (Implantate)	Silikonimplantat Patienten (Implantate)
Postoperativ (1-4 Wochen)	11 (14)	2 (4)
3 Monate	9 (8)	2 (4)
6 Monate	4 (6)	0
12 Monate	0	0
24 Monate	0	0
Postoperatives Ausscheiden aus der Studie	1(1)	1 (3)

* Der Patient mit Avanta Implantat erschien nicht mehr zur Weiterbehandlung bzw. Verlaufskontrolle. Der Patient mit Kontrollimplantat schied nach der postoperativen Verlaufskontrolle nach 3 Monaten aus der Studie aus. Der Grund für das Ausscheiden aus der Studie ist nicht dokumentiert. Die Kontrolle nach 3 Monaten ist die letzte Verlaufskontrolle bei diesen Patienten.

In einer Fallserie berichtet Dr. Sollerman[1] über acht seiner Patienten, denen seit September 1996 insgesamt 11 Avanta PIP-Fingerprothesen implantiert wurden. Das mittlere Alter dieser Patienten beträgt 51 (31-66) Jahre. [illegible]

1. Sollerman, C. Möller, K. PIP Joint Arthroplasty with Noncemented Semiconstrained Implants. Department of Hand Surgery, Sahlgrenska University Hospital, Göteborg, Sweden. 7th Congress of the International Federation of Societies for Surgery of the Hand. Vancouver, Canada May 24-28, 1998.

OPERATIONSVERFAHREN

[illegible]

PATIENTEN-INFORMATIONEN (Siehe auch Warnung)

[illegible]

STERILISATION

[illegible]

BEGRENZTE GARANTIE

[illegible]

EU REPRÄSENTANT
Medical Products International Europe, Schutweg 13a,
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

FRANÇAIS

DISPOSITIF HUMANITAIRE. La prothèse digitale Avanta PIP est agréée par la loi fédérale des États-Unis d'Amérique pour utilisation en arthroplastie de l'articulation PIP dans l'un des deux cas suivants :

- le patient a besoin d'une révision de la ou des prothèses PIP non couronnées de succès ;
- le patient pense qu'il placera ses mains dans des situations de charge qui interdisent l'utilisation d'un autre implant dans l'articulation PIP ostéo-arthritique douloureuse et arthritique post-traumatique.

L'efficacité de ce dispositif pour cet usage n'a pas été démontrée.

MISE EN GARDE

La législation fédérale des États-Unis d'Amérique et limite la vente, la distribution et l'utilisation de cet appareil par un médecin ou sur ordonnance d'un médecin.

DESCRIPTION

[illegible]

Matériaux :

- Composant en alliage chrome cobalt
- PolyMUE

INDICATIONS

La prothèse digitale Avanta PIP est indiquée en arthroplastie de l'articulation PIP dans l'un des deux cas suivants :

- le patient a besoin d'une révision d'une ou plusieurs prothèses PIP non réussies ;
- le patient pense qu'il placera ses mains dans des situations de charge qui interdisent l'utilisation d'un autre implant de l'articulation PIP ostéo-arthritique douloureuse et arthritique post-traumatique.

CONTRE-INDICATIONS

[illegible]

MISES EN GARDE (Voir aussi la partie relative à l'information et conseils destinés au patient)

[illegible]

PRÉCAUTIONS

[illegible]

EFFETS INDÉSIRABLES

EFFETS INDÉSIRABLES RAPPORTÉS

[illegible]

EFFETS INDÉSIRABLES POTENTIELS

[illegible]

EXPÉRIENCE CLINIQUE

[illegible]

Tableau 3. Patients américains

Catégorie de patients	Patients
Total randomisés dans l'étude	31
Total opérés	18
Total entrés enrôlés mais sans chirurgie*	10
Désistement avant chirurgie	3
Désistement après chirurgie (3 mois post-op)	2
Avec données de suivi**	13

* 10 patients n'ont pas abandonné l'étude, mais aucune date de chirurgie n'a été prévue ; 5 sur 10 de ces patients appartiennent au groupe de contrôle.
** Des rapports ont été retournés que sur 13 patients. Tableaux 4-6 décrivent les résultats cliniques pour ces 13 patients.

Tableau 4. Données démographiques pour 13 patients américains avec suivi

Catégorie de patients	Patients avec implant Avanta PIP*	Patients avec implant en silicone	Total
Homme	6	1	7
Femme	5	1	6
Âge moyen, ET**	51,25*17,4 (n=8)	61 (n=1)	
Plage d'âge (années)	34-71	61	
Ostéoarthrite	5	0	5
Arthrite post-traumatique	3	1	4
Arthrite rhumatoïde	2	1	3
Révision de l'implant en silicone	1	0	1

* Description du nombre de patients porteurs de plus d'un implant, 13 patients ont en tout 18 implants : un patient ostéoarthritique a 2 implants ; un patient rhumatoïde du groupe de contrôle a 3 implants ; deux patients post-traumatiques ont deux implants.
** La somme de n n'est pas égale à 13 en raison de l'absence d'indication de l'âge du patient dans 4 cas (3 patients porteurs d'une articulation digitale Avanta PIP et 1 patient porteur d'un implant en silicone).

Tableau 5. Complications pour les patients américains

Complication	Avanta PIP Patients(n=11)	Silicone Patients(n=2)
Douleur (3 mois post-op*)	4	0
Œdème	1	0
Déviation " en coup de vent " cubitale	1	0
Décalage de l'extenseur	1	0
Limitation d'amplitude de mouvement	1	0
Os fendu	1	0
Ressort sur le dos avec flexion du composite	1	0
Ténolyse du fléchisseur	3	0
Subluxation articulaire	0	0
Rotation	0	0
Révision	0	0

* 5 patients Avanta PIP ressentirent de la douleur 3 mois après l'opération ; 5 patients Avanta PIP et 2 patients Silicone ressentirent de la douleur 1 à 4 semaines après l'opération.

Tableau 6. Nombre de patients américains (implants) à chaque point chronologique du suivi*

Durée du suivi	Patients avec implant Avanta PIP (implants)	Patients avec implant en silicone (implants)
Post-op (1 à 4 semaines)	11 (14)	2 (4)
3 mois	9 (8)	2 (4)
6 mois	4 (6)	0
12 mois	0	0
24 mois	0	0
Désistement post-op	1(1)	1 (3)

* Le patient implanté avec Avanta refusa de revenir pour une poursuite de la thérapie ou des visites de suivi. Le patient implanté du groupe de contrôle se désista après la visite post-op à 3 mois. La raison de ce désistement n'est pas documentée. La visite à 3 mois est la dernière visite pour ces patients.

Une série de cas rapportée par le Dr Sollerman[1] concerne huit de ses patients qui ont été implantés avec un total de 11 prothèses digitales Avanta PIP depuis septembre 1996. Ces patients ont un âge moyen de 51 ans (31-66). Les indications rapportées par le Dr Sollerman pour la chirurgie furent : douleur et raideur dues à une arthrose post-traumatique (4), arthrite rhumatoïde (3), ostéoarthrose (3) et syndrome d'Ehlers-Danlos (1). Deux révisions furent effectuées : l'une due au décalage d'extension causé par une résection osseuse insuffisante et l'autre due à une déformation rotationnelle. Le Dr Sollerman a rapporté que ses premiers résultats montrent un excellent soulagement de la douleur et dans la plupart des cas, une amplitude de mouvement fonctionnelle, en moyenne 46 (30-65) degrés avec un décalage d'extension de 11 (-10-35) degrés. La stabilité intrinsèque du dispositif fut excellente dans tous les cas, malgré la rupture des ligaments collatéraux dans sept articulations. Aucun signe de relâchement radiographique n'a été observé lors de cette courte période de suivi non spécifiée.

1. Sollerman, C. Möller, K. PIP Joint Arthroplasty with Noncemented Semiconstrained Implants. Département de chirurgie de la main, Hôpital universitaire Sahlgrenska, Göteborg, Suède. 7e Congrès de la Fédération internationale des sociétés de chirurgie de la main. Vancouver, Canada 24-28 mai, 1998.

PROCÉDURES CHIRURGICALES

Il existe une procédure chirurgicale à suivre dans la mise en œuvre de cette prothèse. Il est de la responsabilité du chirurgien de bien prendre connaissance de cette procédure avant d'utiliser ces produits. De plus, le chirurgien est tenu de prendre des [illegible]

INFORMATION ET CONSEILS DESTINÉS AU PATIENT (Voir également la partie Mises en garde)

[illegible]

STÉRILISATION

[illegible]

GARANTIE LIMITÉE

[illegible]

REPRÉSENTANT EU
Medical Products International Europe, Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

CE

ESPAÑOL

DISPOSITIVO HUMANO

La prótesis digital Avanta PIP está autorizada por las leyes federales para su utilización en artroplastias de la articulación interfalángica proximal de los dedos de la mano (articulación PIP) cuando:

- el paciente necesita una revisión de una o diversas prótesis PIP [illegible] o
- el paciente prevé someter las manos a situaciones de carga que excluyen la utilización de un implante alternativo en la articulación PIP en los casos dolorosos de osteoartritis y artritis postraumática.

La eficacia de este dispositivo para esta finalidad no está demostrada.

PRECAUCIÓN

Las leyes federales de EE.UU. limitan la venta, la distribución y la utilización de este dispositivo a médicos o a personas bajo las órdenes de un médico.

DESCRIPCIÓN

La prótesis de la articulación interfalángica proximal de los dedos de la mano consiste en un componente de polietileno de peso molecular ultra alto (UHMWPe) con un vástago de aleación de titanio que puede cementarse al eje de la falange media previamente preparada, y un componente consistente en un vástago de cromo cobalto el cual se inserta en la falange proximal previamente preparada. La superficie de cromo cobalto se articula con el componente de UHMWPe para formar una prótesis semiconstreñida para la articulación interfalángica proximal. El implante se encuentra disponible en cinco tamaños, cada uno de los cuales puede utilizarse en la mano derecha o izquierda. Para cada tipo de implante existe una gama de tamaños de prueba para facilitar la preparación del hueso.

Materiales:

- Componente distal ASTM F-648 de polietileno de peso molecular ultra alto (UHMWPe)
- Componente proximal ASTM F-75 de cromo cobalto
- Aleación de titanio Ti-6Al-4V ASTM F136

INDICACIONES

La Prótesis digital Avanta PIP está indicada para su utilización en artroplastias de la articulación PIP cuando:

- El paciente necesita una revisión de una o diversas prótesis PIP [illegible] o
- El paciente prevé someter las manos a situaciones de carga que excluyen la utilización de un implante alternativo en la articulación PIP en los casos dolorosos de osteoartritis y artritis postraumática.

CONTRAINDICACIONES

[illegible]

ADVERTENCIAS

[illegible]

PRECAUCIONES

[illegible]

REACCIONES ADVERSAS

REACCIONES ADVERSAS COMUNICADAS

[illegible]

REACCIONES ADVERSAS POSIBLES

[illegible]

EXPERIENCIA CLÍNICA

[illegible]

Tabla 3: Pacientes de EE.UU.

[illegible]

Tabla 4: Datos demográficos de 13 pacientes de EE.UU. con seguimiento

[illegible]

Tabla 5: Complicaciones en los pacientes de EE.UU.

[illegible]

Tabla 6: Número de pacientes de EE.UU. (implantes) en cada momento del seguimiento

[illegible]

PROCEDIMIENTOS QUIRÚRGICOS

[illegible]

INFORMACIÓN PARA EL PACIENTE

[illegible]

ESTERILIZACIÓN

[illegible]

GARANTÍA LIMITADA

[illegible]

REPRESENTANTE EU

Medical Products International Europe, Schutweg 13a, 5145 NP Waalwijk, The Netherlands
31 (0) 416 563764

NEDERLANDS

HUMANITAIRE PROTHESE

[illegible]

OPGELET

[illegible]

BESCHRIJVING

[illegible]

INDICATIES

[illegible]

CONTRA-INDICATIES

[illegible]

WAARSCHUWINGEN

[illegible]

VOORZORGSMAATREGELEN

[illegible]

BIJWERKINGEN

BESCHREVEN COMPLICATIES

[illegible]

POTENTIËLE COMPLICATIES

[illegible]

Tabel 3. Patiënten in de VS

Patiëntencategorie	Patiënten
Totaal aantal gerandomiseerd binnen het onderzoek	31
Totaal aantal dat een ingreep heeft ondergaan	18
Totaal ingeschreven patiënten die geen ingreep hebben ondergaan*	10
Aantal dat zich voor de ingreep heeft teruggetrokken	3
Aantal dat zich na de ingreep heeft teruggetrokken (6 maanden na ingreep)	2
Aantal met follow-upgegevens**	13

* Er zijn 10 patiënten die zich niet hebben teruggetrokken uit het onderzoek, maar voor wie nog geen operatiedatum is gepland; 8/10 van deze patiënten zitten in de [illegible]

** Er zijn uitsluitend CSF-formulieren beschikbaar voor 13 patiënten. De tabellen 4-8 beschrijven de klinische resultaten voor deze 13 patiënten.

Tabel 4. Demografische gegevens voor 13 patiënten in de VS met follow-up

Patiëntencategorie	Patiënten met een Avanta PIP-implantaat	Patiënten met siliconenimplantaat	Totaal
mannen	6	1	7
vrouwen	5	1	6
gemiddelde leeftijd**, SD	51.25*17.4 (n=8)	61 (n=1)	
leeftijdsspreiding (jaar)	24-71	61	
osteoartritis	5	0	5
posttraumatische artrose	3	1	4
reumatoïde artritis	2	1	3
revisie van het siliconenimplantaat	1	0	1

* Beschrijving van het aantal patiënten met meer dan één implantaat. Er zijn 13 patiënten met 18 implantaten; één osteoartritische patiënt heeft 2 implantaten; één controlepatiënt met reumatoïde artritis heeft 3 implantaten; twee posttraumatische patiënten hebben 2 implantaten.

** The sum of n is not equal to 13 because of the failure to record the age of the patient in 4 instances (3 Avanta PIP Finger Joint and 1 silicone implant patients)

Tabel 5. Complicaties bij patiënten in de VS

Complication	Avanta PIP Patients (n=11)	Silicone Patients (n=2)
pijn (3 maanden post-op*)	4	0
Oedeem	1	0
afwijking van de ulna	1	0
extensievertraging	1	0
bewegingsbeperking	1	0
scheur in het bot	1	0
[illegible] over de dorsum manus bij samengestelde [illegible]	1	0
tenolyse van de flexor	3	0
subluxatie van het gewricht	0	0
rotatie	0	0
revisie	0	0

* Er waren 5 patiënten met de Avanta PIP-prothese die 3 maanden na de ingreep pijn ondervonden, en er waren 8 patiënten met de Avanta PIP-prothese en 2 met de siliconenprothese die 1-4 weken na de ingreep pijnervaringen hadden.

Tabel 6. Aantal Amerikaanse patiënten (implantaten) op elk follow-uptijdstip

Duur van de follow-up	Avanta PIP Implant Patients (# implants)	Silicone Implant Patients (# implants)
Na de ingreep (1-4 weken)	11 (14)	2 (4)
3 maanden	8 (9)	2 (4)
6 maanden	4 (5)	0
12 maanden	0	0
24 maanden	0	0
Na terugtrekking	1(1)	1 (3)

* De patiënt met het Avanta-implantaat weigerde terug te komen voor voortzetting van de therapie of voor follow-upbezoeken. De patiënt met het controle-implantaat trok zich terug na het bezoek 3 maanden na de ingreep. De reden voor de terugtrekking is niet bekend. Het bezoek na 3 maanden is het laatste bezoek voor deze patiënten.

[illegible]

CHIRURGISCHE PROCEDURES

[illegible]

PATIËNTINFORMATIE

[illegible]

STERILISATIE

[illegible]

BEPERKTE GARANTIE

[illegible]

EU AFGEVAARDIGDE

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31 (0) 416 563764

KLINISCHE ERVARINGEN

[illegible]

ITALIANO

Protesi del Dito PIP Avanta

DISPOSITIVO UMANITARIO

[illegible]

ATTENZIONE

[illegible]

DESCRIZIONE

[illegible]

INDICAZIONI

[illegible]

CONTROINDICAZIONI

[illegible]

AVVERTENZE

[illegible]

PRECAUZIONI

[illegible]

EVENTI NEGATIVI

EFFETTI INDESIDERATI SEGNALATI

[illegible]

EFFETTI INDESIDERATI POTENZIALI

[illegible]

Tabella 3. Pazienti statunitensi PIP

[illegible]

Tabella 4: Dati demografici per 13 pazienti statunitensi con follow-up

[illegible]

Tabella 6. Complicanze nei pazienti statunitensi

[illegible]

Tabella 8. Numero di pazienti statunitensi (impianti) per scadenza di follow-up

[illegible]

PROCEDURA CHIRURGICA

[illegible]

INFORMAZIONI PER LA CONSULENZA AL PAZIENTE

[illegible]

STERILIZZAZIONE

[illegible]

GARANZIA LIMITATA

[illegible]

RAPPRESENTANTE EU

Medical Products International Europe, Schutweg 13a, 5145 NP Waalwijk, The Netherlands
31 (0) 416 563764

SPERIMENTAZIONE CLINICA

[illegible]

AVANTA
ORTHOPAEDICS
9399 Carroll Park Drive, Suite A, San Diego, CA 92121 USA
(858)455-8300 / (800)433-9915 (toll)

PRODUCT INSERT

Uncoated Ulnar Implant
Uncoated Ulnar Implant w/ Head
Uncoated Ulnar Implant w/ Porous Coated Head
Porous Coated Ulnar Implant
Uncoated Radial Implant
Uncoated Radial Implant w/ Head
Porous Coated Radial Implant
Porous Coated Radial Implant w/ Head

ENGLISH

CAUTION
United States Federal Law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
This hemi joint prosthesis consists of a cobalt chromium stem and articular surface. The implant is designed to be inserted into the end of the prepared bone. The distal cancellous surface promotes on processing bone. The implant is available in several sizes, each of which can be used in right or left hands. A range of head styles for each type of implant is available to aid in bone preparation.

Materials:
- ASTM F-1537 (or equal) cobalt chromium component
- Commercially Pure Titanium (CPTi)

INDICATIONS
Uncoated Ulnar Implant is intended for replacement of the distal radius or joint following ulnar head resection arthroplasty.
Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting the following:
1. Pain and weakness of the wrist joint not improved by conservative treatment
2. Instability of the ulnar head with X-ray evidence of distal subluxation and soluble changes
3. Failed ulnar head resection

Uncoated Radial Implant is intended for replacement of the proximal end of the radius.
1. Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:
   a. Joint destroyed on X-ray examination visible on x-ray
   b. Resistance to conservative treatment
2. Primary replacement after fracture of the radial head
3. Symptomatic sequelae after radial head resection

CONTRAINDICATIONS
1. Malformed, systemic ligatures that preclude stabilization of the ulnar head during pronation/supination (press)
2. Tendon, ligament or distal radioulnar joint which cannot provide adequate support or balance for the prosthesis to head
3. Inadequate skin or musculoskeletal system
4. Growing patients with open epiphyses
5. Previous ulnar fracture or infection to or around the joint
6. Known sensitivity to materials used in this device

WARNINGS (See also the Patient Counseling Information Section):
Improper loading, excessive mobility, and wear debris may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.

Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
Implants are mechanical devices that can be worn away, fatigued or broken. An implant also may become infected, painful, swollen, or inflamed. The ability of the surgeon's bone and soft tissue may be inadequate to support the implant, or may deteriorate in time resulting in instability, deformity, or pain. The benefits from implant surgery may not exist if the patient's expectations are not determined with time. Revision surgery may be necessary to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

PRECAUTIONS
1. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize. Trial sizing components are available to avoid having to open the sterile package prior to actual implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
2. Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance. Polished bearing and taper surfaces must not come in contact with hard or abrasive surfaces.
3. The head and stem should not be modified if the layers are properly discharged, this may increase repeated attaching and detaching.
4. The head of the prosthesis is important so to the neck of the stem. Prior to assembly confirm that the tapers are dry and free from contaminant.

ADVERSE EVENTS
Potential adverse events associated with joint prostheses include pain, loosening, fracture, dislocation, or infection. There have been some reports of patients with metal sensitivity reactions following joint replacement. Implantation of materials such as metals should evaluate whether clinicians may result in foreign body reaction apparent to the implant site, injury to the surrounding nerves, blood vessels, tendons, or soft tissues can serve as a consequence of implanting the device.

SURGICAL PROCEDURES
A surgical procedure for use of the implant device is available. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings)
Physicians should prescribe and subject for implant surgery with documented counseling of potential complications and alternatives, which may include non-surgical procedures such as soft tissue reconstruction or arthrodesis, prior to surgery is necessary. In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient: 1) Adverse effects may necessitate reoperation, revision, or removal of the involved joint. 2) While the expected life of joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However due to the many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

STERILIZATION
The components has been sterilized by ethylene oxide or gamma radiation. The implant is supplied sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason the implant should not be used. Do not resterilize. Trial sizing components are available to avoid having to open the sterile package prior to actual implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics, Inc. warrants that the product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE
Medical Products International Europe, BV
Schroevy 13e
6148 NP Waubach, The Netherlands
31 (0) 416 563764

DEUTSCH

BESCHREIBUNG
Dieses Hemigelenkprothesen besteht aus einem Kobalt-Chrom-Schaft und einer Gelenkfläche. Das Implantat ist zum Einsetzen in das Ende des präparierten Knochens bestimmt. Die Kobalt-Chrom-Basis enthindert ist zum gegenüberliegenden Knochen. Das Implantat ist in mehreren Größen erhältlich, die jeweils für die linke oder rechte Hand verwendet werden können. Eine Auswahl an Gelenk zur Größenbestimmung für einen präoperativen stand für die Knochenvorbereitung zur Verfügung.

Werkstoffe:
- ASTM F-1537-94 Kobalt-Chrom-Molybdänlegierung
- Handelsübliches Reintitan (KPTi)

INDIKATIONEN
Das Ulnar Ulnar Implantat ist für den Ersatz des distalen Radiusabgelenks nach Resektionsarthroplastik bei Ulnakopfresektion vorgesehen.
Ersatz des distalen Ulnakopfgelenk bei rheumatoider, degenerativer oder posttraumatischer Arthritis mit folgenden Befunden:
1. Schmerzen und Schwäche des Handgelenks dieser konservativer Behandlung erfolgte blieb
2. Instabilität des Ulnaköpfchens mit radiologischen Zeichen einer distalen Subluxation und Löslicher Veränderungen
3. Erfolgloser Resektion des Ulnaköpfchens

Das Ulnar Radius-Implantat ist für den Ersatz des proximalen Radiusendes vorgesehen:
1. Ersatz des Radiusköpfchens bei degenerativen oder posttraumatischen Beschwerden mit Schmerzen, Crepitatus und Bewegungseinschränkung im Humeroradial- und/oder proximalen Radioulnargelenk mit folgenden Befunden:
   a. Röntgenologisch sichtbare Gelenkzerstörung oder Nekrotisation
   b. Resistenz gegenüber konservativer Behandlung
2. Primärersatz nach Fraktur des Radiusköpfchens
3. Symptomatische Folgezustände/-störungen nach Radiusköpfchenresektion

PATIENT COUNSELING INFORMATION (Siehe auch Warnings)
Patienten sollen vor einer Implantation über mögliche Komplikationen und Alternativen aufgeklärt werden, die nichtoperative Maßnahmen wie Weichteilrekonstruktion oder Arthrodese, vor einer Operation gegebenenfalls notwendig sein können. Zusätzlich zu den patientenbezogenen Informationen in den Abschnitten „Warnhinweise" und „Komplikationen" müssen die Patienten über folgendes informiert werden: 1) Komplikationen können eine erneute Operation, einen Komponentenwechsel oder Entfernung des Implantats nach sich ziehen. 2) Die zu erwartende Lebensdauer der Gelenkersatzkomponenten ist schwer abzuschätzen, sie ist jedoch begrenzt. Diese Komponenten aus körperfremdem Material werden in den Körper eingesetzt, um die Beweglichkeit wenn möglich wiederherzustellen oder Schmerzen zu verringern. Aufgrund zahlreicher biologischer, mechanischer und physikochemischer Faktoren, die diese Prothesen beeinflussen, können die Komponenten jedoch nicht dem Aktivitätsniveau und der Belastung eines normalen gesunden Knochens über einen unbegrenzten Zeitraum standhalten.

STERILISATION
Die Komponenten wurden mit Ethylenoxid oder Gammastrahlen sterilisiert. Die Prothese in einer unbeschädigten gelieferten Packung ist steril. Falls die Prothese oder die Verpackung beschädigt aussieht, das Verfallsdatum überschritten wurde oder die Sterilität aus irgendeinem Grund infrage gestellt wird, darf die Prothese nicht implantiert werden. Nicht resterilisieren. Größe für Gelenkprobeanordnung stehen zur Verfügung, damit die sterile Verpackung vor Implantation der Prothese nicht geöffnet werden muss. Die Prothese sind dann aus der sterilen Verpackung zu nehmen, wenn die Implantationsstelle vorbereitet und genau ermessen wurden ist.

BEGRENKTE GARANTIE
Avanta Orthopaedics, Inc. garantiert, dass dieses Produkt den Spezifikationen des Herstellers entspricht und zum Zeitpunkt der Lieferung keine Herstellungsfehler aufweist. Garantien, die auf unsachgemäße Behandlung, Missbrauch oder falsche Verwendung des Produkts nach dem Empfang durch den Käufer zurückzuführen sind, sind von dieser Garantie ausdrücklich ausgeschlossen. Avanta Orthopaedics übernimmt keine Garantie für den Ausgang des chirurgischen Eingriffs.

EU-VERTRETER
Medical Products International Europe, BV
Schroevy 13e
6148 NP Waubach, Niederlande
31 (0) 416 563754

FRANÇAIS

DESCRIPTION
Cette prothèse hémiarticulaire est constituée d'une tige et d'une surface articulaire en alliage chrome cobalt. L'implant est conçu pour être inséré dans le cartilage de l'os préparé. La surface en alliage chrome cobalt à l'extrémité avec l'os opposé. L'implant est disponible en plusieurs tailles chacune d'entre elles pouvant être utilisée du côté droit ou du côté gauche. Un jeu de différentes d'essai pour déterminer de la taille est disponible pour chaque type d'implant afin de faciliter la préparation de l'os.

Matériaux :
- ASTM F-1537-94 Composant en alliage chrome cobalt
- Titane pur du qualité commerciale (CPTi)

INDICATIONS
L'implant ulnaire utilisé est destiné au remplacement de l'articulation radio-ulnaire distale après arthroplastie avec résection de la tête du cubitus.
Remplacement de la tête ulnaire distale pour cause d'arthrite rhumatoïde, dégénérative ou post-traumatique présentant les caractéristiques suivantes :
1. Douleur et faiblesse de l'articulation du poignet non améliorées par un traitement conservateur
2. Instabilité de la tête du cubitus avec présence radiographique de subluxation distale et altérations évolutives
3. Échec d'une résection de la tête du cubitus

L'implant radial utilisé est destiné au remplacement de l'extrémité proximale du radius.
1. Remplacement de la tête du radius suite à une invalidité dégénérative ou post-traumatique s'accompagnant de douleur, de crépitations et de perte de mobilité au niveau de l'articulation radio-humérale et ou radio-ulnaire proximale avec :
   a. Destruction articulaire ou subluxation visibles à la radiographie
   b. Résistance à un traitement conservateur
2. Remplacement primaire après fracture de la tête du radius
3. Séquelles symptomatiques après résection de la tête du radius

CONTRE-INDICATIONS
1. Fractures de l'avant-bras mal consolidées empêchant la stabilisation de la tête cubitale lors des mouvements de pronation-supination (presse)
2. Tendon, ligament ou articulation radio-cubitale distale incapable d'offrir un support ou une fixation adéquats à la prothèse (cubitale)
3. Structure osseuse ou musculo-squelettique inappropriée
4. Jeunes patients en cours de croissance présentant des épiphyses ouvertes
5. Antécédents de fracture ouverte ou d'infection au niveau ou à proximité de l'articulation
6. Sensibilité connue aux matériaux utilisés dans le système

MISES EN GARDE (Voir aussi la partie Information et Conseils destinés au patient)
Des contraintes importantes, mobilité excessive et usure des débris peuvent accélérer l'usure et aboutir à une éventuelle défaillance par desserrement, fracture ou dislocation de l'appareil. Les patients doivent être conscients du risque potentiel pour la résistance de l'appareil si on exerce sur lui des contraintes excessives.
Les implants sont des appareils mécaniques qui peuvent s'user, se fatiguer ou se casser. Un site d'implant peut s'infecter, devenir douloureux, se tuméfier ou s'enflammer. L'état de l'os adjacent et du tissu mou peut être inapproprié pour soutenir l'implant ou peut se détériorer avec le temps et aboutir à une instabilité, à une difformité ou une douleur. Les avantages de l'implantation des prothèses peuvent ne plus exister si les attentes du patient ne peuvent s'établir avec le temps et nécessiter une chirurgie de révision pour remplacer l'implant ou mettre en œuvre de procédures alternatives. Les interventions chirurgicales destinées à l'ajout d'implants ne sont pas exceptionnelles.

PRÉCAUTIONS
1. L'implant est fourni stérile dans un emballage intact. Si l'implant ou son emballage semblent endommagés, si la date de péremption est dépassée ou si la stérilité est mise en doute pour une raison quelconque, il faut ne pas l'employer de cet implant. Ne pas re-stériliser.
2. Les implants doivent être manipulés avec des instruments émoussés pour éviter de rayer de les rompre ou d'endiller l'appareil, ce qui risquerait d'avoir un impact défavorable sur les performances de l'implant. Les surfaces d'appui et de connexions présentant poids ne doivent pas entrer en contact avec des surfaces dures ou abrasives.
3. Ne pas implanter la tête et la tige si les composants présentent sont endommagés, afin d'éviter endommagés sous une épaisseur pour l'attachement et la déconnexion à répétition.
4. La tête de la prothèse est importante sur le cône de la tige. Avant de procéder à l'assemblage, s'assurer que les surfaces coniques présentes sont sèches et exemptes de contaminant.

EFFETS INDÉSIRABLES
Parmi les effets indésirables potentiels des prothèses on a signalé la douleur, le desserrement, la fracture, la dislocation ou l'infection. On a signalé quelques cas de patients qui ont manifesté des réactions de sensibilité au métal suite à remplacement de l'articulation. L'implantation de matériaux comme le métallique métal risque de nuire peut se traduire par une réaction allergique au niveau du site de l'implantation. Le tissu des nerfs, vaisseaux sanguins, tendons ou tissus mous environnants peut survenir suite à l'implantation de cet appareil.

PROCÉDURES CHIRURGICALES
Il existe une procédure chirurgicale à suivre dans le mise en œuvre de cette prothèse. Il est de la responsabilité du chirurgien de bien prendre connaissance de cette procédure avant d'utiliser ces produits. De plus, le chirurgien est tenu de prendre connaissance des publications utiles et de consulter ses collègues expérimentés avant d'utiliser cette prothèse avant d'utiliser ces prothèses.

INFORMATION ET CONSEILS DESTINÉS AU PATIENT (Voir également la partie Mises en garde)
Il convient de traiter tout patient programmé pour une implantation envisagée des informations relatives sur les complications et alternatives potentielles, les possibilités chirurgicales des procédures non-chirurgicales comme la reconstruction des tissus mous, si besoin l'arthrodèse. En plus de l'information relative au patient, contenue dans les parties Mises en garde et Effets indésirables, il convient de faire savoir au patient que : 1) Les effets indésirables peuvent nécessiter une nouvelle opération, une correction ou une ablation de l'articulation concernée. 2) Comme la longévité des composants de remplacement de l'articulation est difficile à estimer, elle est limitée. Ces composants sont constitués de matériaux étrangers qui sont placés à l'intérieur du l'organisme en vue de la restauration potentielle de la mobilité ou de la réduction de la douleur. Toutefois, en raison de nombreux facteurs biologiques, mécaniques et physico-chimiques influençant à ces appareils, les composants ne peuvent pas résister indéfiniment au niveau d'activité et aux contraintes d'un os sain normal pendant une durée illimitée.

STÉRILISATION
Ces composant a été stérilisé à l'oxyde d'éthylène ou aux rayons gamma. L'implant par fourni stérile dans un emballage intact. Si l'implant ou son emballage semblent endommagés, si la date de péremption est dépassée ou si la stérilité est mise en doute pour une raison quelconque, il faut ne pas l'employer de cet implant. Ne pas re-stériliser. Il existe des pièces d'essai pour vous aider à ouvrir un emballage stérile avant l'implantation de la prothèse. Il faut retirer l'implant de son emballage stérile seulement après que le site d'implantation a été préparé et correctement dimensionné.

GARANTIE LIMITÉE
Avanta Orthopaedics, Inc. garantit que ce produit satisfait aux spécifications du fabricant et qu'il est exempt de défauts de fabrication au moment de sa livraison. Cette garantie exclut expressément les défauts résultant d'une mauvaise utilisation, d'un usage abusif ou d'une manipulation incorrecte du produit après réception de la part de l'acheteur. Avanta Orthopaedics décline toute responsabilité quant à l'issue de l'intervention chirurgicale.

REPRÉSENTANT UE
Medical Products International Europe, BV
Schroevy 13e
6148 NP Waubach, Pays-Bas
31 (0) 416 563754

CE 0123

ESPAÑOL

DESCRIPCIÓN

Las prótesis articular parcial cementada en un vástago de aleación de titanio moldeado y una superficie articular. El implante está diseñado para insertarse en la diáfisis del húmero proximal. La superficie de cobalto cromo se articula en el húmero opuesto. El implante está disponible en varios tamaños diferentes, cada una de los cuales se puede usar en todo en la parte izquierda como en la derecha. Para cada tipo de implante se dispone de una gama de materiales de piezas que facilitan la preparación del hueso.

Materiales:

- Componente de plástico de polietileno según ASTM F-1937-84
- Tornillo cementado anti giro (PCP)

INDICACIONES

El implante cubital Pilpot está indicado para la sustitución de la articulación humeroulnar dañada tras una extirpación de neoplasia de la cabeza del cúbito, así como para la sustitución de la misma cubital distal como consecuencia de otras anormalidades degenerativas o postraumáticas que presenta las siguientes características:

1. Dolor y debilidad de la articulación de la muñeca que no mejora con el tratamiento conservador.
2. Inestabilidad de la cabeza del cúbito con evidencia radiográfica de subluxación dorsal o palmar incipiente
3. Resección fallida de la cabeza del cúbito

El implante Pilpot Head está indicado para la sustitución del extremo proximal del radio en los siguientes casos:

1. Fracturas de la cabeza radial como consecuencia de discoincidencias diagnosticadas o post operativas que presentan dolor, crepitación y una reducción del movimiento de la articulación radiohumeral, sin indicación de cirugía ósea.
2. Subluxación o dislocación de articular distal en radiografías
3. Presencia de un tratamiento conservador
4. Neurología anterior después de una fractura de la cabeza del radio
5. Síndrome pronunciado después de una resección de la cabeza del radio

CONTRAINDICACIONES

1. Fracturas mal consolidadas del antebrazo que impiden la rehabilitación de la cabeza del radio durante la prótesis (operación ulterior)
2. Sensibilidad, ligamento o articulación radio distal distal que no ofrezca proporcionar el apoyo o la fijación adecuados para la prótesis (ulterior)
3. Piel o sistema musculoesquelético inadecuados
4. Problemas en cicatrización con epífisis distales
5. Presencia abierta previa o infección en la articulación o de la zona alrededor de esta
6. Sensibilidad conocida a los materiales que componen el vástago

ADVERTENCIAS (Véase también la sección Información sobre asistencia al paciente)

Los riesgos asociados, una movilidad excesiva y la inestabilidad articular pueden conducir a un desgaste excesivo y al todo eventual del componente al aflojarse, fracturarse o deformarse. Los pacientes deben ser conscientes de que la posibilidad de fallo aumenta si se le imponen exigencias excesivas.

Los implantes son dispositivos mecánicos que se pueden desgastar, fatigar o romper. El juego de un implante puede aumentar, doler, fatigarse o fracturarse. El grado del hueso adyacente y del tejido blando puede no ser adecuado para amortiguar el implante y puede deteriorarse con el tiempo causando inestabilidad, deformación o artritis. Puede ser que los beneficios de la cirugía de implante no satisfagan las expectativas del paciente o que se deterioren con el tiempo, haciendo necesaria una cirugía de revisión para cambiar el implante o realizar procedimientos alternativos. Si el daño no las materiales, las cargas se elevan en son más.

PRECAUCIONES

1. El implante se presenta estéril en un envase intacto. No se debe usar el implante si este o el envase parecen estar dañados, o la pantalla la fecha de caducidad, o si por cualquier motivo se cree en duda su esterilidad. No lo esterilice de nuevo.
2. Para evitar que los implantes se rayen, corten o melle, y se no sean adecuadamente su funcionamiento, evite se deben manejar con instrumentos rígidos. Las superficies pulidas opuestas y de sellón no deben entrar en contacto con superficies duras o abrasivas.
3. No se deben implantar si la cabeza ni el vástago si existe la posibilidad de que los tejos como resin derivados, incluyendo el acondicionado y desacoplamiento radial.
4. La cabeza de la prótesis será empleadas en el cuello del vástago. Antes del ensamblaje se debe confirmar que los conos están secos y libres de contaminantes.

EVENTOS ADVERSOS

Los eventos adversos potenciales conocidos en cierta de prótesis articulares incluyen dolor, aflojamiento, fractura, dislocación o infección. Se conocen algunos casos de pacientes con reacciones de sensibilidad al metal tras el reemplazo de la artroplastia. La esperanza de materiales tales como la alineación de acetato como pueden dar lugar a una reacción alrededor de la zona del implante debido la presencia de un cuerpo extraño. Como consecuencia de la implantación de este dispositivo se puede producir lesiones en los nervios, vasos sanguíneos, tendones o tejidos blandos circundantes.

PROCEDIMIENTOS QUIRÚRGICOS

Se dispone de un procedimiento quirúrgico que permite el uso de este implante. Es responsabilidad del cirujano familiarizar con el procedimiento antes de utilizar estos productos. Además, antes de utilizarlo el cirujano es responsable de estar familiarizado con la literatura relevante y consultar con colegas con experiencia en el procedimiento.

INFORMACIÓN SOBRE ASISTENCIA AL PACIENTE (Véase también la sección Advertencias)

Antes de la cirugía es necesario proporcionar a cada paciente un espacio de una cirugía de implante información documentada sobre las posibles complicaciones y sobre las alternativas, que pueden consistir en proporcionarles un mantenimiento como la reconstrucción del tejido blando y la artrodesis. Además se la información relacionada con el paciente así se incluye y en las secciones Advertencias y Eventos Adversos, se debe informar al paciente de lo siguiente: (a) Los efectos adversos pueden hacer necesaria la corrección de la osteotomía, la revisión o la sustitución posterior. El tiempo en el cual cesan la duración de los componentes de la artroplastia de sustitución, se sabe que es limitada. Estos componentes están hechos de materiales sintéticos que se colocan dentro del cuerpo para la potencial deposición de la movilidad y reducción del dolor. Sin embargo, debido a los numerosos factores biológicos, mecánicos y fisicoquímicos que afectan a estas dispositivos, no se puede asegurar que dichos componentes resistan el test de actividad y las cargas en un nuevo humano y como durante un periodo de tiempo limitado.

ESTERILIZACIÓN

Este componente no está esterilizado y debe esterilizarse antes de utilizarse. El implante se presenta estéril en un envase intacto. No se debe usar el implante si este o el envase parecen estar dañados, o la pantalla la fecha de caducidad o si, por cualquier motivo, se cree en duda su esterilidad. No lo esterilice de nuevo. Se dispone de varios métodos de proceso para estar seguro que este se encuentra estéril antes de la implantación de la prótesis. El implante se debe tratar de tal manera estará estrictamente después de haber preparado y montado correctamente el lugar del implante.

GARANTÍA LIMITADA

Aurora Orthopaedics, Inc. garantiza que este producto cumple con las especificaciones del fabricante y que, en el momento de entrega, está libre de defectos de fabricación. Esta garantía excluye específicamente los procesos incorrectos así el uso inadecuado, abuso o manipulación inapropiada del producto después de que se compruebe lo verifica. Aurora Orthopaedics no garantiza el resultado del procedimiento quirúrgico.

REPRESENTANTE EN LA UE

Medical Products International Europe, BV
Schijnweg 13b
5145 NP Waalwijk, Holanda
31 (0) 416 560764

NEDERLANDS

BESCHRIJVING

Deze gedeeltelijke prothese bestaat uit een staaf van kobaltchroom en een gietvormcement gegoten. Het implantaat is ontworpen om te worden geïmplanteerd in het proximale humerusschacht. Het kobaltchroom oppervlak beweegt tegen het tegenoverliggende bot. De twee implantaten bestaat uit verschillende maten, voor zowel de rechter- als de linkerhand, zij is ook een aantal peripherieën verkrijgbaar als een het vleesbedden van het te behandelen gemaakt te vergemakkelijken.

Materialen:

- ASTM F-1937-84 hoofdmateriaal component
- Commercieel verkrijgbaar titanium (CPT)

INDICATIES

Het proximale Ulna-implantaat is bedoeld voor de vervanging van de artikulaire humeroulnare na resectie van het hoofd Ulnae

Vervanging van het radiale distale voor nieuw degenerative of posttraumatische aandoeningen die de volgende kenmerken vertonen:

1. Pijn en instabiliteit van het polsgewricht die niet verbetert na conservatieve behandeling
2. Instabiliteit van de ulna met de onderscheidend beeld met röntgenonderzoek
3. Een eerdere vervanging na een traject van de resectie

Het Pilpot radiushoofdimplantaat is bedoeld ter vervanging van het proximale gedeelte van de radius:

1. Vervanging van de radiuskop voor degenerative of posttraumatische artritis of fracturen die niet kunnen worden gerepareerd met een anatomische functie van de arteriële functionaliteit en/of de artikulatie radio-distaal is proximale met
   a. Een pijnbestrijdend gevoel dat of een aan-knobs de ulna van röntgenopnames of met de radius
   b. Verminderd tegen aanwezigheid van onderscheiding
2. Een primaire vervanging na een traject van de resectiekop
3. Symptomatische resterend na resectie van de radiuskop

CONTRA-INDICATIES

1. Niet niet-aansluitende breuken van een onderarm fracturen een distaliteit die in primaire en absolute (uitvoer)
2. Pezen, ligamenten of artikulatie radio-ulnaire distale die onvoldoende stabiliteit of steun van de prothese bieden (primair)
3. Onvoldoende huid- of musculoskeletale system
4. Problemen bij de genezing met open epifysen
5. Een bestaande bestaat of infectie van of rond het wondgebied
6. Bekende overgevoeligheid voor materialen die in de product worden gebruikt

WAARSCHUWINGEN (Zie ook Patiëntinformatie)

Mentie betreffen overmatige mobiliteit en artikulaire instabiliteit kunnen alle leiden tot versnelde slijtage, vervorming of uiteindelijk falen door losheid, breuken of deformatie van het implantaat. Patiënten moeten bewust gemaakt worden van de verhoogde kans op falen van het implantaat als hoge eisen op het gewricht worden gesteld.

Implantaten zijn mechanische prothesen, de bloeien slijten, en kan metaalmoeheid ontstaan en de kunnen breken. De plaats van het implantaat kan gaan losheid, slijtage, pijnlijkheid of artritis. De plaats van het aangrenzende bot en zachte weefsel kunnen onvoldoende zijn voor de ondersteuning van het implantaat of kan in de loop van de tijd verslechteren met instabiliteit, misvorming of botte de gewrig. Het kan zijn dat implantaatvoordelen niet de tevredden bepaalt als de patiënt verwacht, had of dat na verloop in de loop van de tijd achteruit, waardoor revisiechirurgie noodzakelijk is om het implantaat te vervangen of alternatieve procedures te verrichten. Als de beschadiging het implantaten is niet uitgesloten.

VOORZORGSMAATREGELEN

1. Het implantaat wordt steriel geleverd in een onopgeschaagde verpakking. Als het implantaat of de verpakking beschadigd lijken te zijn, als de vervaldatum verstreken is of de verpakking op als ook een of andere reden twijfel bestaat over de sterilteit, mag het implantaat niet gebruikt worden. Niet opnieuw steriliseren.
2. Implantaten moeten niet worden instrumenten worden gemanipuleerd om krassen, bramen of andere beschadigingen op de oppervlakken die de prothese van de prothese mogen worden hantering te voorkomen. De gepolijste gewrichts- en tegenoppervlakken mogen niet in aanraking komen met harde of schurende oppervlakken.
3. De kop en steel mogen niet geïmplanteerd worden als de kans bestaat dat zouden, kussen zijn, zo'n met lymfe, bevestiging door hydrolyse en ontsteken en weer bloeien.
4. De kop van de prothese wordt op de kop van de steel gezet. Controleer voor assemblage of de gekoelde oppervlakken droog en schoon zijn.

GEVAREN

De mogelijke bijeenkomen na gebruik zijn uit het gebruik van vingergewrichtsprothesen van pijn, loosening, breuk(en), dislocatie en infectie. Er is ook een aantal meldingen van patiënten die na gewrichtsvervanging overgevoelig kleuren te zijn voor metaal. Het implantaten van metalen zoals Co-Cr-Mo en/of titanium kan leiden tot allergiereacties bij de pleura van het implantaat. Letsel aan zenuwen, bloedvaten, pezen en zacht weefsel kunnen optreden als gevolg van het toegaan van de implantaat.

CHIRURGISCHE PROCEDURES

Een chirurgische procedure voor het gebruik van dit implantaat is beschikbaar. Het is de verantwoordelijkheid van de chirurg om zich de hoogte te zijn van de procedure voordat hij deze prothesen gebruikt. Het is ook zijn verantwoordelijkheid om op de hoogte te zijn van relevante publicaties en ervaren collega's te raadplegen over de uitvoering van het deze verricht.

PATIËNTINFORMATIE (Zie ook Waarschuwingen)

Het is noodzakelijk een alle patiënten die implantaatchirurgie zullen ondergaan voor de operatie te voorzien van informatie over de mogelijke complicaties en alternatieven. Alternatieven kunnen zijn: niet-implantaat procedures totale gewrichtsvervanging of artrodese. Naast de informatie die betrekking heeft op de patiënt zoals deze is opgenomen onder Waarschuwingen en Bijwerkingen moet de volgende informatie aan de patiënt worden meegedeeld. 1) Bijwerkingen kunnen bijvoorbeeld revisie of een van het implantaat, gewrichtsstijfheid vereisen. 2) De verwachte levensduur van geïmplanteerde organen. Implantaten is mogelijk te vervangen door een gedeeltelijke of totale vervanging. Het is niet bekend hoe lang de implantaten in het lichaam kunnen gebruikt voor patiënten met hoge activiteitsniveaus of voor patiënten jonger/zwaarlijvig. Door de vele biologische, mechanische en fysisch-chemische factoren die deze implantaten beïnvloeden, kan echter niet worden verwacht dat deze componenten voor onbepaalde tijd bestand zijn tegen het optreden van botbreuken en de beëindigen van kunstmatig gebonden.

STERILISATIE

Deze component is gesteriliseerd met ethyleenoxide of gammastralen. Het materiaal wordt steriel geleverd in een ontsmettingsvrije verpakking. Als het implantaat of de verpakking beschadigd lijken te zijn, als de uiterste gebruiksdatum is overschreden of als om de een of andere reden twijfel bestaat over de sterilteit, mag het implantaat niet gebruikt worden. Niet opnieuw steriliseren. Poortransmissiemeten (de verkrijgbaar om te voorkomen dat de sterilisatieverpakking voor het implantaten van de prothese gebruikt moet worden. Het implantaat mag de juiste staat hebben. Ook uit de steriele verpakking gebruikt worden totdat de plaats van het implantaat is voorbereid en de wens moet heeft.

BEPERKTE GARANTIE

Aurora Orthopaedics, Inc. garandeert dat dit product voldoet aan de specificaties van de fabrikant en ten tijde van de levering vrij is van fabricagegebreken. Deze garantie sluit uitdrukkelijk gebruiken uit die het gevolg zijn van verkeerd gebruik, misbruik of onjuiste behandeling van het product. De chirurgijl draagt de kosten. Aurora Orthopaedics gaat geen garantie op het resultaat van de chirurgische ingreep.

EU AFGEVAARDIGDE

Medical Products International Europe, BV
Schijnweg 13b
5145 NP Waalwijk, Nederland
31 (0) 416 560764

ITALIANO

DESCRIZIONE

Questa componente articolare è composta da una superficie articolare e una stelo di cemento. La protesi è indicata per essere inserita nella diafisi dell'omero prossimale. La superficie in cobalto cromo è articola sull'osso opposto. La protesi è disponibile in diverse misure e può essere utilizzata indifferentemente sia a destra che sinistra. Una gamma completa di dispositivi di prova è disponibile per ciascun tipo di protesi per la predisposizione dimensionale dell'osso.

Materiali:

- Componente di polietilene secondo ASTM F-1937-84
- Tassello allo stelo cementato/metallo (CPT)

INDICAZIONI

La protesi ulnare articolare è indicata per la sostituzione dell'articolazione radio-ulnare distale in seguito a resezione articolare della testa dell'ulna.

Sostituzione della testa dell'ulna distale a causa di artrite reumatoide degenerativa o traumatismo nei casi seguenti:

1. Dolore e debolezza dell'articolazione del polso non migliorata dal trattamento conservativo.
2. Instabilità della testa dell'ulna con evidenza radiologica di sublussazione dorsale od anteriore
3. Esito negativo dalla resezione della testa dell'ulna

La protesi radiale Pilpot è indicata per la sostituzione dell'estremità prossimale del radio:

1. Sostituzione per ragionali radiale a causa di evidenza degenerativa o posttraumatica in presenza di dolore, crepitio articolare e riduzione marcata dimostra all'articolazione radiocarpale alla radiografia preoperatoria nei casi seguenti:
   a. distensione e sublussazione dell'articolazione visibile ai raggi X
   b. mancato miglioramento con il trattamento conservativo
2. Sostituzione primaria in seguito a frattura della capolinea radiale
3. Seguale osteonecrosi in seguito a resezione del capolinea radiale

CONTROINDICAZIONI

1. Unione di fratture delle fratture dell'avambraccio che impediscono la mobilitazione della testa dell'ulna durante la stimolazione elettrica (chiusa)
2. Il tendine, i legamenti o l'articolazione radio-ulnare distale non forniscono il supporto o il fissaggio adeguati per la protesi (ulteriore)
3. Insufficiente supporto o muscolo/scheletrico inadeguati.
4. Problemi in sede di presenza non aperta esposta.
5. Precedente frattura esposta o batterica nel sito o nei pressi dell'articolazione.
6. Sensibilità accertata nei confronti dei materiali utilizzati nel presente dispositivo.

AVVERTENZE (si rimanda al paragrafo Informazioni per la consulenza al paziente)

Carichi e mobilità eccessivi e instabilità articolare costituiscono fattori in grado di accelerare l'usura e l'eventuale guasto del componente attraverso un processo di allentamento, frattura o deformazione. I pazienti devono essere consapevoli del fatto che il grado di passato del dispositivo aumenta in caso di sollecitazioni eccessive delle stesso.

Le protesi sono dei dispositivi meccanici soggetti a usura, affaticamento e rottura. Il gioco di impianto di una protesi è soggetto al rischio di allentamento, dolore, usura e sollecitazione. Le condizioni dell'osso e del tessuto molle adiacenti potrebbero essere inadeguati a sostenere la protesi ottimo stesso nonché a deteriorarsi presumo, con conseguente necessità di un intervento. I benefici operativi della protesi non soddisfano alle aspettative del paziente o peggiore la loro qualità nel tempo, in tal caso si consigliano interventi chirurgici di revisione, atti a sostituire la protesi o ad eseguire delle procedure alternative. Gli interventi chirurgici di revisione di protesi non sono rari.

PRECAUZIONI

1. La protesi è fornita in condizioni sterili se all'esterno di una confezione integra. Evitare di utilizzare all'effetto della protesi nel caso in cui sembrati un danno alla stessa o alla confezione, oppure in caso di superamento della data di scadenza o di dubbi di qualsiasi natura sull'effettiva condizione di sterilità. Non risterilizzare.
2. La protesi viene maneggiata esclusivamente con l'ausilio di strumenti articolati, per evitare di graffiarla e di compromettere la prestazione. La superficie di accoppia e cerniera lucidate non devono entrare in contatto con superfici dure o abrasive.
3. La testa e lo stelo non devono essere impiantati in caso la suscettibilità cellulare idrolitica/ossidativa, anche per residui allentati e presenza.
4. La testa della protesi va inserita nel collo dello stelo. Prima di procedere al montaggio, verificare che le superfici coniche siano asciutte e non contaminate.

REAZIONI AVVERSE

Alcune potenziali reazioni avverse riportate in seguito all'impianto di protesi articolari includono dolore, allentamento, frattura, dislocazione o infezione. Sono stati riscontrati dei casi di pazienti che hanno manifestato delle reazioni di sensibilità al metallo in seguito alla sostituzione dell'articolazione. L'impianto di materiale quali il cobalto cromo e/o il titanio possono dar luogo a reazione da corpo estraneo nella zona circostante dell'impianto. In seguito all'impianto di questo dispositivo è possibile verificare danni a nervi, vasi sanguigni, tendini e tessuti molli ed altri rischi propri che fa già di impianto.

PROCEDURA CHIRURGICA

È disponibile un protocollo di procedura chirurgica per l'impiego di questa protesi. È responsabilità del chirurgo conoscere tale tecnica prima di utilizzare questi dispositivi. All'utilizzo di questi prodotti. Lo stesso chirurgo ha la responsabilità di acquisire conoscenza delle principali pubblicazioni del settore e di consultare con colleghi esperti in relazione alla procedura, prima di eseguire l'impianto.

INFORMAZIONI PER LA CONSULENZA AL PAZIENTE (si rimanda al paragrafo Avvertenze)

A ciascun paziente per il quale si è programmato un intervento di impianto di protesi articolare dovrebbe essere data una documentazione in relazione alle possibili complicazioni e alle alternative, che includono un trattamento senza l'impianto di protesi quali ad esempio la ricostruzione dei tessuti molli o l'artrodesi. Oltre alle informazioni per il paziente riportate ai paragrafi Avvertenze e Reazioni avverse, è indispensabile fornire al paziente le seguenti informazioni: 1) L'eventuale insorgenza di reazioni avverse può rendere necessario un secondo intervento chirurgico, una sostituzione o la rimozione dell'articolazione in questione. 2) La durata dei componenti articolari è difficile da prevedere; ma, in ogni caso è limitata. Questi componenti sono costituiti in materiali non biologici e artificiali all'interno dell'organismo per il particolare scopo della mobilità e per la riduzione del dolore. Per via dei diversi fattori di natura biologica, meccanica e fisicochimica che influenzano questi dispositivi non si può assicurare che i componenti siano resistenti per un tempo illimitato, al livello di attività e alle sollecitazioni alle quali sono sottoposte in normali casi simili.

STERILIZZAZIONE

Questo articolo è privo sterilizzato con ossido di etilene o con radiazioni gamma. La protesi è sterile in condizioni sterili se all'esterno di una confezione integra. Evitare di procedere all'utilizzo della protesi nel caso in cui si riscontri un danno alla stessa o alla confezione, oppure in caso di superamento della data di scadenza o di dubbi di qualsiasi natura sull'effettiva condizione di sterilità. Non risterilizzare. Dei dispositivi di prova sono disponibili per evitare che il vecchio apparto la consegnare eventi rischi dell'effettivo impianto della protesi. Si consiglia di portare la protesi dalla propria confezione sterile soltanto dopo aver predisposto e dimensionato della sua sottostante sterile soltanto dopo aver predisposto e dimensionato adeguatamente il sito di impianto.

GARANZIA LIMITATA

Aurora Orthopaedics, Inc. garantisce che questo prodotto soddisfa le specifiche della casa produttrice e non presenta difetti di produzione al momento della consegna. Questa garanzia esclude specificamente qualsiasi difetto derivante da errore errato, abuso o manipolazione impropria del prodotto avvenuti successivamente all'arrivo della stessa presso il luogo del successivo. Aurora Orthopaedics non garantisce l'esito positivo delle procedure chirurgica.

RAPPRESENTANTE EU

Medical Products International Europe, BV
Schijnweg 13b
5145 NP Waalwijk, Paesi Bassi
+31 (0) 416 560764

AVANTA
ORTHOPAEDICS
9369 Carroll Park Drive, Suite A, San Diego, CA 92121 USA
(858)452-8580 / (858)452-9945 (fax)

PRODUCT INSERT

AVANTA MCP FINGER PROSTHESIS
AVANTA MCP-FINGERPROTHESE
PROTHESE DIGITALE AVANTA MCP
PROTESIS DACTILAR AVANTA MCP
AVANTA MCP-VINGERPROTHESE
PROTESI DEL DITO MCP AVANTA

ENGLISH

HUMANITARIAN DEVICE. The Avanta MCP Finger Prosthesis is authorized by Federal law for use in arthroplasty of the MCP joint when either the:

- patient is in need of a revision of failed MCP prosthesis(es); or
- patient expects to place his/her hands under loading situations, which preclude the use of an alternative implant in the painful osteo-arthritic and post traumatic arthritic MCP joint.

The effectiveness of this device for this use has not been demonstrated.

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
The Avanta MCP Finger Prosthesis consists of a distal component which is made of an ultra-high molecular weight polyethylene (UHMWPe) articulating surface and stem, and a proximal component consisting of a cobalt-chromium-molybdenum articulating surface. The joint prosthesis is intended for use with bone cement. The device is semi-constrained because it limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkage. The two components of the implant articulate on their mating surfaces.

The proximal component is designed for implantation into the distal end of the metacarpal. The distal component is designed for implantation into the proximal end of the proximal phalanx. Both components are intended to articulate on each other allowing for 90 degrees of flexion/extension. The articular surfaces prevent dislocation of the joint through simulation of the natural joint implant articular surface. Both the proximal and distal components are designed to be used with cement.

The implant is available in five sizes. An alpha-numeric coding system is used to distinguish sizes. A full surgical instrument set with appropriately sized trials and broaches is available.

Materials:
- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) distal component
- ASTM F75 cobalt chromium proximal component

INDICATIONS
The Avanta MCP Finger Prosthesis is indicated for use in arthroplasty of the MCP joint when either the:
- patient is in need of a revision of failed MCP prosthesis(es); or
- patient expects to place his/her hands under loading situations which preclude the use of an alternative implant in the painful osteo-arthritic and post traumatic arthritic MCP joint.

CONTRAINDICATIONS
- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Infection.
- Skeletal immaturity.

WARNINGS (See also the Patient Counseling Information Section)
- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure when excessive demands are made upon it.

PRECAUTIONS
- Do not resterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.

ADVERSE EVENTS

REPORTED ADVERSE EVENTS
There has been some clinical experience with this device. In the US, 20 patients have been implanted with the device with a maximum length of follow-up of 24 months. In the US patients, the most commonly reported adverse events were:
- post operative pain
- subluxation
- dislocation

For more details see Table 5. Complication for US Patients in the Clinical Experience Section for reported adverse events associated with the device.

POTENTIAL ADVERSE EFFECTS
General Surgery Related Risks
- bleeding
- infection
- loss of use of the hand
- permanent disability
- death

Joint Replacement Related Risks
- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- dislocation of the joint
- cement extrusion injury
- infection
- lengthening or shortening of the finger
- subluxation
- bone weakening around the implant
- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional surgery may be required for reoperation, revision or fusion of the joint
- surgery may be started but a joint replacement cannot be done resulting in fusion of the joint
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

CLINICAL EXPERIENCE
There has been some clinical experience with the device. In the US, 20 patients have been implanted with the Avanta MCP Finger Prosthesis with a maximum length of follow-up of 24 months.

A prospective randomized clinical study is being performed in the US. Patients are randomized into either the experimental group, which received the Avanta MCP Finger Prosthesis, or into the control group, which received a silicone elastomer implant. Thirty-four patients have been randomized into the study to date. However only 29 of these patients, 20 experimental and 9 control, have had surgery performed to implant either the control device or the Avanta MCP Finger Prosthesis. Table 3 describes the patients randomized into the study, patients implanted with a device and the patient dropouts from the study. Twenty nine of these patients have follow-up data, which is summarized in Tables 4-6. Tables 4-6 describe the patient demographics, reported complications and length of follow-up for this clinical study to date.

Table 3: US Patients MCP

Patient Category	Patients with Avanta MCP (patients)	Patients with Silicone Implant (patients/hands)	Total (patients/hands)
Total Randomized Into Study	20	14/15	34/35
Total Who Have Had Surgery	20	9/10	29/30
Withdrew Prior to Surgery	0	5	5
Withdrew After Surgery	6	2	7
With follow-up Data*	20	9/10	29/30

* Data report forms have been returned on 29 patients.
Tables 4-6 describe the clinical results for these 29 patients.

Table 4. Demographics for 29 US Patients with Follow-up

Category	Patients with Avanta MCP Implant	Patients with Silicone Implant	Total
Male	3	1	4
Female	16	8	24
Unknown	0	1	1
Mean Age, SD	58.3±11.3 (n=19)	51.8±8.1(n=8)	56.2±10.3
Age Range (years)	30-77	32-74	30-77
Osteo-arthritis	1	1	2
Polyarthrosis	0	1	1
Rheumatoid Arthritis	18	7	25
Silicone Implant Revision	1	0	1

*Description of number of patients with more than one implant. There are 29 patients with 90 implants: twenty patients with 4 implants; three patients with 3 implants; three patients with 2 implants; four patients with 1 implant.

Table 5. Complications for US Patients

Complication	Avanta MCP Device (n=8 Patients)	Silicone Device (n=0 Patients)
Skin Necrosis	1	0
Wound Dehiscence	1	0
Implant Failure	1	0
Joint Dislocation	3	0
Joint Subluxation	4	0
pain (6 months post-op*)	4	0

* 4 patients experienced pain at 6 months post op

Table 6. Number of US Patients (Implants) at Each follow-up Time Point

Length of follow-up	Avanta MCP Implant Patients (# implants)	Silicone Implant Patients (# implants)
Post-op (1-4 weeks)	20 (68)	8 (31)
3 months	18 (61)	8 (29)
6 months	18 (53)	8 (21)
12 months	8 (32)	2 (12)
24 months	4 (14)	2 (6)
Post-op withdrawal	5(20)	2 (6)

Linscheid[1] reported on sixty-one fingers in 25 patients treated with this device. Eight implants were implanted in eight patients with traumatic or degenerative arthritis. Fifty-three implants were implanted in 17 patients with rheumatoid arthritis. There were 23 women and 2 men, with an average age of 63 years (range = 45-78 years). The average preoperative MCP arc of motion was 46 degrees, with an extension lag averaging 45 degrees. Preoperatively, there was an average of 30 degrees of ulnar deviation. Swan-neck deformities were common in those patients with rheumatoid arthritis.

The follow-up averaged 30 months (range = 4-60 months). The results in single joints with traumatic or degenerative arthritis were better than in the multiple fingers with rheumatoid arthritis. The average arc of motion was 60 degrees (range 25-90 degrees). Extension lag was improved in the rheumatoid patients. The author stated, "Grip and pinch strength showed little change, but discomfort was noticeably better subjectively." The author only reported "Subluxation or dislocation occurred despite repair of the collateral ligaments and recentering of the extensor tendon." The report did not provide the rate of these adverse events. The author states that the complication was addressed through postoperative splinting, or casting, and careful monitoring of joint reduction through the use of x-ray.

SURGICAL PROCEDURES
A manual is available describing detailed surgical procedures for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the implant procedures before use.

PATIENT COUNSELING INFORMATION (See also Warnings)
A patient brochure is available for use in counseling the patient.

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

While the expected life of total joint replacement components is difficult to estimate it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.
- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION
- This component has been sterilized by ethylene oxide or gamma radiation.
- Do not resterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics Inc., warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE
Medical Products International Europe, BV
Schuweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 651754

DEUTSCH

MEDIZINPRODUKT MIT SONDERZULASSUNG GEMÄSS HUMANITARIAN DEVICE EXEMPTION (HDE). [illegible]

[illegible]

FRANÇAIS

DISPOSITIF HUMANITAIRE. [illegible]

[illegible]

ESPAÑOL

DISPOSITIVO HUMANO

La prótesis digital Avenza MCP está indicada para las lesiones faltantes para su utilización en artroplastias de la articulación metacarpiana proximal de los dedos de la mano heterotópico MCP) quedan:

- el paciente necesita una revisión de una o diversas prótesis MCP fallidas) o
- el paciente prevé excesivas las manos a situaciones de carga que evitarían la utilización de un implante alternativo en la articulación MCP en los casos dolorosos de osteoartritis y artritis postraumática.

La eficacia de este dispositivo para sera limitada no está demostrada.

PRECAUCIÓN

Las leyes federales de EE.UU. limitan la venta, la distribución y la utilización de este dispositivo a médicos o a personas bajo las órdenes de un médico.

DESCRIPCIÓN

La prótesis doctor Avenza MCP consta de un componente distal, compuesto a su vez de un vástago y una superficie articular de polietileno de peso molecular ultraelevado (UHMWPE), y de un componente proximal que se una superficie articular hecha de aleación cobalto-cromo-molibdeno. Este proximal articular ha sido diseñado para tener sitio hueso usando cemento óseo. El dispositivo es semirrestrictivo porque limita la translación y la rotación en uno o más planos debido a la geometría de las superficies articulares que lo componen. No tiene ninguna a través de la simulación. Los dos componentes del implante articulan entre sí a través de sus correspondientes superficies articulares.

El componente proximal ha sido diseñado para ser implantado en el extremo distal de un metacarpiano. El componente distal ha sido diseñado para implantarse en el extremo proximal de la primera falange correspondiente. Ambos componentes han sido diseñados para que articulen exclusivamente permitiendo una flexión / extensión de 80 grados. Las superficies articulares previenen la dislocación de la articulación si durante la configuración anatómica que tienen las superficies articulares naturales. Tanto el componente proximal como el componente distal han sido diseñados para fijarse al hueso con cemento.

El implante se suministra en cinco tamaños diferentes, los cuales se distinguen entre sí mediante un código diferenciador. Se suministra además un set quirúrgico de instrumentos auxiliares que incluye protesis de prueba y extensiones de tamaños escalonados.

Materiales

- Componente distal ASTM F-648 de polietileno de peso molecular ultra alto (UHMWPE)
- Componentes proximal ASTM F-75 de cromo cobalto

INDICACIONES

La Prótesis digital Avenza MCP está indicada para su utilización en artroplastias de la articulación MCP cuando:

- El paciente necesita una revisión de una o diversas prótesis MCP fallidas) o
- El paciente prevé excesivas las manos a las exigencias de carga que evitarían la utilización de un implante alternativo en la articulación MCP en los casos dolorosos de osteoartritis y artritis postraumática.

CONTRAINDICACIONES

- Huéspeo, musculatura, tendones o tejidos blandos adyacentes afectados por una enfermedad, una infección o un implante previo de manera que no pueden proporcionar un soporte o fijación adecuados para la prótesis.
- Infección local activa o sistémica
- Pacientes en desarrollo con epífisis abiertas

ADVERTENCIAS (Véase también el apartado de información para el paciente)

Cargas aplastantes, movilidad excesiva y / o estabilidad articular pueden conducir a un desgaste acelerado y, con el tiempo y fallos causados por soltarse, quebrantos o descarse el dispositivo. Los pacientes deben ser conscientes de la posibilidad a un fallo de un dispositivo aumenta significativamente si se le imponen exigencias excesivas.

PRECAUCIONES

- No volver a esterilizar. El implante se suministra estéril en un envoltorio en perfectas condiciones. Si el implante o el envoltorio se encuentran dañados, se ha sufrido la fecha de caducidad o se cuestione la esterilidad por cualquier motivo, el implante no debería utilizarse.
- La preparación meticulosa del lugar de implantación y la selección del tamaño adecuado del implante aumenta la probabilidad de obtener un resultado satisfactorio.
- El implante únicamente debe activarse de su envoltorio estéril una vez preparado el lugar de implantación o seleccionado el tamaño adecuado.
- Los implantes deben manipularse con instrumentos romos para evitar rayar, cortar o marcar el dispositivo.

REACCIONES ADVERSAS

REACCIONES ADVERSAS COMUNICADAS

Existe una cierta experiencia clínica con este dispositivo. En los EE.UU., 26 pacientes han sido tratados con este implante y sometidos a seguimiento, con una duración mínima de 24 meses. En este grupo de pacientes estudiados/tratados, los efectos adversos observados con mayor frecuencia fueron los siguientes:

- dolor post-operatorio
- subluxación
- disfunción

- Para más detalles sobre reacciones adversas comunicadas asociadas al dispositivo, vease la tabla 5: Complicaciones en los pacientes de EE.UU. del ensayo de Experiencia Clínica.

REACCIONES ADVERSAS POSIBLES

Riesgos relacionados con la cirugía general

- hemorragia
- infección
- pérdida de la funcionalidad de la mano
- incapacidad permanente
- muerte

Riesgos relacionados con la sustitución articular

- dolor
- lesión de los nervios, vasos sanguíneos, tendones o tejidos blandos circundantes (p. ej. entumecimiento)
- rigidez
- dolor moderado o relacionado con el clima
- pérdida de movilidad
- rotura del implante
- rotación del implante
- desgaste excesivo de los componentes del dispositivo
- desarrollo del tejido de interfaces a los huesos
- luxación de la articulación
- lesión por esfuerzo del cemento
- infección
- alargamiento o acortamiento del dedo
- amputación
- dislocación del hueso articulador del implante
- disminución del arco de movimiento
- alergia o otra reacción adversa a los materiales metálicos o de plástico
- puede ser necesaria una nueva intervención quirúrgica para reimplantación, revisión o fusión de la articulación
- parte sustituida que es necesario amputación quirúrgica pero no puede restablecer la sustitución articular, debido como resultado la lesión de la articulación
- Notificación con arreglo a la Ley de California de 1986 sobre seguridad del agua potable y el consumo humano y productos tóxicos ("California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)): este producto contiene un componente químico con capacidad conocida por el Estado de California una posible cáncer y/o defectos congénitos y otros daños de fecundidad en mujeres lactantes.

EXPERIENCIA CLÍNICA

Existe ya cierta experiencia clínica con este dispositivo. En los EE.UU., 26 pacientes han sido tratados con prótesis doctores Avenza MCP y sometidos a seguimiento con una duración mínima de 24 meses.

Se está llevando a cabo un estudio clínico prospectivo randomizado en los EE.UU.. Los pacientes son asignados, en forma aleatoria, al grupo experimental que recibe la prótesis doctor Avenza MCP o a un grupo control, que recibe un implante hecho de elastómero de silicona. Hasta la fecha se ha randomizado de esa manera a treinta y cuatro pacientes en este estudio. Sin embargo, sólo 26 de ellos – varios en el grupo experimental y nueve del grupo control – han sido operados, quedando el dispositivo control o la prótesis doctor Avenza MCP. La Tabla 3 describe a los pacientes randomizados en el estudio, a los que han recibido un dispositivo de sustitución articular y a quienes han abandonado el estudio. Veintinueve de dichos pacientes tienen datos de seguimiento, los cuales se resumen en las Tablas 4 a 8. Las Tablas 4 a 8 muestran los datos demográficos de los pacientes, las complicaciones observadas y la duración del seguimiento obtenida en este estudio clínico hasta la fecha.

Tabla 3. Pacientes con prótesis inicialmente randomizados en los EE.UU.

Categoría de pacientes	Prótesis con implante Avenza MCP (pacientes)	Prótesis con implante de silicona (pacientes/manos)	Total (pacientes/ manos)
Total de pacientes randomizados en el estudio	20	14/16	34/36
Total de pacientes operados	20	8/10	28/30
Retiro antes de la cirugía	0	5	5
Retiro después de la cirugía	5	2	7
Con datos de seguimiento*	20	8/10	28/30

Se ha explicado los tratamientos diversos por 26 pacientes. Las Tablas 4 a 8 muestran los resultados clínicos de esos 28 pacientes.

Tabla 4. Datos demográficos de 26 pacientes de los EE.UU. con seguimiento

Categoría de pacientes	Pacientes con implante Avenza MCP	Pacientes con implante de silicona	Total
Sexo masculino	3	1	4
Sexo femenino	16	6	24
En zurdo	0	1	1
Edad promedio, rango (desviación estándar	53-77 (13,3 (n=19)	51,9-68,1(n=8)	58,2 ±10,5
Osteoartritis	1	1	2
Psiriasis	0	1	1
Artritis reumatoidea	18	7	25
Revisión del implante de silicona	1	0	1

*Descripción del número de pacientes que recibieron más de un implante. Hay 26 pacientes, con un total de 28 implantes: veinte pacientes con 1 implantes; tres pacientes con 2 implantes; tres pacientes con 2 implantes y cuatro pacientes con 1 implante.

Tabla 5. Complicaciones en los pacientes de los EE.UU.

Complicación	Implante Avenza MCP (N Pacientes)	Implante de silicona (N Pacientes)
Neuritis cubital	1	0
Deficiencia de la herida	1	0
Fractura del implante	1	0
Dislocación de la articulación	0	0
Subluxación de la articulación	4	0
Dolor a mayor después de la operación)	4	0

*4 pacientes tenían dolor 6 meses después de la operación

Tabla 6. Número de pacientes de los EE.UU. disponibles en cada fecha del seguimiento

Length of follow-up	Pacientes con implante Avenza MCP (pacientes	Pacientes con implante de silicona (implantes)
Post-op (1-4 semanas)	20 (66)	9 (31)
3 meses	19 (61)	8 (29)
6 meses	16 (53)	6 (21)
12 meses	9 (32)	2 (12)
24 meses	4 (14)	2 (6)
Pesos post-operatorio	20(6)	2 (6)

Linsotheit* ha publicado resultados obtenidos en silencio y un dados, operados en 25 pacientes tratados con esta dispositivo. Se trataba cotro implantes en ocho pacientes con artritis degenerativa o de origen traumático. Se extrajo cinco unos y tres implantes a 17 pacientes con artritis reumatoidea. De esos pacientes, 21 eran mujeres y 2, varones, con una edad promedio de 58 años (rango = 45 a 76 años). El seguimiento de esos pacientes fue de 3 años de promedio (rango de la articulación metacarpofalángica era de 46 grados; dos grados, con un retraso promedio de la extensión de 48 grados. Antes de la operación había una desviación cubital promedio de 20 grados. La deformación en cuello de cisne fue más frecuente antes los pacientes con artritis reumatoidea.

El periodo de seguimiento tuvo una duración promedio de 30 meses (rango de 4 a 60 meses). Los resultados fueron mejores en los articulaciones proximales afectadas de artritis post-traumática o degenerativa, que en caso de implantación en varios dedos con artritis reumatoidea. El alivio promedio de medida) alcanzar fue del 60 grados (rango de 25 a 80 grados). El recorrido de la movilidad o disminución del dolor. Sin embargo, dentro a los numerosos factores biológicos, mecánicos y físico-químicos que afectan a estos dispositivos, no puede asegurarse que los componentes sean capaces de soportar al nivel de actividad y de carga de un hueso sano durante un periodo de tiempo ilimitado.

- Los riesgos asociados de este dispositivo pueden requerir la reintervención, revisión o fusión de la articulación afectada.

ESTERILIZACIÓN

Este componente ha sido esterilizado mediante óxido de etileno o radiación gamma. No volver a esterilizar. El implante se suministra estéril en un envoltorio en perfectas condiciones. Si el implante o el envoltorio se encuentran dañados, se ha superado la fecha de caducidad o se cuestione la esterilidad por cualquier motivo, el implante no debe utilizarse. Existen componentes disponibles para combatir el cemento y evitar así tener que retirar el cemento durante la implantación de la prótesis. El implante sólo debe sustituirse de su envoltorio estéril una vez preparado el lugar de implantación y seleccionado el tamaño adecuado.

GARANTÍA LIMITADA

Avenza Orthopaedics, Inc. garantiza que este producto cumple las especificaciones del fabricante en el momento de la entrega. Esta garantía sustituye de manera exclusiva los defectos resultantes de la utilización inadecuada, abuso o manipulación incorrecta del producto posteriores a la recepción por parte del comprador. Avenza Orthopaedics, Inc. no garantiza el estado del procedimiento quirúrgico.

1. Linscheid R.L., Metacarpophalangeal arthroplasties: prosthetic design considerations. Hand Arthroplasties. Federation of European Societies for Surgery of the Hand, June 2000.

REPRESENTANTE EU

Medical Products International Europe, Schuteweg 13a
5142 NP Waalwijk, The Netherlands:
31 (0) 416 663764

NEDERLANDS

HUMANITAIRE PROTHESE

De Avenza MCP-vingerprothese mag op grond van de federale wetgeving (VS) worden toegepast bij artsassistenten van het MCP-gewricht (of vervangt).

- de te patient een nieuwe revisieoperatie is vervangt een defecte MCP-prothese(n); of
- de patient verwacht dat zijn/haar handen zodanig zullen worden belast dat gebruik van een alternatief implantaat in het carpometacarpale en postraumatische artritisleide MCP-gewricht niet haalbaar is.

De effectiviteit van deze prothese voor dit gebruiksdoel is niet aangetoond.

ORGELET

Krachtens de federale wetgeving (VS) mag de medische hulpmiddel uitsluitend door of op voorschrift van een arts worden verkocht.

BESCHRIJVING

De Avenza MCP-vingerprothese bestaat uit een distale component met een gewricht-oppervlak en een proximale component met gewricht-oppervlak van kobalt, chroom en molybdeen. De gewrichtsoppervlakken zijn voor gebruik met botcement. De proximale en hulpscharnierend ontlast de translatie en rotatie van de prothese in een of meer vlakken wordt begrensd door de configuratie van de gewrichtsoppervlakken. Er is geen 'loss het gewrichts' koppeling. De twee componenten van het implantaat articuleren via corresponderende oppervlakken.

De proximale component dient voor implantatie op het distale uiteinde van de metacarpus. De distale component dient voor implantatie in het proximale uiteinde van de betreffende proximale falanx (phalanx manus). De twee componenten kunnen op elkaar te articuleren en voorzien in een flexie-extensie van 90 graden. De gewrichtsoppervlakken voorkomen dislocatie van het gewricht door het gewrichtsoppervlak van het vervolgens gewricht te simuleren. Zowel de proximale als distale componenten mogen worden gecementeerd.

Het implantaat is verkrijgbaar in vijf maten. De maten worden onderscheiden door een schermerkend toebehorenstelsel. Er is een volledige chirurgische instrumentenset verkrijgbaar met proefprothesen en tussenstukken in een uitgebreide mate.

Materialen

- ASTM F-648 ultrahoog molecuulgewicht polyethyleen (UHMWPE) distaal component
- ASTM F-75 kobalt chroom proximaal component

INDICATIES

De Avenza MCP-vingerprothese is geindiceerd voor gebruik bij artrodesteen van het MCP-gewricht, maar uitsluitend wanneer:

- bij de patiënt een nieuwe revisieoperatie is vereenge een defecte MCP-prothese(n); of
- de patiënt verwacht dat zijn/haar handen zodanig zullen worden belast dat gebruik van een alternatief implantaat in het carpometacarpale en postraumatische artritisleide MCP-gewricht niet haalbaar is.

CONTRA-INDICATIES

- Bot, spier, pees of ligament waar deze ontoereikend ondersteuning of fixatie van de prothese kunnen bieden vanwege eerdere of huidige infectie, ziekte of verwonding veroorzaakt.
- Actieve lokale of systemische infectie
- Patiënten in de groei met open epifysen

WAARSCHUWINGEN

Linscheid* heeft 81 vingers bij 26 patiënten behandeld met deze prothese beschreven. Acht implantaten werden gedurende de eerste 6 maanden verwijderd wegens infectie. Twee implantaten werden gedurende de eerste 6 maanden verwijderd wegens fibreuze ankylose. Er werden 63 implantaten geïnventariseerd bij 17 patiënten met een minimale follow-up van 24 maanden. Het een gemiddelde leeftijd van 53 jaar (spreiding = 45-76 jaar). De gemiddelde MCH-bewegingsboog voorafgaand aan de ingreep was 48 graden. Het een extensiecontractuur van gemiddeld 45 graden. Voor de ingreep was er sprake van een ulnaire deviatie van gemiddeld 20 graden. Zestien (twaalf patiënten) hadden vóór de ingreep reumatoïde artritis.

De follow-upperiode bedroeg gemiddeld 30 maanden (spreiding = 4-60 maanden). De metingen met een vinkpil gemeten bij traumatische of degenerative artritis anders heren dan met vingerprothesen bij reumatoïde artritis. De gemiddelde bewegingsboog bedroeg 80 graden (spreiding 25-80 graden). Er trad verbetering in de functievaardigheid op bij de patiënten reumatoïde artritis. De auteur vaststelde, "Er was weinig verandering in de grip- en knijpkracht, maar het tripsmak was substantief gezien samenvattelijk minder." De auteurs samen stelden "Subluxatie of dislocatie treden een probleem op bij de patiënten reumatoïde artritis. De auteurs vermelden, "Er was een verschil in de ligamenten en het aanwezig zwakken van de extensorpees." Het rapport gaf geen indicatie voor het percentage van deze complicaties. De auteur verklaarde de deze complicaties van gemiddeld met postoperatieve spalken of gipsverband en door zorgvuldig gewrichtsbeschermende oefeningen.

CHIRURGISCHE PROCEDURES

Een chirurgische procedure voor het gebruik van dit implantaat is beschikbaar. Het is de verantwoordelijkheid van de chirurg om de te hoogte te zijn van de procedure voordat hij deze procedure gebruikt. Het is ook zijn verantwoordelijkheid om de hoogte te zijn van relevante publicaties en ervaren collega's te raadplegen over de procedure en de voordels en risks daarvan.

PATIËNTINFORMATIE (Zie ook Waarschuwingen)

Er is een patiëntenvoorlichtingsbrochure beschikbaar voor gebruik bij het counselen van de patiënt. Neem de informatie de beschrijving heeft op de patiënt zoals deze is opgenomen onder Waarschuwingen en Bijwerkingen moet de volgende informatie aan de patiënt worden meegedeeld: 1) Bijwerkingen kunnen herhaalbaar, revisie of falen van het bereiken gewricht noodzakelijk maken. 2) De verwachte levensduur van prothesebewegingsgewrichten is niet bekend. Het is mogelijk de vuilheden, meer te vinding. Deze componenten zijn verkrijgbaar van Schoenmaermetal materialen die in het Schoenmaker geplaatst voor potentieel herstel van mobiliteit of voor preventie pijnverdichting. Deze zijn biologische, mechanische en fysicochemische factoren die deze implantaten beïnvloeden, kan echter niet verwacht worden dat deze componenten voor onbepaalde dat bestand zijn tegen het activiteitsniveau en de belastingen van normaal gezond lot.

STERILISATIE

Deze componenten is gesterliseerd met ethyleenoxide of gammastralen. Het implantaat wordt steriel geleverd in een antiseptische verpakking. Als het implantaat of de verpakking beschadigd blijkt te zijn, als de uiterste gebruiksdatum is overschreden of als om de een of andere reden twijfel bestaat over de sterilisatie, mag het implantaat niet gebruikt worden. Het opnieuw sterilliseren.

Het componenten zijn verkrijgbaar om te voorkomen dat de steriele verpakking voor het implanteren van een prothese gescheurd raakt worden. Het implantaat mag de pas mag pas uit de steriele verpakking gehaald worden vlakbij de plaats van het implantaat is voorbereid en de juiste maat heeft.

BEPERKTE GARANTIE

Avenza Orthopaedics, Inc. garandeert dat dit product voldoet aan de specificaties van de fabrikant en ten tijde van de levering vrij is van fabricagedefecten. Deze garantie sluit uitdrukkelijk gebreken uit die het gevolg zijn van verkeerd gebruik, misbruik of onjuiste behandeling van het product na ontvangst door de koper. Avenza Orthopaedics, Inc. garandeert geen geschikt ook het resultaat van de chirurgische ingreep.

1. Linscheid R.L., Metacarpophalangeal arthroplasties: prosthetic design considerations. Hand Arthroplasties. Federation of European Societies for Surgery of the Hand, June 2000.

EU AFGEVAARDIGDE

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5145 NP Waalwijk, The Netherlands
31 (0) 416 663764

ITALIANO

DISPOSITIVO UMANITARIO

La Protesi del Dito MCP Avenza è autorizzata dalla legge federale vigente negli Stati Uniti per l'impiego in articolazioni dell'articolazione MCP qualora si verifichi uno dei seguenti casi:

- il paziente necessita di una revisione dallora protesi MCP malfunzionante(i) oppure
- il paziente prevede di utilizzare le mani in situazioni di stress, che precludono l'impiego di un impianto alternativo nell'articolazione MCP dolorose osteo-artritiche e artritica post-traumatica.

L'efficacia del dispositivo per questo tipo d'impiego non è stata dimostrata.

ATTENZIONE

La legge federale (Stati Uniti) limita la vendita, la distribuzione e l'uso di questo dispositivo a od ordine o previa prescrizione degli stessi.

DESCRIZIONE

La Protesi del Dito MCP Avenza è costituita da una componente distale formata da stelo e superficie articolare in polietilene a peso molecolare ultra-alto (UHMWPE), e da una componente prossimale formata da una superficie articolare in cobalto-cromo-molibdeno. La protesi distale articolazione è destinata ad essere utilizzata con cemento osseo. Il dispositivo è semi-vincolativo in quanto limita la traslazione e la rotazione lungo uno o più piani per effetto della forma geometrica delle proprie superfici d'articolazione, non è dotato di nessun legame strutturale. I due componenti del impianto si articolano sulle rispettive superfici d'accoppiamento.

La componente prossimale è progettata per essere impiantata sull'estremità distale della falange metacarpale. La componente distale è progettata per essere impiantata sull'estremità prossimale della falange prossimale. Entrambe le componenti devono articolarsi l'una sull'altra consentendo una flesso-estensione di 90 gradi. Le superfici articolari previengono la lussazione dell'articolazione simulando la superficie articolare dell'impianto dell'articolazione naturale. Sia la componente distale che quella prossimale sono progettate per essere utilizzate con cemento.

L'impianto è disponibile in cinque misure, ciascuna delle quali differenziata mediante un sistema alfa-numerico. E' disponibile un set chirurgico con gli appositi strumenti nelle opportune misure.

Materiali

- Cromo-cobalto
- UHMWPE

INDICAZIONI

La Protesi del Dito MCP Avenza è indicata nell'artroplastica dell'articolazione MCP qualora si verifichi una dei seguenti casi:

- il paziente necessita di una revisione dallora protesi MCP malfunzionante(i) oppure
- il paziente prevede di utilizzare le mani in situazioni di stress, che precludono l'impiego di un impianto alternativo nell'artroplastica MCP dolorose osteo-artritiche e artritica post-traumatica.

CONTROINDICAZIONI

- Ossi, muscolatura, tendini o tessuti molli adiacenti compromessi da malattie, infezioni o lesioni tali da non consentire impianto che non forniscano il supporto o il fissaggio adeguato per la protesi.
- Infezione attiva locali o sistemiche
- Pazienti in sviluppo con epifisi aperta.

AVVERTENZE (si rimanda al paragrafo relativo alle informazioni per la Consulenza al Paziente)

I carichi schiacciami, una mobilità eccessiva e l'instabilità articolare costituiscono fattori in grado di accelerare l'usura e l'eventuale danno del dispositivo attraverso un processo di logoramento. Inoltre o dislocazione, i pazienti devono essere avvertiti del fatto che il rischio di danni o dispositivo aumenta in caso di collegio sono mediante dello stesso.

PRECAUZIONI

La protesi viene fornita in condizioni sterili, all'interno di una confezione integra. Evitare di procedere all'utilizzo della protesi nel caso in cui si constati un danno alla stessa o alla confezione, acquisti in caso di superamento della data di scadenza o di dubbi di qualsiasi natura sull'integrità e condizione di sterilità. Non riutilizzare la stessa persona. Dopo la rimozione dall'involucro sterile e prima dell'inserimento di impianto, la protesi di una esame consentono in una soluzione sulfato sterile.

La protesi andrà maneggiata esclusivamente con l'ausilio di strumenti smussati, per evitare di graffiarla. Una preparazione accurata del sito di impianto ed una corretta scelta delle dimensioni della protesi aumentano la probabilità di successo dell'intervento. Una volta rimossa dalla confezione sterile, la protesi deve essere impiantata entro 24 ore dalla rimozione dell'osso, di eccezione di esimere la protesi dalle giuste dimensioni delle ossa preparate. Non riutilizzare gli stessi dispositivi dopo aver precedentemente impiantato e successivamente rimossi.

Per maggiori particolari sugli argomenti di rimando alla Tabella 5: Complicazioni per i Pazienti osteotomizzati nella Sezione di Sperimentazione Clinica relative agli effetti indesiderati associati al dispositivo.

EFFETTI INDESIDERATI POTENZIALI

Rischi chirurgici generici

- emorragia
- infezione
- perdita della funzionalità della mano
- disabilità permanente
- morte

Rischi correlati alla sostituzione dell'articolazione

- dolore
- lesione dei nervi circostanti, dei vasi sanguigni, dei tendini o dei tessuti molli (per es., torpidità)
- rigidità
- dolore moderato o dolore correlato al tempo
- perdita di movimento
- rottura dell'impianto
- rotazione dell'impianto
- usura eccessiva dei componenti del dispositivo
- crescita dell'osso nelle interfacce dell'osso
- lussazione dell'articolazione
- lesione per sollecitazione del cemento
- infezione
- allungamento o accorciamento del dito
- amputazione
- dislocazione osseo articolare dell'impianto
- riduzione del range di movimento
- reazioni allergiche o di altro tipo a plastica o metallo
- può rendersi necessario un successivo intervento chirurgico per un secondo intervento, revisione o fusione dell'articolazione
- la parte sostituita che è necessario l'amputazione chirurgica ma non è possibile ripristinare la sostituzione articolare, dando come risultato la lesione della articolazione
- Notificazione con arreglo a la Ley de California de 1986 sobre seguridad del agua potable y el consumo humano y productos tóxicos ("California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)): este producto contiene un componente químico con capacidad conocida por el Estado de California una posible cáncer y/o defectos congénitos y otros daños de fecundidad en mujeres lactantes.

ESPERIENZA CLINICA

Questo dispositivo è stato oggetto di sperimentazione clinica. Negli Stati Uniti, a 26 pazienti è stata impiantata la Protesi del Dito MCP Avenza con follow-up di durata minima di 24 mesi.

Negli Stati Uniti è in corso uno studio prospettico randomizzato. I pazienti sono stati selezionati in modo casuale nel gruppo sperimentale a cui è stata impiantata la Protesi del Dito MCP Avenza, o nel gruppo di controllo, a cui è stato assicurato un impianto elastomerico di silicone. A tutt'oggi nello studio sono stati randomizzati tentaquattro pazienti, di cui ventuno soltanto 26 (26) del gruppo sperimentale e 9 del gruppo di controllo sono stati sottoposti a intervento chirurgico per l'impianto del dispositivo di controllo o della Protesi del Dito MCP Avenza. Nella Tabella 3 sono descritti i pazienti randomizzati nello studio, i pazienti a cui è stato impiantato un dispositivo e i pazienti che hanno abbandonato lo studio. Per ventinove di questi pazienti sono disponibili i dati relativi al follow-up, valutati nelle Tabelle 4-8. Nelle suddette tabelle sono riportati i dati demografici dei pazienti, le complicanze osservate e la durata del follow-up relativi a questo studio clinico.

Tabella 3. Pazienti sottoposti a MCP

Categoria di pazienti	Pazienti con impianto MCP Avenza (pazienti)	Pazienti con impianto in silicone (pazienti / mani)	Totale (pazienti / mani)
Numero totale di pazienti randomizzati nello studio	20	14/16	34/36
Numero totale di pazienti sottoposti a trattamento chirurgico	20	8/10	28/30
Ritirati prima del trattamento chirurgico	0	5	5
Ritirati dopo il trattamento chirurgico	5	2	7
Con dati relativi al follow-up*	20	8/10	28/30

* Sono stati esaminati i seminari clinici relativi a 26 pazienti. Nella tabella sono riportati i risultati clinici relativi a questi pazienti.

Tabella 4. Dati demografici dei 26 pazienti sottoposti a follow-up

Categoria di pazienti	Pazienti con impianto MCP Avenza (pazienti)	Pazienti con impianto in silicone (pazienti / mani)	Totale
Maschi	3	1	4
Femmine	16	6	24
Sconosciuti	0	1	1
Età media, SD	56,8±11,3 (n=19)	51,9-68,1(n=8)	58,2 ±10,5
Range d'età (anni)	53-77	52-74	53-77
Osteoartrite	1	1	2
Psoriasi	0	1	1
Artrite reumatoide	18	7	25
Revisione dell'impianto in silicone	1	0	1

*Descrizione del numero di pazienti aventi d'un un impianto. Vi sono 26 pazienti con un impianto, aventi pazienti più 4 impianti; tre pazienti con 3 impianti; tre pazienti con 2 impianti; quattro pazienti con 1 impianto.

Tabella 5. Complicanze per i pazienti sottoposti a follow-up

Complicanze	Impianto MCP Avenza (impianto pazienti)	Impianto silicone (Pazienti)
Neuriti cubitale	1	0
Deficienza della ferita	1	0
Frattura del impianto	1	0
Lussazione dell'articolazione	0	0
Subluxazione dell'articolazione	4	0
Dolore (o mayor dopo l'intervento)	4	0

* 4 pazienti hanno lamentato dolori 6 mesi dopo l'intervento chirurgico

Tabella 6. Numero di pazienti sottoposti (impianti) per ogni scadenza di follow-up

Durata del follow-up	Pazienti con impianto MCP Avenza (impianto)	Pazienti con impianto in silicone (impianti)
Postoperatorio (1-4 settimane)	20 (66)	9 (31)
3 mesi	19 (61)	8 (29)
6 mesi	16 (53)	6 (21)
12 mesi	9 (32)	2 (12)
24 mesi	4 (14)	2 (6)
Retro postoperatorio	20(6)	2 (6)

Linscheid* ha riferito i dati relativi a sessantuno dita in 26 pazienti trattati con questo dispositivo. Otto impianti sono stati applicati a otto pazienti affetti da artrite degenerativa o traumatica. Cinquanta tre impianti sono stati applicati a 17 pazienti con artrite reumatoide. I casi si riferiscono a 53 dita in 17 pazienti, con un età media di 55 anni (range = 45-76 anni). L'arco di movimento medio MCP precedentemente era di 48 gradi, con un ritardo medio di estensione pari a 48 gradi. In tale precedenza di 17 vista una media di 20 gradi di deviazione ulnare. Nei pazienti affetti da artrite reumatoide sono risultate comuni la deformazione a collo di cigno.

Il follow-up hanno avuto una media di 30 mesi (range = 4-60 mesi). I risultati relativi alla gamma arrotolatore con artrite traumatica o degenerativa sono stati migliori rispetto a quelli registrati per più dita con artrite reumatoidea. L'arco medio di movimento era di 56 gradi (range 20-80 gradi). Nel paziente reumatoide è migliorata la forma di estensione. Nonostre la perdita dell'estensione. "La forza di presa e pinzamento non è migliorata per alcuni pazienti. Si sono sviluppate deformità e instabilità". L'autore ha osservato soltanto che "la sublussazione o la lussazione si sono verificate maggiori la recurrence dei segmenti collaterali e il ricentreggio dei tendini estensores." Non vene riferito la frequenza di queste complicanze. L'autore attribuisce alcune di queste complicanze a stata attribuita applicando una stecca di contenzione postoperatoria, ovvero mediante la stabilizzazione di tentaggio presso, a mantenendo attentamente la indicazioni adottando tramite radiografia.

PROCEDURA CHIRURGICA

E' disponibile un procedura di procedura chirurgica per l'impiego di questa protesi. E' responsabilità del chirurgo acquisire familiarità con tale procedura prima di procedere all'utilizzo di questi pazienti. Le stessi chirurgo ha la responsabilità di acquisire conoscenza delle principali pubblicazioni del settore e di consultare con colleghi esperti in relazione alla procedura, prima di eseguire l'impianto.

INFORMAZIONI PER LA CONSULENZA AL PAZIENTE (si rimanda alle Avvertenze)

E' disponibile una brochure che riporta importanti consigli per il paziente. Oltre alle informazioni per il paziente riportate al paragrafo "Avvertenze" e "Eventi negativi", è indispensabile fornire a paziente le seguenti informazioni: 1) il eventuale frequenza di eventi negativi (ed) vendere necessitano di revisione, fusione o rimozione del dispositivo a causa della frattura dell'articolazione in questione; 2) la durata del componenti sostitutivi dell'articolazione è difficile da prevedere ma, in ogni caso, sono un numero. Queste componenti sono realizzati in materiali che potrebbero causare reazioni allergiche. L'organismo può il potenziale rigetto della medicina o per la reazione del corpo. Determinate, per via dei diversi tipi di reazioni biologica meccanica e fisico-chimica che influenzano questi dispositivi, non è possibile garantire che i componenti siano resistenti, per un tempo illimitato, al livello di attività e alle sollecitazioni da parte di quali siano sottoposte in normali casi sano.

STERILIZZAZIONE

Questo articolo è stato sterilizzato con ossido di etilene o con irradiazione gamma. La protesi è fornita in condizioni sterili all'interno di una confezione integra. Evitare di procedere all'utilizzo della protesi nel caso in cui si constati un danno alla stessa o alla confezione, acquisti in caso di superamento della data di scadenza o di dubbi di qualsiasi natura sull'integrità e condizione di sterilità. Non riportare la sterilizzazione. Dal disponibili di prova sono disponibili per evitare una e si debba aprire la contenzione sterile prima del momento dell'impianto della protesi. Le protesi va estratta dalla sua contenzione sterile soltanto dopo aver precisamente e immediatamente adeguatamente il sito di impianto.

GARANZIA LIMITATA

Avenza Orthopaedics, Inc. garantisce che questo prodotto soddisfa le specifiche della casa produttrice e non presenta difetti di produzione al momento della consegna. Questa garanzia esclude esplicitamente qualsiasi difetto derivante da utilizzo errato, abuso o maneggiamento improprio del prodotto successivi alla ricezione da parte dell'acquirente. Avenza Orthopaedics, Inc. non garantisce l'esito positivo della procedura chirurgica.

1. Linscheid R.L., Metacarpophalangeal arthroplasties: prosthetic design considerations. Hand Arthroplasties. Federation of European Societies for Surgery of the Hand, giugno 2000.

RAPPRESENTANTE EU

Medical Products International Europe, Schuteweg 13a.
5145 NP Waalwijk, The Netherlands
31 (0) 416 663764

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- Implante radial fijo
- Impianto Testina Ulnare Fissa
- Impianto Testina Radiale Fissa

ENGLISH

CAUTION
United States Federal Law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
The hand joint prosthesis consists of a cobalt chromium stem and articular surface. The implant is designed to be inserted into the shaft of the prepared bone. The cobalt chromium surface articulates on opposing bone. The implant is available in several sizes, each of which can be used in right or left hands. A range of implant sizes for each type of implant is available to aid in bone preparation.

Materials:
- ASTM F-1537-94 cobalt chromium component
- Commercially Pure Titanium (CPT)

INDICATIONS
Ulnar/ Ulnar Implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty.
Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting the following:
1. Pain and weakness of the wrist joint not improved by conservative treatment
2. Instability of the ulnar head with x-ray evidence of distal subluxation and erosive changes
3. Failed ulnar head resection

Head Radial Implant is intended for replacement of the proximal end of the radius:
1. Replacement of the radial head for ungunestative, or post-traumatic disabilities presenting pain, crepitation and decreased motion of the radiocarpal and or proximal radio-ulnar joint with:
   a. Joint destruction or subluxation visible on x-ray
   b. Resistance to conservative treatment
2. Primary replacement after fracture of the radial head
3. Symptomatic sequelae after radial head resection

CONTRAINDICATIONS
1. Inadequate tendons tissues that preclude stabilization of the ulnar head during pronation/supination (Ulnar)
2. Tension, ligament, or distal radioulnar joint which cannot provide adequate support or fixation for the prosthesis (Ulnar)
3. Inadequate skin or musculoskeletal system
4. Growing patients with open epiphyses
5. Previous open fracture or infection in or around the joint
6. Known sensitivity to materials used in this device

WARNINGS (See also the Patient Counseling Information Section)
Strenuous loading, excessive mobility, and articular malleability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.

Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
Implants are mechanical devices that can be worn away, fatigued or broken. An implant site may become infected, painful, swollen, or inflamed. The status of the adjacent bone and soft tissue may be inadequate to support the implant, or may deteriorate in time resulting in instability, deformity, or both. The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

PRECAUTIONS
1. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, sterilization data has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize.
2. Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance. Polished bearing and taper surfaces must not come in contact with hard or abrasive surfaces.
3. The head and stem should not be implanted if the tapers are possibly damaged. The modulars separated scratching and debedding.
4. The head of the prosthesis is impacted on to the neck of the stem. Prior to assembly confirm that the tapers are dry and free from contaminant.

ADVERSE EVENTS
Potential adverse events reported with joint prosthesis include pain, loosening, fracture, dislocation, or infection. There have been some reports of patients with metal sensitivity reactions following joint replacement. Implantation of materials such as cobalt chrome and/or titanium may result in foreign body reaction adjacent to the implant site, injury to the surrounding nerves, blood vessels, tendons, or soft tissue can occur as a consequence of implanting this device.

SURGICAL PROCEDURES
A surgical procedure for use of this implant device is available. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure's potent use.

PATIENT COUNSELING INFORMATION (See also Warnings)
Providing each patient scheduled for implant surgery with documented counseling of potential complications and alternatives, which may include non-implant procedures such as soft tissue reconstruction or arthrodesis, prior to surgery is necessary. In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be communicated to the patient: 1) Adverse effects may necessitate revision, revision, or fusion of the implant joint. 2) While the expected life of joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an indefinite period of time.

STERILIZATION
This component has been sterilized by ethylene oxide or gamma radiation. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, sterilization date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize. Trial sizer components are available to avoid having to open the sterile package prior to proximal implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics, Inc. warrants that this product meets the manufacture's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE
Medical Products International Europe, BV
Schuttweg 10e
5145 NP Waalwijk, The Netherlands
31 (0) 416 665764

DEUTSCH

BESCHREIBUNG
Dieses Handgelenksprothese besteht aus einem Cobalt-Chrom-Schaft mit Gelenkfläche. Das Implantat ist zum Einsetzen in den Schaft des präparierten Knochens bestimmt. Die Cobalt-Chrom-Fläche artikuliert mit dem Gegenknochen. Das Implantat ist in mehreren Größen erhältlich, die jeweils für die linke oder die rechte Hand verwendet werden können. Ein Reihe von Probeschaftsizern für jeden Implantattyp ist zur Erleichterung der Knochenvorbereitung erhältlich.

Werkstoffe:
- Cobalt-Chrom-Komponente
- Handelsübliches Reintitan (CPT)

INDIKATIONEN
Das Ulnar/ Ulna-Implant ist vorgesehen für den Ersatz des distalen Radioulnargelenks nach Resektionsarthroplastik des Ulnakopfchens. Ersatz des distalen Ulnakopfchens bei rheumatoidem, degenerativer oder posttraumatischer Arthritis mit:
1. Schmerzen und Schwäche des Handgelenks, die sich durch konservative Behandlung nicht bessern
2. Instabilität des Ulnakopfchens mit radiologischen Zeichen einer dorsalen Subluxation und erosiver Veränderungen
3. Erfolgloser Resektion des Ulnakopfchens

Das Head Radius-Implantat ist vorgesehen für den Ersatz des proximalen Radiusendes:
1. Ersatz des Radiuskopfchens bei degenerativen oder posttraumatischen Behinderungen mit Schmerzen, Crepitatio und Bewegungseinschränkung im Handgelenk- und/oder proximalen Radioulnargelenk mit:
   a. im Röntgenbild sichtbarer Gelenkzerstörung oder Subluxation
   b. Resistenz gegenüber konservativer Behandlung
2. Primärersatz nach Fraktur des Radiuskopfchens
3. Symptomatische Folgeerscheinungen nach Radiuskopfchenresektion

GEGENANZEIGEN
1. Im Falle fehlende verfügte Unterarmstrukturen, die eine Stabilisation des Ulnakopfchens bei Pronation/Supination (Ulnar) ausschließen
2. Sehnen, Band oder distales Radioulnargelenk, bietet keinen ausreichenden Halt oder Fixierung für die Prothese (Ulnar)
3. Insuffiziente Haut- oder Muskulaturverhältnisse
4. Bei im Wachstum begriffenen Patienten mit offenen Epiphysen
5. Frühere offene Fraktur oder Infektion im Gelenk oder im Umfeld des Gelenks
6. Bekannte Überempfindlichkeit gegenüber den implantierten Materialien

WARNUNGEN (Siehe auch den Abschnitt Patientenhinweise)
Extreme Belastungen, zu große Mobilität und artikulärer Instabilität können zu schädlichen Verschleiss und eventuellen Versagen der Prothese durch Lockern, Brechen oder Verrutschen führen. Der Patient sollte über die erhöhte Rate eines Versagens der Prothese bei Überbeanspruchung aufgeklärt werden.
Prothesen sind mechanische Hilfsmittel, die verschleissen oder brechen können. Eine Implantationsstelle kann sich infizieren, schmerzen, anschwellen oder sich entzünden. Die Qualität des Knochens und des Weichgewebes kann unzureichend sein, um die Prothese aufzunehmen, oder sie kann sich mit der Zeit verschlechtern und zu Instabilität und Deformierung oder beidem führen. Die Vorteile einer Prothese können eventuell den Erwartungen des Patienten nicht entsprechen oder mit der Zeit abnehmen. Eine weitere Operation kann notwendig werden, um die Prothese zu ersetzen oder alternative Verfahren anzuwenden. Zwischenfälle bei Zusammenfügung mit Prothesen sind nicht ausgeschlossen.

ACHTUNG
Die Prothese wird steril in einer unbeschädigten Verpackung geliefert. Sollte entweder die Prothese oder die Verpackung beschädigt sein, sollte die Prothese nicht verwendet werden. Nicht erneut sterilisieren. Die Implantate sollten mit stumpfen Instrumenten gehandhabt werden, damit keine Kratzer, Einschnitte oder Kerben entstehen, die die Leistungsfähigkeit des Implantats beeinträchtigen. Die polierten Gelenk- und Konusoberflächen dürfen nicht mit harter oder abrasiven Oberflächen in Kontakt kommen.
Der Kopf und der Schaft sollten nicht implantiert werden, wenn die Konusse möglicherweise beschädigt sind; dies ist auch bei wiederholtem Anbringen und Zerlegen der Fall.
Der Kopf der Prothese wird auf den Hals des Schafts geschlagen. Vor dem Zusammensetzen ist darauf zu achten, dass die Konusse trocken und sauber sind.
Eine gründliche Vorbereitung der Implantationsstelle und die Wahl der richtigen Prothesengröße erhöhen die Chance eines erfolgreichen Eingriffs. Zur Erleichterung der Knochenvorbereitung ist eine große Auswahl von Musterprothesen erhältlich. Die Prothese ist nur bestimmt Größe und nur der sterilen Packung nehmen, wenn die Implantationsstelle sachgemäß vorbereitet wurde.

KOMPLIKATIONEN
Gelegentlich mögliche Komplikationen mit Gelenkersatzprothesen sind Schmerzen, Lockerung, Fraktur, Verrutschen oder Infektionen. Bei einigen Patienten traten Überempfindlichkeitsreaktionen gegen Metall nach dem Gelenkersatz auf. Die Implantation von Materialien wie Co-Cr-Mo und/oder Titan können zu Abstoßungsreaktionen gegen Fremdkörper im Umfeld der Implantatstelle führen. Darüber hinaus können Verletzungen der umgebenden Nerven, Blutgefäße, Bänder oder der Weichteile auftreten.

OPERATIONSVERFAHREN
Eine Operationsanweisung zur Verwendung dieser Prothese ist erhältlich. Der Chirurg hat sich vor der Verwendung dieser Produkte mit den Operationsverfahren vertraut zu machen. Darüber hinaus liegt es in der Verantwortung des Chirurgen, vor Verwendung dieser Produkte die relevanten Publikationen zur Kenntnis zu nehmen und sich mit in dieser Angelegenheit erfahrenen Kollegen auszutauschen.

PATIENTEN INFORMATIONEN (Siehe auch Warnung)
Jeder Patient, bei dem eine Implantation geplant ist, sollte vor der Operation fundiert über mögliche Komplikationen und Alternativen aufgeklärt werden, zu denen auch Verfahren ohne Implantat gehören, wie eine Rekonstruktion der Weichteile oder Gelenkversteifung. Zusätzlich zu den patientenbezogenen Informationen in den Abschnitten Warnung und Komplikationen sollte der Patient über Folgendes informiert werden: 1) Komplikationen können eine neue Operation, eine neue Implantatlösung oder Fusion des betroffenen Gelenks erfordern. 2) Die Lebensdauer der Gelenkersatz-Komponenten ist begrenzt. Ihre Lebensdauer lässt sich nur schwer voraussagen. Die Komponenten sind aus körperfremden Materialien hergestellt, die in den Körper eingebracht werden, um möglichst die Mobilität wiederherzustellen und Schmerzen zu verringern. Aufgrund zahlreicher biologischer, mechanischer und physiologischer Faktoren, die diese Komponenten beeinflussen, können die Komponenten der Aktivitätsstufe und die Belastung eines normalen gesunden Knochens nicht über einen unbegrenzten Zeitraum aushalten.

STERILISATION
Dieses Produkt wurde mit Ethylenoxid oder mittels von Gammastrahlen sterilisiert. Es wird steril in einer unbeschädigten Verpackung geliefert. Sollte entweder die Prothese oder die Verpackung beschädigt sein, die Verfallsdaten überschritten oder die Sterilität aus irgendeinem Grunde zweifelhaft sein, sollte die Prothese nicht verwendet werden.
Nicht erneut sterilisieren.
Um die sterile Verpackung nicht nur wegen der Feststellung der richtigen Größe der Prothese vor der Implantation öffnen zu müssen, stehen Größenmuster zur Verfügung. Die Prothese erst aus der sterilen Verpackung entfernen, nachdem die Implantatstelle ausreichend vorbereitet und die richtige Größe der Prothese ermittelt wurde.

BESCHRÄNKTE GARANTIE
Avanta Orthopaedics, Inc. garantiert, dass dieses Produkt den Spezifikationen des Herstellers entspricht und zum Zeitpunkt der Lieferung keine Herstellungsfehler aufweist. Diese Garantie bezieht sich nicht auf Schäden, die auf unsachgemäße Behandlung, Missbrauch oder falsche Verwendung des Produkts durch den Benutzer zurückzuführen sind. Avanta Orthopaedics gewährleistet nicht den Erfolg des chirurgischen Eingriffs.

EU REPRÄSENTANT
Medical Products International Europe, BV
Schuttweg 10e
5145 NP Waalwijk, The Netherlands
31 (0) 416 665764

FRANÇAIS

DESCRIPTION
Cette prothèse métacarpienne est constituée d'une tige et d'une surface articulaire en alliage chrome cobalt. L'implant est conçu pour être inséré dans le diaphyse de l'os préparé. La surface en alliage chrome cobalt s'articule avec l'os opposé. L'implant est disponible en plusieurs tailles, chacune d'entre elles pouvant être utilisée du côté droit ou du côté gauche. Un jeu de dispositifs d'essai pour détermination de la taille est disponible pour chaque type d'implant afin de faciliter la préparation de l'os.

Matériaux :
- Composant en alliage chrome cobalt
- Titane pur de qualité commerciale (CPT)

INDICATIONS
L'implant ulnaire/ ulnaire est destiné au remplacement de l'articulation radio-cubitale distale après arthroplastie avec résection de la tête du cubitus. Remplacement de la tête ulnaire distale pour cause d'arthrite rhumatoïde, dégénérative ou post-traumatique présentant les caractéristiques suivantes :
1. Douleur et faiblesse de l'articulation du poignet non améliorés par un traitement conservateur
2. Instabilité de la tête du cubitus avec évidence radiographique de subluxation distale et altérations érosives
3. Échec d'une résection de la tête du cubitus

L'implant radial/ tête est destiné au remplacement de l'extrémité proximale du radius :
1. Remplacement de la tête du radius suite à une invalidité dégénérative ou post-traumatique s'accompagnant de douleur, de crépitation et de perte de mobilité au niveau de l'articulation radio-carpienne et/ou radio-ulnaire proximale avec :
   a. Destruction articulaire ou subluxation visible à la radiographie
   b. Résistance à un traitement conservateur
2. Remplacement primaire après fracture de la tête du radius
3. Séquelles symptomatiques après résection de la tête du radius

CONTRE-INDICATIONS
1. Présence de l'avant-bras mal consolidées empêchant la stabilisation de la tête du cubitus lors des mouvements de pronation/supination (Ulnaire)
2. Tendon, ligament ou articulation radio-ulnaire distale inappropriées d'offrir un support ou une fixation adéquate à la prothèse (ulnaire)
3. Système cutané ou musculo-squelettique inapproprié
4. Jeunes patients en cours de croissance présentant des épiphyses ouvertes
5. Antécédents de fracture ouverte ou d'infection au niveau ou à proximité de l'articulation
6. Sensibilité connue aux matériaux utilisés dans le prothèse

MISES EN GARDE (Voir aussi la partie relative à l'information et conseils destinés au patient)
Contraintes importantes, mobilité excessive et instabilité articulaire peuvent toutes entraîner l'usure et aboutir à une avancement défaillance par décollement, fracture ou dislocation de l'appareil. Les patients doivent être conscients du risque potentiel de la défaillance de l'appareil si on tentait subit des contraintes excessives. Les implants sont des appareils mécaniques qui peuvent s'user, se fatiguer ou se casser. Un site de l'implant peut s'infecter, devenir douloureux, se tuméfier ou s'enflammer. L'état de l'os adjacent et du tissu mou peuvent être inappropriés pour soutenir l'implant ou peuvent se détériorer avec le temps et aboutir à une instabilité, à une déformité ou aux deux. Les avantages de l'implantation orthopédique peuvent ne pas répondre aux attentes du patient ou peuvent s'altérer avec le temps et nécessiter seuil une chirurgie réparatrice pour remplacer l'implant ou imposer le mise en oeuvre de procédures alternatives. Les interventions chirurgicales correctrices à l'aide d'implants ne sont pas exceptionnelles.

PRÉCAUTIONS
L'implant est fourni stérile dans un emballage intact. Si l'implant ou son emballage apparaît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en doute pour une raison quelconque, il faut prossrire l'emploi de cet implant. Ne pas re-stériliser.
Les implants doivent être manipulés avec des instruments à pointe mousse pour éviter de les griffer, de les couper ou de les ébrécher, ce qui risquerait d'avoir un impact défavorable sur les performances de l'implant. Les surfaces de support et les connecteurs pyramidaux polis ne peuvent pas entrer en contact avec des surfaces dures ou abrasives. Ne pas implanter la tête et la tige si les connecteurs pyramidaux sont susceptibles d'être endommagés ; seul vieil également pour l'assemblement et le désassemblement à répétition. Le tête de la prothèse est enclenchée sur le pivot de la tige. Avant de procéder à l'assemblage, s'assurer que les connecteurs pyramidaux sont secs et exempts de contaminant.
Une préparation méticuleuse du site d'implantation et le choix de la taille appropriée de l'implant augmentent la chance de succès de l'implantation. Il existe une gamme complète de gabarits pour aider à la préparation de l'os. On recommande de retirer l'implant de taille appropriée de son emballage stérile seulement lorsque que le site d'implantation a été préparé et correctement dimensionné.

EFFETS INDÉSIRABLES
Parmi les effets indésirables potentiels des prothèses on a signalé la douleur, le déboîtement, la fracture, la déviation ou l'infection. On a signalé quelques cas de patients qui ont manifesté des réactions de sensibilité au métal après remplacement de l'articulation. L'implantation de matériaux comme le Co-Cr- Mo et/ou à titane peut se traduire par une réaction allergique au voisinage du site d'implantation. Le tissu nerveux, sanguins, tendons ou tissus mous environnants peut survenir suite à l'implantation de cet appareil.

PROCÉDURES CHIRURGICALES
Il existe une procédure chirurgicale à suivre dans la mise en oeuvre de cette prothèse. Il est de la responsabilité du chirurgien de bien prendre connaissance de cette procédure avant d'utiliser ces produits. De plus, le chirurgien est tenu de prendre des connaissances des publications utiles et de consulter des confrères expérimentés quant à cette procédure avant qu'il utilise ces prothèses.

INFORMATION ET CONSEILS DESTINÉS AU PATIENT (Voir également la partie Mises en garde)
Il convient de fournir à tout patient programmé pour une implantation chirurgicale des informations détaillées sur les complications et alternatives potentielles – qui peuvent comprendre des procédures non-implantatoires comme la reconstruction des tissus mous, l'arthrodèse. En plus de l'information relative au patient, contenue dans les parties Mises en garde et Effets indésirables, il convient de faire savoir au patient que: 1) Les effets secondaires peuvent nécessiter une nouvelle opération, une correction ou une fusion de l'articulation concernée. 2) Comme la longévité des composants de remplacement de l'articulation est difficile à estimer, elle est limitée. Ces composants sont constitués de matériaux étrangers qui sont placés à l'intérieur de l'organisme en vue de la restauration potentielle de la mobilité ou de la réduction de la douleur. Toutefois, en raison des nombreux facteurs biologiques, mécaniques et physico-chimiques influençant à ces appareils, les composants ne peuvent pas résister indéfiniment au niveau d'activité et aux contraintes d'un os sain normal.

STÉRILISATION
Ce composant a été stérilisé à l'oxyde d'éthylène ou aux rayons gamma. L'implant est fourni stérile dans un emballage intact. Si l'implant ou son emballage apparaît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en doute pour une raison quelconque, il faut prossrire l'emploi de cet implant. Ne pas re-stériliser. Il existe des gabarits d'essai pour vous éviter d'ouvrir un emballage stérile avant l'implantation de la prothèse. Il faut retirer l'implant de son emballage stérile seulement après que le site d'implantation a été préparé et correctement dimensionné.

GARANTIE LIMITÉE
Avanta Orthopaedics, Inc. garantit que ce produit satisfait aux spécifications du fabricant et qu'il est dénué de défauts de fabrication au moment de sa livraison. Cette garantie exclue expressément les défauts résultant d'une mauvaise utilisation, d'un de l'usage abusif ou d'une manipulation incorrecte du produit après que ce dernier a été réceptionné par l'acheteur. Avanta Orthopaedics décline toute responsabilité quant à l'issue de l'intervention chirurgicale.

REPRÉSENTANT EU
Medical Products International Europe, BV
Schuttweg 10e
5145 NP Waalwijk, The Netherlands
31 (0) 416 665764

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ESPAÑOL

DESCRIPCIÓN

La prótesis semiarticular consiste en un vástago de acero inoxidable y una superficie articular. El implante está diseñado para ser insertado en el eje del húmero proximal. La superficie de externo colocada en artículo sobre el hueso opuesto. El implante se encuentra disponible en varios tamaños, esto lleva de los cuales puede utilizarse para la mano derecha e izquierda. Para cada tipo de implante existen una gama de tamaños de prótesis para facilitar la preparación del hueso.

Materiales:

- Componentes de acero inoxidable ASTM F-1537-94
- OPTI

INDICACIONES

El implante de cúpula unipolar presenta cualitiva la articulación radiocubital distal después de una artroplastia con resección de la cabeza del cúbito. Sustitución de la cabeza del cúbito distal en artritis reumatoidea, degenerativa o postraumática con las siguientes características:

1. Dolor y debilidad de la articulación de la muñeca que se mejora con tratamiento conservador.
2. Inestabilidad de la cabeza del cúbito con evidencia radiológica de subluxación dorsal y cambios erosivos.
3. Resección total de la cabeza del cúbito.

El implante de radio mixed presencia sustituir el extremo proximal del radio:

1. Sustitución de la cabeza del radio en incapacitantes degenerativa o postraumáticas que presentan dolor, crepitaciones y disminución de la movilidad a nivel de las articulaciones radio-humeral y/o radio-cubital proximal son:
   a. Destrucción de la articulación o subluxación visible mediante radiografía
   b. Posteriores al tratamiento conservador
2. Sustitución primaria después de una fractura de la cabeza del radio
3. Secuelas dolorosas después de la resección de la cabeza del radio.

CONTRAINDICACIONES

1. Fracturas mal consolidadas del antebrazo que impiden la estabilización de la cabeza del cúbito durante la pronación/supinación (sí/no)
2. Tendones, ligamentos o articulación radiocubital distal inadecuados de proporcionar un soporte a (fijación adecuados de la prótesis (sí/no)
3. Piel o sistema musculoesquelético inadecuado.
4. Posteriores un diagnóstico con quistes óseos.
5. Fractura abierta previa o infección en o alrededor de la articulación
6. Sensibilidad conocida a los materiales utilizados en este dispositivo

ADVERTENCIAS (véase también el Período Informativo sobre Asistencia al Paciente)

Cirujas ajustadores, movilidad excesiva y inestabilidad articular pueden conducir a un desgaste prolongado y con el tiempo a daños osseous por soltarse, quitarse o dislocarse el dispositivo. Los pacientes deben ser advertidos de la posibilidad o un fallo de un dispositivo aumenta significativamente si se le imponen exigencias excesivas.

Los implantes son dispositivos mecánicos que se pueden desgastar, fatigar o romper. Una zona de implante se puede deformar, hacerse doloroso, hinchazón o folículos. El tejido del hueso adyacente puede ser inadecuado para soportar el implante o puede deteriorarse con el tiempo causando inestabilidad, osteonecrosis o atrofia. Puede ser que los vástagos de una aparición quiz que el inventor no patologías las especialidad del paciente o que se detectan con el tiempo, obligando una revisión qui rápos para sustituir el implante o llevar a cabo procedimientos alternativos. Operaciones quirúrgicas de revisión de implantes no son excepciones.

PRECAUCIONES

El implante no suministro usado en un envoltorio en protectos unidiciones. Si el envase o el envoltorio no encuentran dañados, no los supongas la fecha de caducidad o si cuestiona la esterilidad por cualquier motivo, el implante no debe utilizarse. No volver a esterilizar.

La preparación meticulosa del lugar de implantación y la selección del tamaño adecuado del implante aumenta la probabilidad de un resultado satisfactorio. Ejemplos Ordinarios datos estrictos de un envoltorio estéril una vez preparado el lugar de implantación y seleccionado el tamaño adecuado.

Los implantes deben manipularse con instrumentos romos para evitar rayar, cortar o matar el discretivo y no perjudicar así el funcionamiento del implante. Las superficies deslizantes y abrirse no deben entrar en contacto con superficies duras o sonosas. Se deben implantarse la cabeza y el vástago al estar la posibilidad de que los conos están dañados, lo cual incluye la articulación y desarticulación repetidas. La colocación de la prótesis no impedirá sobre el cuello del vástago. Antes del ensamblaje, hay que comprobar que los cuellos estén secos y libres de contaminantes.

EVENTOS ADVERSOS

Eventos adversos potenciales relacionados con prótesis para la artroplastia de un codo del que incluyen dolor, rotura, fricción, disincrustación o infección. Estos efectos adversos de posterior son necesarios quirúrgicos complementos de metal expulsión de una sustitución de la articulación. La implantación de materiales tales como Co-Cr-Mo y/o titanio pueden resultar en una reacción de cuerpos extraños adyacentes y la zona del implante. La implantación de este dispositivo puede causar lesiones en los nervios circundantes, masa sanguínea, tendones o tejidos suaves.

PROCEDIMIENTOS QUIRÚRGICOS

Hay disponible un procedimiento quirúrgico para el uso de este dispositivo de implantable. Es la responsabilidad del quirúrgico familiarizarse con el procedimiento antes de utilizar estos productos. Antes de usar dicho dispositivo, el quirúrgico se, además, responsable de familiarizarse con las publicaciones pertinentes y mantener contacto con asociados especialmente respecto al procedimiento.

INFORMACIÓN SOBRE ASISTENCIA AL PACIENTE (véase también Advertencias)

Antes de la operación qui'gica se ha de proporcionar a cada paciente que se ha previsto para una operación qui'gica de un implante, estándar, documentada sobre posibles complicaciones y alternativas que puedan incluir procedimientos sin implantación así como recomendación del tejido suave o semidura. Además de la información relevante al paciente que ya describe en los párrafos de Advertencias y Eventos Adversos, he ha de informar al paciente sobre lo siguiente:

1) Ejercicios adecuados para después del procedimiento, evitando o todos de la articulación en cuestión. 2) A pesar de que es difícil estimar la vida supuesta de los componentes sustitutivos de una artroplastia, ésta no finita. Distos componentes son de materiales estrictos al cuerpo y se han colocado dentro del cuerpo para la restauración potencial de la movilidad o la reducción de dolor. No obstante y debido a numerosos factores biológicos, mecánicos y fisiológicos que pueden afectar estos dispositivos, no se puede esperar de los componentes que realicen por un período ilimitado al nivel de actividad y la carga de los huesos normales y sanos.

ESTERILIZACIÓN

Este componente ha sido esterilizado por dosis de cobalto a radiación gamma. El implante se entrega estéril en un paquete interior. Si sea el implante o el paquete exterior sean dañados, los esterilizado la fecha de caducidad o el por esterilizar motivo ordenen dudas sobre la esterilidad, el implante no se debe usar. No lo esterilice nuevamente. Hay disponible esterilizante de prueba para saber que se haya de abrir el paquete estéril previamente a la inspiración de la prótesis. El implante solamente se ha de sacar del paquete estéril cuando la zona de implantación se ha preparado y suficiente apropiadamente.

GARANTÍA LIMITADA

Avanta Orthopaedics, Inc. garantiza que este producto cumple con las especificaciones del fabricante y que en el momento de entrega sin libre de defectos de fabricación. Dicha garantía excluye específicamente defectos causados por mal uso, abuso o mental inspección del producto posterior al recibo del comprador. Avanta Orthopaedics no garantiza el resultado de un procedimiento qui'gico.

REPRESENTANTE EU
Medical Products International Europe, BV
Schuineg 19a
5146 NP Waalwijk, The Netherlands
31 (0) 416 663764

NEDERLANDS

BESCHRIJVING

Deze Humi prothese bestaat uit een kobalt chroom steel en hol gesloten vervangend oppervlak. Het implantaat is ontworpen om te worden geïmplanteerd in het hoofd van het kubitt proximale gedeelte van de ellepijp. Het oppervlak is ontworpen om te worden overliggende bot. De extra implantaten bestaat uit verschillende maten, voor zowel de rechter als de linkerhand. Er is een aantal proef prothesen verkrijgbaar, dit om het voorbereiden van het te behandelen gewricht te vergemakkelijken.

Materialen:

- Kobalt chroom component
- Gammastraal verkrijgbaar titanium(OPTI)

INDICATIES

Het uitvoeren Ulnar implantaat is bedoeld voor de vervanging van het radiushoofd gevormd na resectie van de ulna-top. Vervanging van het distale ulnare kopje voor trauma, degenerative, of posttraumatische artritis met duurzaam onderhavige klachten:

1. Pijn en instabiliteit van het pols gewricht hebben niet verbeterd na conservatieve behandeling.
2. Instabiliteit van de Ulnar met als onderstaand bewijs van röntgen opname.
3. Een serieus ulnar resectie die niet het gewenste resultaat heeft opgeleverd.

Het R-vorm radius kop implantaat is bedoeld ter vervanging van het gedeeltelijk gedeelte van de radius.

1. Vervanging van het radius kopje voor degenerative, of post-traumatische blessures gewricht pijn en slecht dynamische functie van radius-humerale en/of het proximale radius ulnare gewricht met:
   a. Een gedocumenteerd gevolgd of van sub-luxatie die d.m.v. een röntgenopname is vast te stellen.
   b. Met gevolg voor conservatieve behandeling
2. Een primaire vervanging na een breuk van de radius kop
3. Symptomatisch gevolg na resectie van het radius kopje.

CONTRA-INDICATIES

1. Na niet anatomische heling van een onderarm fractuur een instabiele ulnar in pronatie en supinatie (sí/nee)
2. Beschadigingen of instabiliteit van de ligg. banden die onvoldoende stabiliteit geven, en hierdoor een goed functioneren van het implantaat in de weg staan (sí/nee)
3. Onvoldoend huid- of musculoskeletale systeem.
4. Patiënten in de groei met open epifysen.
5. Een gebeurtenismatig breuk of blessie van el rand niet herkenbaar.
6. Bekende overgevoeligheid voor materialen die in dit product worden gebruikt.

WAARSCHUWINGEN (Zie ook het gedeelte over Informatie over verzekering van de patiënt)

Slechte bekading, overmatige mobiliteit en gewrichts instabiliteit kunnen alle leiden tot vervroegde slijtage en uiteindelijk faser door loslating, fracturen of dislocatie van het implantaat. Patiënten moeten bewust gemaakt worden van de verhoogde kans op falen van het implantaat als hier overmatige inval van gewrocht vindt.

Implantaten zijn mechanische producten; ze kunnen slijten, en kan metaalmoeheid optreden en ze kunnen breken. De plaats van het implantaat kan gedeformeerd, pijnlijk, gezwollen of ontstoken zijn. De status van het aangrenzende bot en zachte weefsel kan verandering zijn voor de ondersteuning van het implantaat of kan in de loop van de tijd verslechteren met botafbraak, osteonecrose of botzijn als gevolg. Het kan zijn dat beslissingschirurgie niet de voorbeeld biedt die de patiënt verwacht heeft of dat de waarschijn in de loop van de tijd stoornen, meegroter revisiechirurgie noodzakelijk is en het implantaat te vervangen of alternatieve procedures te voorzien. Revisiechirurgie of implantaten is een ingrijpbaarheid.

VOORZORGSMAATREGELEN

Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Als het implantaat of de verpakking beschadigd lijken te zijn, als de datums gedenkdatum is overschreden of als een de aan of enigere reden twijfel bestaat over de sterilitiet, mag het implantaat niet gebruikt worden. Niet opnieuw steriliseren.

Implantaten mogen niet met andere instrumenten worden gemanipuleerd, dit om krassen, breuken of andere beschadigingen op de prothese te voorkomen Glazuur aanwezig weet worden vergroten en kan het precieze oppervlas en de laser bevestiging van bouw af vlakt). Metalen of toch beschadigingen zijn opgetreden dient dit implantaat niet meer te worden gebruikt Let op tijdens plaatsen niet het kopje herhaaldelijk van de stem afbreek). Om de fixeer verbinding optimaal te behouden moet na plaatsing het kopje op de stem worden vastgehamerd door middel van een lichte hamerslag. Niet gebruikmaking van het in de instrumentenset geleverde instrument. Zorg er voor dat tijdens plaatsing van het kopje de kepel en het kopje niet droog en vrij van verontreiniging zijn.

Zeer beschadigende hoornverslag van de pezels van het implantaat en de kootte van de. Lotte moet implantaat verkrijgen de kans op een succesvol resultaat. Een volledig assechtoge preoperatieve planning is verkrijgbaar ter ondersteuning van de behandelbeslissing. Goedchoend wordt om het implantaat met de juiste maat pas uit de steriele verpakking te halen nadat de plaats van het implantaat is voorbereid en de juiste maat hoek.

BIJWERKINGEN

De mogelijke bijwerkingen die gewoon zijn bij het gebruik van vinger gewrichtsprothe zijn: loosening, fracture, dislocatie en infectie. Er is ook een aantal mededingen van artikelen die de gewrichtsvervanging overgevoelig blijken te zijn voor metaal. Het implantaat van materialen zoals Co-Cr-Mo en/of Titanium kan leiden tot allergische reacties bij de plaats van het implantaat. Letsel aan duiker omringende zenuwen, bloedvaten, pezen en zachte weefsel kunnen optreden als gevolg van het toepassen van dit implantaat.

CHIRURGISCHE PROCEDURES

Een chirurgische processure voor het gebruik van dit implantaat is beschikbaar. Het is de verantwoordelijkheid van de chirurg om op de hoogte te zijn van de procedure voordat hij deze prothese gebruikt. Het is ook zijn verantwoordelijkheid om op de hoogte te zijn van relevante publicaties en eventen omtrent de toepassen over de procedure voordat hij deze verricht.

PATIËNTINFORMATIE (Zie ook Waarschuwingen)

Het is noodzakelijk om alle patiënten die implantaatdrukingen zullen ondergaan vóór de operatie te voorzien van informatie over de mogelijke complicaties en alternatieven. Alternatieven kunnen zijn: niet-invasieve procedures zoals mooimeubele van het zachte weefsel of weefsel. Naast de informatie die betrekking heeft op de patiënt zoals deze is opgenomen onder Waarschuwingen en bijwerkingen moet de volgende informatie aan de patiënt worden meegedeeld:

1) Oefeningen tijdens bovenstaande, breuk of Late van het betrokken gewricht functioneelt regels. 2) De verwachte levensduur van gewrichtsvervangingscomponenten is moeilijk te schatten, maar is steeds. Deze componenten zijn vervaardigd van lichaamsvreemde materialen die in het lichaam worden geplaatst voor potentieel herstel van mobiliteit of voor potentiële vijverstoring. Door de vele biologische, mechanische en fysiologische factoren die een inplantaten beïnvloeden, kan echter niet verwacht worden dat deze componenten voor onbepaalde tijd bestand zijn tegen het activiteitsniveau en de belastingen van normaal gezond bot.

STERILISATIE

Deze component is gesteriliseerd met ethyleenoxide of gammastraalen. Het implantaat wordt steriel geleverd in een ontsmettingsbare verpakking. Als het implantaat of de verpakking beschadigd lijken te zijn, als de uiterste gebruiksdatum is overschreden of als een de aan of enigere reden twijfel bestaat over de sterilitiet, mag het implantaat niet gebruikt worden. Niet opnieuw steriliseren.

Preoperatieoperaties zijn verkrijgbaar om te voorkomen dat de steriele verpakking vóór het inspiteren van de prothese gebruikt moet worden. Het implantaat mag de juiste maat mag pas uit de steriele verpakking gehaald worden nadat de plaats van het implantaat is voorbereid en de juiste maat heft.

BIJPERKTE GARANTIE

Avanta Orthopaedics, Inc. garandeert dat dit product voldoet aan de specificaties van de fabrikant en ten tijde van de levering vrij is van lastopgegeven en. Deze garantie valt uitsluitend tijdperken uit die het gevolg zijn van verkeerd gebruik, misbruik of onjuiste behandeling van het product na overmacht door de koper. Avanta Orthopaedics geeft geen garantie op het resultaat van de chirurgische ingreep.

EU AFGEVAARDIGDE
Medical Products International Europe, BV
Schuineg 19a
5146 NP Waalwijk, The Netherlands
31 (0) 416 663764

ITALIANO

DESCRIZIONE

Questa protesi emiarticolare è composta da una superficie articolare e uno stelo di cromo-cobalto. L'impianto è stato progettato per essere inserito nel fusto dell'osso prossimale. La superficie lo cromo-cobalto è articolata sull'osso opposto. L'impianto è disponibile in varie misure e può essere utilizzato indifferentemente sia sull'arto destro che su quello sinistro. E' possibile usufruire di una gamma di calibratori di prova sulla base di preparazione dell'osso.

Materiali:

- Componente in cromo-cobalto
- Titanio alla stato commercialmente puro (OPTI)

INDICAZIONI

L'impianto ulnare ul-lacci è destinato alla sostituzione dell'articolazione radio-ulnare distale in seguito ad asportazione articolatoria della testa dell'ulna. Sostituzione della testa distale dell'ulna e ossea di artrite post-traumatica, degenerativa o reumatoide nei casi seguenti:

1. Dolore e debolezza dell'articolazione del polso non migliorata da trattamento conservativo.
2. Instabilità della testa dell'ulna con segno radiologico che evidenzia una subLussazione dorsale e modifiche erosive
3. Esito negativo dell'asportazione della testa dell'ulna

L'impianto radiale mixed è destinato alla sostituzione dell'estremità prossimale del radio:

1. Sostituzione della testa del radio a causa di invalidità post-traumatica o degenerative in presenza di dolore, crepito articolare e capacità motoria diminuita all'articolazione radio-omerale e/o radio-ulnare prossimale nei casi seguenti:
   a. Distruzione o subLussazione dell'articolazione visibile a raggi-x
   b. Insieme impiantamento con il trattamento conservativo
2. Sostituzione primaria in seguito a frattura della testa del radio
3. Sequele sintomatiche in seguito ad asportazione della testa del radio

CONTROINDICAZIONI

1. Sistema effettuato dalla frattura dell'avambraccio che impediscono la stabilizzazione della testa dell'ulna durante la pronazione/supinazione (sí/no)
2. I tendine, i legamenti o l'articolazione radio-ulnare distale non formazione il supporto o il fissaggio adeguato per la protesi (sí/no)
3. Inadeguatezza del sistema scheletrico o di quello muscolo-tendineo
4. Pazienti in crescita con epifisi aperte.
5. Precedente frattura esposta o infezione nel sito o nel pressi dell'articolazi
6. Accertata sensibilità nei confronti dei materiali utilizzati nel presente dispositivo

AVVERTENZE (si rimanda al paragrafo relativo alle informazioni per la Consulenza al Paziente)

I lavori sottocarrelli, una eccessiva mobilità e l'instabilità articolare conducono fattori in grado di accelerare l'usura e l'eventuale danno del dispositivo stesso con processo di allentamento, frattura e dislocazione. I pazienti devono essere avvertiti del fatto che il rischio di danni al dispositivo aumenta in caso di utilizzo poco moderato dello stesso. Le protesi sono dei dispositivi meccanici soggetti a logoramento, affaticamento e rottura. Le sedi di una protesi li soggetto al rischio di infezioni, dolore, edema e infiammazione. Le condizioni dell'osso e del tessuto molle adiacenti è possibilmente essere inadeguate a sostenere la protesi, eseguire ancora invasive a deterioramento graduale, con conseguente instabilità e/o osteolisi. E' possibile che i benefici apportati dalla protesi non rispondano alle aspettative del paziente e perdano la loro qualità nel tempo. In tal caso si renderebbe indispensabile eseguire un intervento chirurgico di revisione, oltre a prestare la protesi o ad eseguire delle procedure alternative. Gli interventi chirurgici di revisione di protesi non sono rari.

PRECAUZIONI

Le protesi viene fornita in condizioni sterili, all'interno di una confezione integra. Evitare di procedere all'utilizzo della protesi nel caso in cui si riscontri un danno alla stessa o alla confezione, oppure in caso di superamento della data di scadenza o di dubbi di qualsiasi natura sull'effettiva sterilizzazione di sterilità. Non risterare le sterilizzazione.

Gli impianti devono essere maneggiati con strumenti non appuntiti per evitare di graffiare, tagliare o bruciare il dispositivo e compromettere di conseguenza la funzionalità ottimale dell'impianto. Il supporto levigato e le superfici scorrevole non devono entrare in contatto con superfici dure o abrasive. Lo stelo e la testa non devono essere impiantati nel caso in cui le superfici coniche risultino danneggiate, anche per ripetuti urtosoli e distacchi. La testa dello protesi viene montata nel cono dello stelo.

Prima di procedere al montaggio verificare che le superfici coniche siano asciutte e non contaminate.

Una preparazione accurata del sito d'impianto ed una corretta scelta delle dimensioni della protesi aumentano la probabilità di successo dell'intervento. Una gamma completa di dispositivi di prova è disponibile per la predisposizione dimensionata del tessuto. Si consiglia di estrarre la protesi della giusta dimensione della sua confezione sterile soltanto dopo aver predisposto e dimensionato adeguatamente il sito di impianto.

EVENTI NEGATIVI

Azioni potenziali eventi negativi riportati in seguito all'impianto di protesi dell'articolazione a cerniera, glenoidemia, frattura, dislocazione e infezione. Sono stati riportati dei casi di pazienti che hanno manifestato delle reazioni di sensibilità al or metalli in seguito alla sostituzione dell'articolazione. L'impianto di materiali quali I Co-Cr-Mo e/o il titanio possono dar luogo a reazione da corpo estraneo nelle adiacenze al sito di impianto. In seguito all'impianto di questo dispositivo, si possono verificare danni a nervi, vasi sanguigni, tendini e tessuti molli situati nell'area circostante al sito di impianto.

PROCEDURA CHIRURGICA

E' disponibile un protocollo di procedura chirurgica per l'impiego di questa protesi E' responsabilità del chirurgo acquisire familiarità con tale protocollo prima di procedere all'utilizzo di questi prodotti. Le stesso chirurgo ha la responsabilità di acquisire conoscenza delle principali pubblicazioni del settore e di consultarsi con colleghi esperti in relazione alla procedura, prima di eseguire l'intervento.

INFORMAZIONI PER LA CONSULENZA AL PAZIENTE (si rimanda alle Avvertenze)

A ciascun paziente per il quale si è programmato un trattamento di impianto di protesi articolare mediante una consulenza circunstanziata in relazione alle possibili complicazioni che potranno insorgere e alle alternative, che includono un intervento senza l'impianto di protesi, specialmente nella ricostruzione dei tessuti molli o nell'immobilizzazione dell'articolazione. Oltre alle informazioni per il paziente riportate al paragrafo "Avvertenze" e "Eventi negativi", è indispensabile fornire ai pazienti le seguenti informazioni:

1) l'eventuale insorgenza di eventi negativi può rendere necessario un secondo intervento chirurgico, una revisione o la sostituzione dell'articolazione in questione.

2) La durata dei componenti sostitutivi dell'articolazione è difficile da prevedere esattamente. Sebbene questi componenti siano realizzati in materiali non biologici e collocati all'interno dell'organismo per il potenziale ripristino della mobilità e per la riduzione del dolore. Ciononostante, per via dei diversi fattori di natura biologica, meccanica e fisico-chimica che influenzano questi dispositivi, non ci si può aspettare che i componenti siano realizzati, per un tempo illimitato, al livello di attività e alle sollecitazioni da carico ai quali sono sottoposte le normali ossa sane.

STERILIZZAZIONE

Questo articolo è stato sterilizzato con ossido di etilene e con radiazioni gamma. La protesi è fornita in condizioni sterili all'interno di una confezione integra. Evitare di procedere all'utilizzo della protesi nel caso in cui si constati un danno alla stessa o alla confezione, oppure in caso di superamento della data di scadenza o di dubbi di qualsiasi natura sull'effettiva condizione di sterilità. Non risterare la sterilizzazione. Dal dispositivo di prova sono disponibili per vetare che è distinto tutto il contenuto sterile prima dell'effettivo impianto della protesi. La protesi va estratta dalla sua confezione sterile soltanto dopo aver predisposto e dimensionato adeguatamente il sito di impianto.

GARANZIA LIMITATA

Avanta Orthopaedics, Inc. garantisce che questo prodotto soddisfa le specifiche della casa produttrice e non presenta difetti di produzione al momento della consegna. Questa garanzia esclude esplicitamente qualsiasi difetto derivante da utilizzo improprio, abuso o maneggiamento improprio del prodotto avvenuti successivamente al ricevimento stesso presso il ricevente dell'acquirente. Avanta Orthopaedics non garantisce l'esito positivo della procedura chirurgica.

RAPPRESENTANTE EU
Medical Products International Europe, BV
Schuineg 19a
5146 NP Waalwijk, The Netherlands
31 (0) 416 663764

AVANTA
ORTHOPAEDICS
9369 Carroll Park Drive, Suite A, San Diego, CA 92121 USA
(858)452-8580 / (858)452-9945 (fax)

PRODUCT INSERT

AVANTA rHEAD RECON IMPLANT
rHEAD RECON IMPLANTAT
IMPLANT rHEAD RECON
IMPLANTE rHEAD RECON
rHEAD RECON IMPLANTAAT
rHEAD RECON IMPLANT

ENGLISH

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
This rHead Recon prosthesis consists of a cobalt chromium stem and a cobalt chromium head with a polyethylene articulating insert. The stem of the implant is designed to be inserted into the shaft of the proximal radius. The head of the implant articulates with the capitellum. The implant is available in several sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation.

Materials:
- ASTM F-1537 wrought cobalt chromium molybdenum alloy for surgical implants
- ASTM F-1580 titanium powders for coatings of surgical implants
- ASTM F-648 ultra-high molecular weight polyethylene powder fabricated form for surgical implants.

INDICATIONS
rHead Recon Implant is intended for replacement of the proximal end of the radius:
1. Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:
   a. Joint destruction or subluxation visible on x-ray
   b. Resistance to conservative treatment
2. Primary replacement after fracture of the radial head
3. Symptomatic sequelae after radial head resection

CONTRAINDICATIONS
1. Inadequate skin or musculotendinous system
2. Growing patients with open epiphyses
3. Previous open fracture or infection in or around the joint
4. Known sensitivity to materials used in this device

WARNINGS (See also the Patient Counseling Information Section)
- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
- Implants are mechanical devices that can be worn away, fatigued or broken. An implant site may become infected, painful, swollen or inflamed. The status of the adjacent bone and soft tissue may be inadequate to support the implant, or may deteriorate in time resulting in instability, deformity, or both. The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

PRECAUTIONS
1. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. **Do not resterilize.**
2. Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance. Polished bearing and taper surfaces must not come in contact with hard or abrasive surfaces.
3. The head and stem should not be implanted if the articulating surfaces are possibly damaged, this includes repeated attaching and detaching.
4. The head of the prosthesis is impacted on to the ball of the stem. Prior to assembly confirm that tyhe articular surfaces are dry and free from contaminant.

ADVERSE EVENTS
Potential adverse events reported with joint prostheses include pain, loosening, fracture dislocation or infection. There have been some reports of patients with metal sensitivity reactions following joint replacement. Implantation of materials such as cobalt chrome and/or titanium may result in foreign body reaction adjacent to the implant site. Injury to the surrounding nerves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device.

SURGICAL PROCEDURES
A surgical procedure for use of this implant device is available. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings)
Providing each patient scheduled for implant surgery with documented counseling of potential complications and alternatives, which may include non-implant procedures such as soft tissue reconstruction or arthrodesis, prior to surgery is necessary. In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient: 1) Adverse effects may necessitate reoperation, revision, or fusion of the involved joint. 2) While the expected life of joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

STERILIZATION
This component has been sterilized by ethylene oxide or gamma radiation. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. **Do not resterilize.** Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics, Inc. warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics, Inc. does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

19-0365 rev. A

DEUTSCH

ACHTUNG
Laut US-Bundesgesetz darf dieses Produkt nur von einem Arzt oder in dessen Auftrag verkauft, vertrieben oder eingesetzt werden.

BESCHREIBUNG
Diese rHead Recon Prothese besteht aus einem Cobalt-Chrom-Schaft und einem Cobalt-Chrom-Kopf mit einem Gelenkeinsatz aus Polyethylen. Der Schaft des Implantats ist zum Einsetzen in den Schaft des proximalen Radius bestimmt. Der Kopf des Implantats artikuliert mit dem Humeruskköpfchen. Das Implantat ist in mehreren Größen erhältlich, die jeweils für die linke oder die rechte Hand verwendet werden können. Zur Erleichterung der Knochenpräparation ist ein Satz Probeimplantate für jeden Implantattyp erhältlich.

Werkstoffe:
- Cobalt-Chrom-Molybdän-Knetlegierung für chirurgische Implantate gemäß ASTM F-1537
- Titanpulver für Beschichtungen von chirurgischen Implantaten gemäß ASTM F-1580
- Pulvergefertigte Form aus ultrahochmolekularem Polyethylen (UHMW-PE) für chirurgische Implantate gemäß ASTM F-648.

INDIKATIONEN
Das rHead Recon Implantat ist zum Ersatz des proximalen Radiusendes bestimmt:
1. Ersatz des Radiusköpfchens bei degenerativen oder posttraumatischen Behinderungen mit Schmerzen, Crepitatio und Bewegungseinschränkung am Radiohumeral- und/oder proximalen Radioulnargelenk mit:
   a. Radiologisch sichtbarer Gelenkzerstörung oder Subluxation
   b. Resistenz gegenüber konservativer Behandlung
2. Primärersatz nach Fraktur des Radiusköpfchens
3. Symptomatische Folgeerscheinungen nach Radiusköpfchenresektion

KONTRAINDIKATIONEN
1. Inadäquate Haut oder inadäquates Muskel-Sehnen-System
2. Im Wachstum begriffene Patienten mit offenen Epiphysen
3. Frühere offene Fraktur oder Infektion im Gelenk oder im Umkreis des Gelenks
4. Bekannte Überempfindlichkeit gegenüber den Implantatwerkstoffen

WARNHINWEISE (Siehe auch Abschnitt Patienteninformationen)
Extreme Belastungen, übermäßige Mobilität und Gelenkinstabilität können zu frühzeitigem Verschleiß und eventuellem Versagen der Prothese durch Lockern, Brechen oder Verlagern führen. Der Patient sollte über das erhöhte Risiko eines Versagens der Prothese bei Überbeanspruchung aufgeklärt werden.
Prothesen sind mechanische Produkte, die verschleißen, ermüden oder brechen können. An der Implantationsstelle können Infektionen, Schmerzen, Schwellungen oder Entzündungen auftreten. Das umliegende Knochen- oder Weichteilgewebe kann in einem Zustand sein, der keinen ausreichenden Halt für das Implantat bietet, oder kann sich mit der Zeit verschlechtern und dadurch eine Instabilität oder Deformität oder beides nach sich ziehen. Der Nutzen der Implantation kann unter Umständen den Erwartungen des Patienten nicht gerecht werden oder mit der Zeit abnehmen, sodass ein Revisionseingriff zum Austausch der Prothese oder zur Durchführung alternativer Verfahren erforderlich ist. Revisionseingriffe sind bei Prothesen nicht selten.

VORSICHTSMASSNAHMEN
1. Die Prothese wird steril in einer unbeschädigten Verpackung geliefert. Sollte entweder die Prothese oder die Verpackung beschädigt, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grunde zweifelhaft sein, darf die Prothese nicht verwendet werden. **Die Prothese nicht erneut sterilisieren.**
2. Prothesen sollten ausschließlich mit stumpfen Instrumenten gefasst werden, um Kratzer, Schnitte und Kerben auf der Prothese zu vermeiden. Polierte Gelenk- und Konusoberflächen dürfen nicht mit harten oder abrasiven Oberflächen in Kontakt kommen.
3. Der Kopf und der Schaft sollten nicht implantiert werden, wenn die Gelenkflächen möglicherweise beschädigt sind; dies ist auch bei wiederholtem Zusammensetzen und Zerlegen der Fall.
4. Der Kopf der Prothese wird auf die Kugel des Schafts geschlagen. Vor dem Zusammensetzen ist darauf zu achten, dass die Gelenkflächen trocken und sauber sind.

KOMPLIKATIONEN
Bekannte mögliche Komplikationen bei Gelenkprothesen sind Schmerzen, Lockerung, Fraktur, Dislokation oder Infektionen. Bei einigen Patienten traten Überempfindlichkeiten gegen Metall nach dem Gelenkersatz auf. Die Implantation von Materialien wie Cobalt-Chrom und/oder Titan kann zu Fremdkörperreaktionen in der Umgebung der Implantationsstelle führen. Darüber hinaus können Verletzungen der umgebenden Nerven, Blutgefäße, Bänder oder Weichteile auftreten.

OPERATIONSVERFAHREN
Ein Operationsverfahren zur Verwendung dieser Prothese ist erhältlich. Der Chirurg muss sich vor der Verwendung dieser Produkte mit dem Operationsverfahren vertraut machen. Außerdem liegt es in der Verantwortung des Chirurgen, vor der Verwendung dieser Produkte die relevanten Publikationen zu Rate zu ziehen und sich mit erfahrenen Kollegen über das Operationsverfahren auszutauschen.

PATIENTENINFORMATIONEN (Siehe auch Warnhinweise)
Vor der Operation muss jeder Patient schriftlich über potenzielle Komplikationen und mögliche Alternativen aufgeklärt werden. Hierzu können auch Maßnahmen ohne Prothesen, wie z.B. Weichteilrekonstruktionen oder Arthrodesen zählen. Zusätzlich zu den Patienteninformationen in den Abschnitten Warnhinweise und Komplikationen sollte der Patient über Folgendes informiert werden: 1) Komplikationen können eine neue Operation, einen Revisionseingriff oder eine Fusion des betroffenen Gelenks erfordern. 2) Die Lebensdauer der Gelenkersatz-Komponenten ist nur schwer vorherzusagen, in jedem Fall aber begrenzt. Die Komponenten bestehen aus körperfremdem Material und werden in den Körper eingepflanzt, um die Beweglichkeit möglichst wiederherzustellen und Schmerzen zu vermindern. Aufgrund zahlreicher biologischer, mechanischer und physiochemischer Faktoren, die auf diese Komponenten einwirken, können diese dem Aktivitätsniveau und der Belastung eines gesunden Knochens nicht über einen unbegrenzten Zeitraum standhalten.

STERILISATION
Dieses Produkt wurde mit Ethylenoxid oder mit Hilfe von Gammastrahlen sterilisiert. Es wird steril in einer unbeschädigten Verpackung geliefert. Sollte entweder die Prothese oder die Verpackung beschädigt, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grunde zweifelhaft sein, darf die Prothese nicht verwendet werden. **Die Prothese nicht erneut sterilisieren.** Um die sterile Verpackung nicht zur Feststellung der richtigen Größe der Prothese vor der Implantation öffnen zu müssen, stehen Probeimplantate zur Verfügung. Die Prothese darf erst dann aus der sterilen Verpackung entnommen werden, wenn die Implantationsstelle ausreichend vorbereitet und die richtige Größe der Prothese ermittelt wurde.

BEGRENZTE GEWÄHRLEISTUNG
Avanta Orthopaedics, Inc. garantiert, dass dieses Produkt den Spezifikationen des Herstellers entspricht und zum Zeitpunkt der Lieferung frei von Herstellungsfehlern ist. Diese Gewährleistung schließt ausdrücklich Schäden aus, die auf unsachgemäße Behandlung, Missbrauch oder falsche Verwendung durch den Benutzer zurückzuführen sind. Avanta Orthopaedics, Inc. gibt keine Gewährleistung für einen Erfolg des chirurgischen Eingriffs.

EU REPRÄSENTANT
Medical Products International Europe
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

FRANÇAIS

ATTENTION
Les lois fédérales des États-Unis d'Amérique exigent que la vente, la distribution et l'utilisation de cet appareil soient assurées ou prescrites par un médecin.

DESCRIPTION
Cette prothèse rHead Recon consiste en une tige et une tête en cobalt-chrome ainsi qu'en un module d'articulation en polyéthylène. La tige de l'implant est prévue pour une insertion dans le corps du radius proximal. La tête de l'implant s'articule sur le condyle de l'humérus. L'implant est disponible en plusieurs tailles, utilisables du côté droit comme du côté gauche. Une série de calibreurs d'essai est disponible pour chaque type d'implant, en tant qu'assistance à la préparation osseuse.

Matériaux :
- Alliage de cobalt-chrome-molybdène façonné pour implants chirurgicaux (conforme à la norme ASTM F-1537)
- Poudres de titane pour enrobages d'implants chirurgicaux (conformes à la norme ASTM F-1580)
- Forme de poudre de polyéthylène à poids moléculaire ultra élevé traitée pour implants chirurgicaux (conforme à la norme ASTM F-648).

INDICATIONS
L'implant rHead Recon est prévu pour le remplacement de l'extrémité proximale du radius :
1. Remplacement de la tête radiale en raison d'incapacités dégénératives ou post-traumatiques accompagnées de douleur, crépitation et perte de mouvement de l'articulation radio-humérale et/ou radio-ulnaire proximale avec :
   a. Destruction de l'articulation ou subluxation visible aux rayons x
   b. Résistance à un traitement conservateur
2. Remplacement primaire après fracture de la tête radiale
3. Séquelles symptomatiques après résection de la tête radiale

CONTRE-INDICATIONS
1. Incompatibilité de la peau ou du système musculo-tendineux
2. Patients en cours de croissance et ayant des épiphyses ouvertes
3. Antécédent de fracture ouverte ou d'infection dans ou autour de l'articulation
4. Allergie avérée aux matériaux de ce dispositif

AVERTISSEMENTS (Voir aussi la section Conseils donnés au patient)
De fortes charges, une mobilité excessive et une instabilité articulaire peuvent accélérer l'usure du dispositif et entraîner un échec éventuel par relâchement, fracture ou dislocation. Il faut informer le patient de l'augmentation du risque d'échec du dispositif en cas de sollicitations excessives.
Les implants sont des dispositifs mécaniques. En tant que tels, ils peuvent s'user ou se casser. Le site d'un implant peut devenir douloureux, s'infecter, s'enfler ou être le siège d'inflammations. Il se peut que l'état de l'os adjacent et des tissus mous ne permette pas la pose de l'implant ou se détériore avec le temps, entraînant une instabilité, une difformité ou les deux. Il se peut que les avantages de l'implantation ne répondent pas aux attentes du patient ou diminuent au fil du temps, nécessitant une chirurgie de révision afin de remplacer l'implant ou le recours à d'autres procédures. Il n'est pas rare de pratiquer une chirurgie de révision sur un implant.

PRÉCAUTIONS
1. L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou la stérilité mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant. **Ne pas restériliser.**
2. Les implants doivent être manipulés avec des instruments à bout mousse pour ne pas rayer, couper ou entailler le dispositif et ne pas perturber les performances de l'implant. Le palier poli et les surfaces coniques ne doivent pas entrer en contact avec des surfaces abrasives ou dures.
3. Il ne faut pas implanter la tête et la tige s'il y a un risque d'endommager les surfaces articulaires, notamment en cas de pose et de dépose répétées.
4. La tête de la prothèse est fixée sur la bille de la tige. Avant l'assemblag, vérifier que les surfaces articulaires sont sèches et qu'elles ne sont pas contaminées.

EFFETS INDÉSIRABLES
Les effets indésirables éventuels qui ont été rapportés avec des prothèses articulaires sont la douleur, le relâchement, la fracture avec luxation ou l'infection. Des cas de patients présentant des réactions d'allergie au métal suite à un remplacement d'articulation ont été rapportés. L'implantation de matériaux tels que le cobalt-chrome et/ou le titane peut entraîner une réaction au corps étranger adjacente au site de l'implant. L'implantation de ce dispositif peut avoir pour conséquence une lésion traumatique des nerfs, des vaisseaux sanguins, des tendons ou des tissus mous.

PROCÉDURES CHIRURGICALES
Une procédure chirurgicale concernant l'utilisation de cet implant est disponible. La connaissance de cette procédure est de la responsabilité du chirurgien. Il incombe également au chirurgien de se tenir au courant des publications pertinentes et de consulter des confrères expérimentés au sujet de la procédure à utiliser.

CONSEILS DONNÉS AU PATIENT (Voir aussi Avertissements)
Avant l'opération chirurgicale, il est nécessaire de fournir à chaque patient programmé pour une chirurgie d'implant des conseils et des informations sur les complications éventuelles et les solutions de remplacement, notamment la reconstruction de tissus mous ou l'arthrodèse. Outre l'information relative au patient contenue dans les sections Avertissements et Effets indésirables, le patient doit recevoir l'information suivante : 1) Des effets indésirables peuvent nécessiter la réopération, la révision ou la fusion de l'articulation concernée. 2) Il est difficile d'estimer la durée de vie prévue des composants de remplacement d'articulation, mais ils ne sont pas inusables. Ces composants sont en effet fabriqués dans des matériaux étrangers au corps humain et implantés afin de restaurer la mobilité ou de réduire la douleur. Toutefois, en raison des nombreux facteurs biologiques, mécaniques et physio-chimiques qui affectent ces dispositifs, les composants ne peuvent pas supporter le même niveau d'activité et les mêmes charges qu'un os sain pendant une période illimitée.

STÉRILISATION
Ce composant a été stérilisé par oxyde d'éthylène ou rayons gamma. L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant. **Ne pas restériliser.** Des calibreurs d'essai sont disponibles : ils évitent d'ouvrir l'emballage stérile avant l'implantation de la prothèse. Il faut enlever l'implant de son emballage stérile uniquement après la préparation et le dimensionnement correct du site de l'implant.

GARANTIE LIMITÉE
Avanta Orthopaedics, Inc. garantit que ce produit est conforme aux spécifications du fabricant et qu'il est livré sans défaut de fabrication. Cette garantie exclut spécifiquement les défauts résultant d'une utilisation incorrecte ou abusive, ou d'une manipulation incorrecte du produit postérieure à la réception par l'acheteur. Avanta Orthopaedics, Inc. ne garantit pas l'issue de la chirurgie.

REPRÉSENTANT EN EUROPE
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Pays-Bas
31 (0) 416 563754

ESPAÑOL

PRECAUCION
La legislación federal de los EE.UU. restringe la venta, la distribución y el uso de este producto, permitiendo que se efectúen solamente por un médico o por orden de un médico.

DESCRIPCION
La prótesis rHead Recon está compuesta de un vástago de cromo-cobalto y de una cabeza del mismo material, con un núcleo articulante de polietileno. El vástago del implante ha sido diseñado para insertarse en el extremo proximal de la diáfisis del
La cabeza del implante articula con el cóndilo humeral. Este implante se
stra en varios tamaños, cada uno de los cuales puede aplicarse
mente para la extremidad superior derecha o izquierda. Con el propósito de
ar la preparación del hueso, se suministra una gama de prótesis de prueba de distintos tamaños para cada tipo de implante.

Materiales
- ASTM F-1537: Aleación forjada de cobalto-cromo-molibdeno para implantes quirúrgicos;
- ASTM F-1580: Polvo de titanio para el revestimiento de implantes quirúrgicos;
- ASTM F-648: Forma fabricada de polvo de polietileno de peso molecular ultraelevado para implantes quirúrgicos.

INDICACIONES
El implante rHead Recon ha sido diseñado para la sustitución protésica de la epífisis proximal del radio:
1. Sustitución de la cabeza radial en caso de afecciones degenerativas o post-traumáticas que producen dolor, crepitación y restricción de la movilidad a nivel de la articulación húmero-radial y/o de la articulación radio-cubital proximal, con:
   a. Destrucción articular o subluxación visible a rayos X;
   b. Falta de respuesta o respuesta insatisfactoria al tratamiento conservador;
2. Sustitución primaria en caso de fractura de la cabeza radial;
3. Tratamiento de secuelas sintomáticas post-resección de la cabeza radial.

CONTRAINDICACIONES
1. Condiciones inadecuadas de la piel o del sistema músculo-tendinoso;
2. Pacientes en edad de crecimiento, con epífisis abiertas ;
3. Fractura abierta previa o infección en o alrededor de la articulación;
4. Hipersensibilidad conocida a los materiales utilizados para la fabricación de este implante.

ADVERTENCIAS (Ver también el apartado "Información y asesoría del paciente")
La sobrecarga mecánica extrema, la movilidad excesiva y la inestabilidad articular pueden conducir a un desgaste acelerado y a un fallo eventual por aflojamiento, fractura o dislocación del implante. Deberá explicarse a los pacientes que el riesgo de fallo del dispositivo aumenta si ésta es sometido a una sobrecarga mecánica excesiva.
Los implantes son dispositivos mecánicos susceptibles de desgaste, fatiga de material o fractura. El sitio de implantación puede presentar infección, dolor, hinchazón o inflamación. La calidad del hueso y de los tejidos blandos adyacentes puede ser inadecuado para proporcionar sustentación al implante , o puede deteriorarse con el tiempo, pudiendo producirse inestabilidad, deformidad o ambas complicaciones. Los beneficios de la cirugía implantatoria pueden no satisfacer las expectativas del paciente o pueden aminorarse con el tiempo, haciendo necesaria la cirugía de revisión para sustituir el implante o para efectuar procedimientos alternativos. En la cirugía de implantes, las intervenciones de revisión no son infrecuentes.

PRECAUCIONES
1. El implante se suministra estéril en un envase intacto. No utilizar el producto si el implante o el envase están dañados, si la fecha de caducidad se ha sobrepasado, o si por cualquier otra razón la esterilidad se considera dudosa. **No reesterilizar** el producto.
2. Los implantes deberán manipularse con instrumentos romos para evitar las rayaduras, los cortes o las melladuras, y para no alterar su funcionamiento. Las superficies pulimentadas de sostén o ahusadas no deben entrar en contacto con superficies duras ni abrasivas.
3. La cabeza y el vástago no deberán implantarse si se sospecha que sus superficies articulares puedan estar dañadas. Esto incluye el caso de su inserción
y desinserción retardas.
   a cabeza de la prótesis es impactada sobre la estera del vástago. Antes del ontaje, comprobar que las superficies articulares estén secas y libres de ustancias contaminantes.

REACCIONES ADVERSAS
Los posibles efectos desfavorables observados en caso de implantación de articulaciones protésicas incluyen dolor, aflojamiento, fractura, dislocación o infección. Se ha publicado algunos casos de pacientes con reacciones de hipersensibilidad al metal después de la sustitución articular. La implantación de materiales tales como el cobalto-cromo y/o el titanio puede traer como consecuencia una reacción de cuerpo extraño alrededor del sitio de implantación. Pueden ocurrir lesiones de los nervios, los vasos sanguíneos, los tendones o los tejidos blandos circundantes como consecuencia de la implantación de este dispositivo.

TECNICA QUIRURGICA
Se suministra una descripción de la técnica quirúrgica a aplicar para la implantación del producto. El cirujano tiene la responsabilidad de familiarizarse con el procedimiento quirúrgico antes de usar estos productos. El tiene, además, la responsabilidad de mantenerse informado de las publicaciones científicas relevantes al respecto y de consultar a expertos acerca del procedimiento, antes de la aplicación clínica del producto.

INFORMACION Y ASESORIA DEL PACIENTE (Ver también "Advertencias")
Antes de la intervención, es indispensable asegurar que todo paciente que haya de someterse a la cirugía de implantación reciba una documentada asesoría acerca de las complicaciones eventuales y sobre las posibles intervenciones alternativas, las cuales pueden incluir procedimientos no implantatorios, tales como la reconstrucción de tejidos blandos o la artrodesis. Además de la información contenida en los apartados "Advertencias" y "Reacciones adversas", debe proporcionarse al paciente la siguiente información: 1) Las reacciones adversas pueden hacer necesaria la reoperación, la revisión o eventualmente la fusión de la articulación comprometida, y 2) Si bien la vida útil que cabe esperar de los componentes articulares protésicos es difícil de estimar, ellos no son infinitos. Estos componentes están hechos de materiales extraños al organismo y se los coloca para restablecer la movilidad o para reducir el dolor. En todo caso, debido a la gran cantidad de factores biológicos, mecánicos y físico-químicos que afectan a estos dispositivos, no puede esperarse que ellos resistan el mismo nivel de actividad y las sobrecargas mecánicas que el hueso normal sano durante un período de tiempo ilimitado.

ESTERILIZACION
Este componente ha sido esterilizado con óxido de etileno o por rayos gamma. El implante se suministra esterilizado y en un envase intacto. No utilizar el producto si el implante o el envase están dañados, si la fecha de caducidad se ha sobrepasado, o si por cualquier otra razón la esterilidad se considera dudosa. **No reesterilizar el producto.** El suministro incluye componentes de prueba para que el cirujano no tenga que abrir el envase estéril hasta el momento mismo de implantar la prótesis. El implante deberá sacarse de su envase estéril solamente después de que el sitio de implantación haya sido completamente preparado y recién después de haber determinado apropiadamente el tamaño requerido.

GARANTIA LIMITADA
Avanta Orthopaedics, Inc. garantiza que, en el momento de su entrega, este producto cumple las especificaciones del fabricante y está libre de de defectos de fabricación. La presente garantía excluye específicamente los fallos que resulten como consecuencia del mal uso, del abuso o de la manipulación incorrecta del producto, con posterioridad a su recepción por parte del comprador. Avanta Orthopaedics, Inc. no garantiza el resultado del procedimiento quirúrgico.

RESENTANTE EN LA UE
cal Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

NEDERLANDS

LET OP
Krachtens de federale wetgeving (VS) mag dit medische hulpmiddel uitsluitend door of op voorschrift van een arts worden verkocht, gedistribueerd of toegepast.

BESCHRIJVING
De rHead Recon prothese bestaat uit een steel van kobaltchroom en een kop van kobaltchroom met een articulerend inzetstuk van polyethyleen. De steel van het implantaat dient om te worden ingebracht in de schacht van de proximale radius. De kop van het implantaat articuleert met het capitulum. Het implantaat is in verscheidene maten verkrijgbaar, die elk in de rechter- of linkerhand kunnen worden toegepast. Voor elk type implantaat is een reeks proefpassers verkrijgbaar ter ondersteuning van het gereedmaken van het bot.

Materiaal:
- ASTM F-1537 gesmede legering van kobalt, chroom en molybdeen voor chirurgische implantaten
- ASTM F-1580 titaanpoeders voor het coaten van chirurgische implantaten
- ASTM F-648 UHMWP (Ultra-High Molecular Weight Polyethylene) vervaardigd in de vorm van een poeder voor chirurgische implantaten.

INDICATIES
Het rHead Recon implantaat dient voor de vervanging van het proximale uiteinde van de radius:
1. Vervanging van de radiuskop vanwege degeneratieve of posttraumatische invaliditeit die gepaard gaat met pijn, crepitatie en verminderde beweeglijkheid van het radiohumerale en/of proximale radio-ulnaire gewricht en tevens:
   a. Gewrichtsafbraak of subluxatie die zichtbaar is op een röntgenopname
   b. Ongeschiktheid voor een conservatieve behandeling
2. Primaire vervanging na een fractuur van de radiuskop
3. Symptomatische sequelae na resectie van de radiuskop

CONTRA-INDICATIES
1. Onvoldoende beschikbare huid of spieren/pezen
2. Patiënten in de groei met open epifysen
3. Een eerdere open fractuur of infectie in of rond het gewricht
4. Bekende overgevoeligheid voor in de prothese gebruikt materiaal

WAARSCHUWINGEN (zie ook het onderdeel Informatie over advisering van de patiënt)
Zware belasting, overmatige mobiliteit en articulaire instabiliteit kunnen allemaal leiden tot versneide slijtage en uiteindelijk falen door losraken, breuk of dislocatie van de prothese. Patiënten moet duidelijk worden gemaakt dat er een verhoogde kans op defect raken van de prothese bestaat als deze wordt overbelast.
Implantaten zijn mechanische hulpmiddelen die kunnen afsliten, onderworpen zijn aan materiaalmoeheid en kunnen breken. Een implantatiepiaats kan geïnfecteerd, pijnlijk, gezwollen of ontstoken raken. Het natuurlijke bot en de naastliggende weke delen kunnen onvoldoende steun geven aan het implantaat of kunnen in de loop der tijd achteruitgaan, waardoor instabiliteit kan ontstaan of misvorming kan optreden. De voordelen van operatieve implantatie kunnen niet overeenkomen met de verwachtingen van de patiënt of het implantaat kan na verloop van tijd achteruitgaan, waardoor revisie ter vervanging van het implantaat of alternatieve ingrepen noodzakelijk kunnen worden. Revisies van implantaties zijn niet ongebruikelijk.

VOORZORGSMAATREGELEN
1. Het implantaat wordt steriel in een onbeschadigde verpakking geleverd. Als het implantaat of de verpakking beschadigd lijkt of de vervaldatum is verstreken, of als de steriliteit om enige reden wordt betwijfeld, dan mag het implantaat niet worden gebruikt. **Niet opnieuw steriliseren.**
2. Implantaten moeten worden gehanteerd met stompe instrumenten om te voorkomen dat krassen, sneden of bramen op de prothese ontstaan die het functioneren ervan nadelig kunnen beïnvloeden. Gepolijste lageroppervlakken en taps toelopende vlakken mogen niet in aanraking komen met harde of schurende oppervlakken.
3. De kop en steel mogen niet worden geïmplanteerd als de articulerende oppervlakken mogelijk beschadigd zijn; dit is ook het geval bij herhaald aanbrengen en wegnemen.
4. De kop van de prothese wordt op de bal van de steel geïmpacteerd. Controleer, alvorens de groep samen te stellen, of de articulaire vlakken droog en vrij van verontreinigingen zijn.

COMPLICATIES
Potentiële complicaties beschreven met gewrichtsimplantaten zijn onder meer pijn, losraken, breuk, dislocatie of infectie. Er zijn patiënten beschreven met metaalovergevoeligheid na een gewrichtsvervanging. Implantatie van materialen als kobaltchroom en/of titaan kunnen een reactie op lichaamsvreemde voorwerpen naast de implantatiepiaats tot gevolg hebben. Er kan letsel van de omringende zenuwen, bloedvaten, pezen of weke delen optreden als gevolg van implantatie van deze prothese.

CHIRURGISCHE PROCEDURES
Er is een chirurgische procedure bij gebruik van dit implantaat verkrijgbaar. Het valt onder de verantwoordelijkheid van de chirurg om, voorafgaand aan gebruik van deze producten, vertrouwd te zijn met de procedure. Daarnaast valt het onder de verantwoordelijkheid van de chirurg om vertrouwd te zijn met de relevante publicaties en voorafgaand aan gebruik advies te vragen aan ervaren collegae omtrent de procedure.

INFORMATIE OVER ADVISERING VAN DE PATIËNT (zie ook Waarschuwingen)
Het is noodzakelijk om elke patiënt die implantatie zal ondergaan tevoren documentatie en advies te geven betreffende de potentiële complicaties en alternatieven, waaronder mogelijk het afzien van implantatie, bijvoorbeeld reconstructie van weke deie of artrodese. Naast de patiëntgerelateerde informatie in het onderdeel Waarschuwingen en het onderdeel Complicaties moet de volgende informatie aan de patiënt kenbaar worden gemaakt. 1) Complicaties kunnen een nieuwe ingreep, revisie of fusie van het betreffende gewricht noodzakelijk maken. 2) Hoewel de verwachte levensduur van de onderdelen van de gewrichtsvervanging moeilijk is te schatten, is deze eindig. Deze onderdelen zijn gemaakt van lichaamsvreemd materiaal en worden in het lichaam ingebracht om, waar mogelijk, de mobiliteit te herstellen of de pijn te verminderen. Als gevolg van de diverse biologische, mechanische en fysiochemische factoren die invloed hebben of een dergelijke prothese, kan van de onderdelen niet worden verwacht dat ze gedurende onbeperkte tijd de mate van activiteit en de belasting van normaal gezond bot kunnen weerstaan.

STERILISATIE
Dit onderdeel is gesteriliseerd door middel van ethyleenoxide of gammastraling. Het implantaat wordt steriel en in een onbeschadigde verpakking geleverd. Als het implantaat of de verpakking beschadigd lijkt of de vervaldatum is verstreken, of als de steriliteit om enige reden wordt betwijfeld, dan mag het implantaat niet worden gebruikt. **Niet opnieuw steriliseren.** Er zijn profondordelen verkrijgbaar, zodat de steriele verpakking voorafgaand aan de prothese-implantatie niet hoeft te worden geopend. Het implantaat mag uitsluitend uit de steriele verpakking worden genomen nadat de implantatiepiaats is voorbereid en grondig is opgemeten.

BEPERKTE GARANTIE
Avanta Orthopaedics, Inc. garandeert dat dit product ten tijde van de levering voldoet aan de specificaties van de fabrikant en vrij is van productiefouten. Deze garantie sluit specifiek defecten uit die het gevolg zijn van verkeerd gebruik, misbruik of verkeerde omgang met het product na ontvangst door de koper. Avanta Orthopaedics, Inc. geeft geen garanties omtrent de uitkomst van de chirurgische ingreep.

VERTEGENWOORDIGER BINNEN DE EU
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Nederland
0031 416 563754

ITALIANO

ATTENZIONE
La legge federale (degli Stati Uniti) limita la vendita, la distribuzione e l'uso del presente dispositivo al personale medico o al caso di prescrizione medica.

DESCRIZIONE
La presente protesi rHead Recon è costituita da uno stelo e da una testa in lega di cobalto-cromo con inserto articolare in polietilene. Lo stelo dell'impianto è stato progettato per l'inserimento nel fusto del radio prossimale. La testa dell'impianto si articola nel capitello. L'impianto è disponibile in varie misure, ciascuna delle quali può essere utilizzata per la mano destra o sinistra. Inoltre, a ogni tipo viene abbinata una serie di calibratori di prova, che possono fornire un ausilio per la preparazione dell'osso.

Materiali:
- Lega ASTM F-1537 di cobalto-cromo-molibdeno per la lavorazione plastica di impianti chirurgici
- Polveri di titanio ASTM F-1580 per il rivestimento di impianti chirurgici
- Componenti in polvere di polietilene ASTM F-648 ad altissimo peso molecolare per la realizzazione di impianti chirurgici.

INDICAZIONI
rHead Recon impiant è destinato alla sostituzione dell'estremità prossimale del radio:
1. Sostituzione della testa radiale in seguito a disabilità degenerative o post-traumatiche caratterizzate da dolore, crepitazione o mobilità ridotta dell'articolazione radio-omerale e/o radio-ulnare prossimale con:
   a. distruzione o sublussazione dell'articolazione visibile ai raggi x
   b. resistenza al trattamento conservativo
2. Sostituzione primaria dopo la frattura della testa radiale
3. Sequele sintomatiche dopo la resezione della testa radiale

CONTROINDICAZIONI
1. Apparato cutaneo o muscolo-tendineo inadeguato
2. Pazienti in crescita con epifisi aperte
3. Frattura aperta o infezione pregressa all'interno o intorno all'articolazione
4. Accertata ipersensibilità ai materiali impiegati in questo dispositivo

AVVERTENZE (Si veda anche la Sezione relativa alle Informazioni per la Consulenza al Paziente)
I carichi particolarmente pesanti, la mobilità eccessiva e l'instabilità articolare possono accelerare l'usura e determinare l'eventuale danno della protesi per allentamento, frattura o dislocazione. Si raccomanda di informare i pazienti sulla maggiore probabilità che si verifichi tale evenienza, se vengono esercitate sollecitazioni eccessive.
Gli impianti sono dispositivi meccanici esposti a usura, sforzo o rottura. Il sito di un impianto potrebbe essere colpito da infezione, procurare dolore, gonfiarsi o infiammarsi. Lo stato dell'osso adiacente e del tessuto molle potrebbe risultare inadeguato a sostenere l'impianto, oppure potrebbe deteriorarsi nel corso del tempo evidenziando instabilità, deformità o entrambi i problemi. I benefici della chirurgia implantologica potrebbero non soddisfare le aspettative del paziente o deteriorarsi nel corso del tempo, richiedendo un intervento di revisione per sostituire l'impianto o l'esecuzione di procedure alternative. Le operazioni chirurgiche di revisione non sono infrequenti.

PRECAUZIONI
1. L'impianto viene fornito sterile in confezione integra. Non utilizzarlo se il dispositivo stesso o la confezione sembrano danneggiati, se è superata la data di scadenza o in caso di dubbi per qualsiasi motivo sulla sterilità della confezione. **Non risterilizzare.**
2. Manipolare gli impianti con strumenti smussati per evitare graffi, tagli o incisioni che ne comprometterebbero il funzionamento. Le superfici lucidate del cono e del supporto non devono venire a contatto con parti dure o abrasive.
3. Non impiantare la testa e lo stelo, qualora le superfici di articolazione dovessero presentare danni dovuti anche al ripetuto attacco e distacco.
4. La testa della protesi s'incastra sulla sfera dello stelo. Prima dell'assemblaggio, accertarsi che le superfici di articolazione siano asciutte e prive di contaminanti.

EVENTI NEGATIVI
I potenziali eventi negativi resi noti in merito alle protesi articolari comprendono dolore, perdita, lussazione o infezione. Alcuni pazienti hanno riportato reazioni di ipersensibilità ai metalli dopo la sostituzione dell'articolazione. L'impianto di materiali come le leghe di cobalto-cromo e/o il titanio può determinare una reazione al corpo estraneo in prossimità del sito dell'impianto. In seguito, all'introduzione del presente dispositivo possono verificarsi lesioni ai nervi circostanti, ai vasi sanguigni, ai tendini o ai tessuti molli.

PROCEDURE CHIRURGICHE
È disponibile una procedura chirurgica destinata all'uso del presente dispositivo per impianto. E' responsabilità del chirurgo acquisire familiarità con tale procedura prima di utilizzare questi prodotti. Il chirurgo è altresì tenuto a conoscere la documentazione sull'argomento e a consultarsi con colleghi esperti in merito alla procedura prima di eseguire l'intervento.

INFORMAZIONI PER LA CONSULENZA AL PAZIENTE (Si vedano anche le Avvertenze)
Prima di effettuare l'intervento, ogni paziente in lista d'attesa per la chirurgia implantologica deve ricevere una consulenza documentata sulle potenziali complicanze e sulle alternative, che potrebbero comprendere procedure di non-impianto come la ricostruzione dei tessuti molli o l'artrodesi. Oltre alle informazioni specifiche, riportate nelle Avvertenze e negli Eventi negativi, si raccomanda di comunicare al paziente anche quanto segue: 1) L'eventuale insorgenza di eventi negativi potrebbe richiedere un secondo intervento, la revisione o la fusione dell'articolazione coinvolta. 2) I componenti sostitutivi dell'articolazione hanno una durata limitata che, purtroppo, risulta di difficile stima. Essi sono realizzati con materiali estranei, che vengono introdotti nel corpo per ripristinare la mobilità o ridurre il dolore. Tuttavia, considerando i molti fattori biologici, meccanici e fisicochimici legati a questi dispositivi, non si può partire dal presupposto che siano in grado di sostenere il livello di attività e i carichi di un osso normalmente sano per un periodo di tempo illimitato.

STERILIZZAZIONE
Il presente componente è stato sterilizzato con ossido di etilene o raggi gamma. L'impianto risulta sterile nella confezione integra. Non utilizzarlo se il dispositivo stesso o la confezione sembrano danneggiati, se è trascorsa la data di acadenza o se si dubita della sterilità per qualsiasi motivo. **Non risterilizzare.** Sono disponibili dei calibratori di prova per evitare l'apertura della confezione sterile prima d'impiantare la protesi. Prelevare l'impianto dalla confezione sterile solo dopo aver preparato e correttamente dimensionato il sito dell'impianto.

GARANZIA LIMITATA
Avanta Orthopaedics, Inc. garantisce che il presente prodotto risponde alle specifiche del fabbricante e non presenta difetti di lavorazione al momento della consegna. La presente garanzia esclude specificamente i difetti risultanti da uso improprio, abuso o manipolazione scorretta del prodotto dopo il ricevimento da parte dell'acquirente. Avanta Orthopaedics, Inc. non risponde per l'esito della procedura chirurgica.

RAPPRESENTANTE PER L'UE
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Paesi Bassi
31 (0) 416 563754

CE 0123

AVANTA
ORTHOPAEDICS
9369 Carroll Park Drive, Suite A, San Diego, CA 92121 USA
Tel: +1(858)452-8580 / (858)452-9943 (fax)

PRODUCT INSERT

AVANTA rHEAD RECON IMPLANT
AVANTA rHEAD RECON IMPLANTAT
IMPLANT AVANTA rHEAD RECON
IMPLANTE AVANTA rHEAD RECON
AVANTA rHEAD RECON IMPLANTAAT
IMPIANTO AVANTA rHEAD RECON

ENGLISH

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
This rHead Recon implant consists of a cobalt chromium stem and a cobalt chromium head with a polyethylene articulating insert. The stem of the implant is designed to be inserted into the shaft of the proximal radius. The head of the implant articulates with the capitellum. The implant is available in several sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation.

Materials:
- ASTM F-1537 wrought cobalt chromium molybdenum alloy for surgical implants
- ASTM F-1580 titanium powders for castings of surgical implants
- ASTM F-648 ultra-high molecular weight polyethylene powder fabricated form for surgical implants

INDICATIONS
rHead Recon Implant is intended for replacement of the proximal end of the radius:
1. Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:
   a. Joint destruction or subluxation visible on x-ray
   b. Resistance to conservative treatment
2. Primary replacement after fracture of the radial head
3. Symptomatic sequelae after radial head resection

CONTRAINDICATIONS
1. Inadequate skin or musculotendinous system
2. Growing patients with open epiphyses
3. Previous open fracture or infection in or around the joint
4. Known sensitivity to materials used in this device

WARNINGS (See also the Patient Counseling Information Section)
- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
- Implants are mechanical devices that can be worn away, fatigued or broken. An implant site may become infected, painful, swollen or inflamed. The status of the adjacent bone and soft tissue may be inadequate to support the implant, or may deteriorate in time resulting in instability, deformity, or both. The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

PRECAUTIONS
1. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. **Do not resterilize.**
2. Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance. Polished bearing and taper surfaces must not come in contact with hard or abrasive surfaces.
3. The head and stem should not be implanted if the articulating surfaces are possibly damaged, this includes repeated attaching and detaching.
4. The head of the prosthesis is impacted on to the ball of the stem. Prior to assembly confirm that the articular surfaces are dry and free from contaminant.

ADVERSE EVENTS
Potential adverse events reported with joint prostheses include pain, loosening, fracture, dislocation or infection. There have been some reports of patients with metal sensitivity reactions following joint replacement. Implantation of materials such as cobalt chrome and/or titanium may result in foreign body reaction adjacent to the implant site. Injury to the surrounding nerves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device.

SURGICAL PROCEDURES
A surgical procedure for use of this implant device is available. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings)
Providing each patient scheduled for implant surgery with documented counseling of potential complications and alternatives, which may include non-implant procedures such as soft tissue reconstruction or arthrodesis, prior to surgery is necessary. In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient: 1) Adverse effects may necessitate reoperation, revision, or fusion of the involved joint. 2) While the expected life of joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

STERILIZATION
This component has been sterilized by ethylene oxide or gamma radiation. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. **Do not resterilize.** Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics, Inc. warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics, Inc. does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

19-0366 rev. B

DEUTSCH

BESCHREIBUNG
Diese rHead Recon Prothese besteht aus einem Cobalt-Chrom-Schaft und einem Cobalt-Chrom-Kopf mit einem Gelenkeinsatz aus Polyethylen. Der Schaft des Implantats ist zum Einsetzen in den Schaft des proximalen Radius bestimmt. Der Kopf des Implantats artikuliert mit dem Humeruskӧpfchen. Das Implantat ist in mehreren Größen erhältlich, die jeweils für die linke oder die rechte Hand verwendet werden können. Zur Erleichterung der Knochenpräparation ist ein Satz Probeimplantate für jeden Implantattyp erhältlich.

Werkstoffe:
- Cobalt-Chrom-Molybdän-Knetlegierung für chirurgische Implantate gemäß ASTM F-1537
- Titanpulver für Beschichtungen von chirurgischen Implantaten gemäß ASTM F-1580
- Pulvergefertigte Form aus ultrahochmolekularem Polyethylen (UHMW-PE) für chirurgische Implantate gemäß ASTM F-648

ANWENDUNGSGEBIETE
Das rHead Recon Implantat ist zum Ersatz des proximalen Radiusendes bestimmt:
1. Ersatz des Radiusköpfchens bei degenerativen oder posttraumatischen Behinderungen mit Schmerzen, Crepitatio und Bewegungseinschränkung am Radiohumeral- und/oder proximalen Radioulnargelenk mit:
   a. Radiologisch sichtbarer Gelenkzerstörung oder Subluxation
   b. Resistenz gegenüber konservativer Behandlung
2. Primärersatz nach Fraktur des Radiusköpfchens
3. Symptomatische Folgeerscheinungen nach Radiusköpfchenresektion

GEGENANZIEGEN
1. Inadäquate Haut oder inadäquates Muskel-Sehnen-System
2. Im Wachstum begriffene Patienten mit offenen Epiphysen
3. Frühere offene Fraktur oder Infektion im Gelenk oder im Umkreis des Gelenks
4. Bekannte Überempfindlichkeit gegenüber den Implantatwerkstoffen

WARNHINWEISE (Siehe auch Abschnitt „Informationen zur Patientenberatung")
- Extreme Belastungen, übermäßige Mobilität und Gelenkinstabilität können zu frühzeitigem Verschleiß und eventuellem Versagen der Prothese durch Lockern, Brechen oder Verlagern führen. Der Patient sollte über das erhöhte Risiko eines Versagens der Prothese bei Überbeanspruchung aufgeklärt werden.
- Prothesen sind mechanische Produkte, die verschleißen, ermüden oder brechen können. An der Implantationsstelle können Infektionen, Schmerzen, Schwellungen oder Entzündungen auftreten. Das umliegende Knochen- oder Weichteilgewebe kann in einem Zustand sein, der keinen ausreichenden Halt für das Implantat bietet, oder kann sich mit der Zeit verschlechtern und dadurch eine Instabilität oder Deformität oder beides nach sich ziehen. Der Nutzen der Implantation kann unter Umständen den Erwartungen des Patienten nicht gerecht werden oder mit der Zeit abnehmen, sodass ein Revisionseingriff zum Austausch der Prothese oder zur Durchführung alternativer Verfahren erforderlich ist. Revisionseingriffe sind bei Prothesen nicht selten.

VORSICHTSMAßNAHMEN
1. Die Prothese wird steril in einer unbeschädigten Verpackung geliefert. Sollte entweder die Prothese oder die Verpackung beschädigt, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grunde zweifelhaft sein, darf die Prothese nicht verwendet werden. **Die Prothese nicht erneut sterilisieren.**
2. Prothesen sollten ausschließlich mit stumpfen Instrumenten gefasst werden, um Kratzer, Schnitte und Kerben auf der Prothese zu vermeiden. Polierte Gelenk- und Konusoberflächen dürfen nicht mit harten oder abrasiven Oberflächen in Kontakt kommen.
3. Der Kopf und der Schaft sollten nicht implantiert werden, wenn die Gelenkflächen möglicherweise beschädigt sind; dies ist auch bei wiederholtem Zusammensetzen und Zerlegen der Fall.
4. Der Kopf der Prothese wird auf die Kugel des Schafts geschlagen. Vor dem Zusammensetzen ist darauf zu achten, dass die Gelenkflächen trocken und sauber sind.

NEBENWIRKUNGEN
Bekannte mögliche Komplikationen bei Gelenkprothesen sind Schmerzen, Lockerung, Fraktur, Dislokation oder Infektionen. Bei einigen Patienten traten Überempfindlichkeiten gegen Metall nach dem Gelenkersatz auf. Die Implantation von Materialien wie Cobalt-Chrom und/oder Titan kann zu Fremdkörperreaktionen in der Umgebung der Implantationsstelle führen. Darüber hinaus können Verletzungen der umgebenden Nerven, Blutgefäße, Bänder oder Weichteile auftreten.

CHIRURGISCHE VERFAHREN
Ein Operationsverfahren zur Verwendung dieser Prothese ist erhältlich. Der Chirurg muss sich vor der Verwendung dieser Produkte mit dem Operationsverfahren vertraut machen. Außerdem liegt es in der Verantwortung des Chirurgen, vor der Verwendung dieser Produkte die relevanten Publikationen zu Rate zu ziehen und sich mit erfahrenen Kollegen über das Operationsverfahren auszutauschen.

INFORMATIONEN ZUR PATIENTENBERATUNG (Siehe auch Warnhinweise)
Vor der Operation muss jeder Patient schriftlich über potenzielle Komplikationen und mögliche Alternativen aufgeklärt werden. Hierzu können auch Maßnahmen ohne Prothesen, wie z.B. Weichteilrekonstruktionen oder Arthrodesen zählen. Zusätzlich zu den Patienteninformationen in den Abschnitten Warnhinweise und Komplikationen sollte der Patient über Folgendes informiert werden: 1) Komplikationen können eine neue Operation, einen Revisionseingriff oder eine Fusion des betroffenen Gelenks erfordern. 2) Die Lebensdauer der Gelenkersatz-Komponenten ist nur schwer vorherzusagen, in jedem Fall aber begrenzt. Die Komponenten bestehen aus körperfremdem Material und werden in den Körper eingepflanzt, um die Beweglichkeit möglichst wiederherzustellen und Schmerzen zu verringern. Aufgrund zahlreicher biologischer, mechanischer und physiochemischer Faktoren, die auf diese Komponenten einwirken, können diese dem Aktivitätsniveau und der Belastung eines gesunden Knochens nicht über einen unbegrenzten Zeitraum standhalten.

STERILISATION
Dieses Produkt wurde mit Ethylenoxid oder mit Hilfe von Gammastrahlen sterilisiert. Es wird steril in einer unbeschädigten Verpackung geliefert. Sollte entweder die Prothese oder die Verpackung beschädigt, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grunde zweifelhaft sein, darf die Prothese nicht verwendet werden. **Die Prothese nicht erneut sterilisieren.** Um die sterile Verpackung nicht zur Feststellung der richtigen Größe der Prothese vor der Implantation öffnen zu müssen, stehen Probeimplantate zur Verfügung. Die Prothese darf erst dann aus der sterilen Verpackung entnommen werden, wenn die Implantationsstelle ausreichend vorbereitet und die richtige Größe der Prothese ermittelt wurde.

EINGESCHRÄNKTE GEWÄHRLEISTUNG
Avanta Orthopaedics, Inc. garantiert, dass dieses Produkt den Spezifikationen des Herstellers entspricht und zum Zeitpunkt der Lieferung frei von Herstellungsfehlern ist. Diese Gewährleistung schließt ausdrücklich Schäden aus, die auf unsachgemäße Behandlung, Missbrauch oder falsche Verwendung durch den Benutzer zurückzuführen sind. Avanta Orthopaedics, Inc. gibt keine Gewährleistung für einen Erfolg des chirurgischen Eingriffs.

EU REPRÄSENTANT
Medical Products International Europe
Schutweg 13a
5145 NP Waalwijk, Die Niederlande
31 (0) 416 563754

FRANÇAIS

DESCRIPTION
Cette prothèse rHead Recon consiste en une tige et une tête en cobalt-chrome ainsi qu'en un module d'articulation en polyéthylène. La tige de l'implant est prévue pour une insertion dans le corps du radius proximal. La tête de l'implant s'articule sur le condyle de l'humérus. L'implant est disponible en plusieurs tailles, utilisables à la main droite ou gauche. Une série de calibreurs d'essai est disponible pour chaque type d'implant, en tant qu'assistance à la préparation osseuse.

Matériaux :
- Alliage de cobalt-chrome-molybdène façonné pour implants chirurgicaux (conforme à la norme ASTM F-1537)
- Poudres de titane pour enrobages d'implants chirurgicaux (conformes à la norme ASTM F-1580)
- Forme de poudre de polyéthylène à poids moléculaire ultra élevé frittée pour implants chirurgicaux (conforme à la norme ASTM F-648)

INDICATIONS
L'implant rHead Recon est prévu pour le remplacement de l'extrémité proximale du radius :
1. Remplacement de la tête radiale en raison d'incapacités dégénératives ou post-traumatiques accompagnées de douleur, crépitation et perte de mouvement de l'articulation radio-humérale et/ou radio-ulnaire proximale avec :
   a. Destruction de l'articulation ou subluxation visible aux rayons x
   b. Résistance à un traitement conservateur
2. Remplacement primaire après fracture de la tête radiale
3. Séquelles symptomatiques après résection de la tête radiale

CONTRE-INDICATIONS
1. Incompatibilité de la peau ou du système musculo-tendineux
2. Patients en cours de croissance et ayant des épiphyses ouvertes
3. Antécédent de fracture ouverte ou d'infection dans ou autour de l'articulation
4. Allergie avérée aux matériaux de ce dispositif

MISES EN GARDE (voir aussi la section Conseils donnés au patient)
- De fortes charges, une mobilité excessive et une instabilité articulaire peuvent accélérer l'usure du dispositif et entraîner un échec éventuel par relâchement, fracture ou dislocation. Il faut informer le patient de l'augmentation du risque d'échec du dispositif en cas de sollicitations excessives.
- Les implants sont des dispositifs mécaniques. En tant que tels, ils peuvent s'user ou se casser. Le site d'un implant peut devenir douloureux, enflammé, s'infecter ou s'enfler. Il se peut que l'état de l'os adjacent et des tissus mous ne permette pas la pose de l'implant ou se détériore avec le temps, entraînant une instabilité, une difformité ou les deux. Il se peut que les avantages de l'implantation ne répondent pas aux attentes du patient ou diminuent au fil du temps, nécessitant une chirurgie de révision afin de remplacer l'implant ou le recours à d'autres procédures. Il n'est pas rare de pratiquer une chirurgie de révision sur un implant.

PRÉCAUTIONS
1. L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant. **Ne pas restériliser.**
2. Les implants doivent être manipulés avec des instruments à bout mousse pour ne pas rayer, couper ou entailler le dispositif et ne pas perturber les performances de l'implant. Le palier poli et les surfaces coniques ne doivent pas entrer en contact avec des surfaces abrasives ou dures.
3. Il ne faut pas implanter la tête et la tige s'il y a un risque d'endommager les surfaces articulaires, notamment en cas de pose et de dépose répétées.
4. La tête de la prothèse est fixée sur la bille de la tige. Avant l'assemblage, vérifier que les surfaces articulaires sont sèches et qu'elles ne sont pas contaminées.

EFFETS INDÉSIRABLES
Les effets indésirables éventuels qui ont été rapportés avec des prothèses articulaires sont douleur, relâchement, fracture, luxation ou infection. Des cas de patients présentant des réactions d'allergie au métal suite à un remplacement d'articulation ont été rapportés. L'implantation de matériaux tels que le cobalt-chrome et/ou le titane peut entraîner une réaction au corps étranger adjacente au site de l'implant. L'implantation de ce dispositif peut avoir pour conséquence une lésion traumatique des nerfs, des vaisseaux sanguins, des tendons ou des tissus mous.

PROCÉDURES CHIRURGICALES
Une procédure chirurgicale concernant l'utilisation de cet implant est disponible. La connaissance de cette procédure est de la responsabilité du chirurgien. Il incombe également au chirurgien de se tenir au courant des publications pertinentes et de consulter des confrères expérimentés au sujet de la procédure à utiliser.

CONSEILS DONNÉS AU PATIENT (Voir aussi Mises en garde)
Avant l'opération chirurgicale, il est nécessaire de fournir à chaque patient devant subir un implant des conseils et des informations sur les complications éventuelles et les solutions de remplacement, notamment la reconstruction de tissus mous ou l'arthrodèse. Outre l'information relative au patient contenue dans les sections Mises en garde et Effets indésirables, le patient doit recevoir l'information suivante : 1) Des effets indésirables peuvent nécessiter la réopération, la révision ou la fusion de l'articulation concernée. 2) Il est difficile d'estimer la durée de vie prévue des composants de remplacement d'articulation, mais ils ne sont pas inusables. Ces composants sont en effet fabriqués dans des matériaux étrangers au corps humain et implantés afin de restaurer la mobilité ou de réduire la douleur. Toutefois, en raison des nombreux facteurs biologiques, mécaniques et physio-chimiques qui affectent ces dispositifs, les composants ne peuvent pas supporter le même niveau d'activité et les mêmes charges qu'un os sain pendant une période illimitée.

STÉRILISATION
Ce composant a été stérilisé par oxyde d'éthylène ou rayons gamma. L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant. **Ne pas restériliser.** Des calibreurs d'essai sont disponibles : ils évitent d'ouvrir l'emballage stérile avant l'implantation de la prothèse. Il faut enlever l'implant de son emballage stérile uniquement après la préparation et la dimensionnement correct du site de l'implant.

GARANTIE LIMITÉE
Avanta Orthopaedics, Inc. garantit que ce produit est conforme aux spécifications du fabricant et qu'il est livré sans défaut de fabrication. Cette garantie exclut spécifiquement les défauts résultant d'une utilisation incorrecte ou abusive, ou d'une manipulation incorrecte du produit postérieure à la réception par l'acheteur. Avanta Orthopaedics, Inc. ne garantit pas l'issue de la chirurgie.

REPRÉSENTANT POUR L'UE
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Pays-Bas
31 (0) 416 563754

ESPAÑOL

DESCRIPCIÓN
La prótesis rHead Recon está compuesta de un vástago de cobalto-cromo y de una cabeza del mismo material, con una inserción articulante de polietileno. El vástago del implante ha sido diseñado para insertarse en el extremo proximal de la diáfisis del radio. La cabeza del implante articula con el capitellum. Este implante se suministra en varios tamaños, cada uno de los cuales puede aplicarse indistintamente para la mano derecha o izquierda. Con el propósito de facilitar la preparación del hueso, se suministra una gama de prótesis de prueba de distintos tamaños para cada tipo de implante.

Materiales:
- ASTM F-1537: Aleación forjada de cobalto-cromo-molibdeno para implantes quirúrgicos;
- ASTM F-1580: Polvo de titanio para el revestimiento de implantes quirúrgicos;
- ASTM F-648: Forma fabricada de polvo de polietileno de peso molecular ultraelevado para implantes quirúrgicos

INDICACIONES
El implante rHead Recon ha sido diseñado para la sustitución protésica de la epífisis proximal del radio:
1. Sustitución de la cabeza radial en caso de afecciones degenerativas o post-traumáticas que producen dolor, crepitación y restricción de la movilidad a nivel de la articulación húmero-radial y/o de la articulación radio-cubital proximal, con:
   a. Destrucción articular o subluxación visible a rayos X;
   b. Resistencia al tratamiento conservador;
2. Sustitución primaria en caso de fractura de la cabeza radial;
3. Tratamiento de secuelas sintomáticas post-resección de la cabeza radial.

CONTRAINDICACIONES
1. Condiciones inadecuadas de la piel o del sistema musculotendinoso;
2. Pacientes en edad de crecimiento, con epífisis abiertas;
3. Fractura abierta previa o infección en o alrededor de la articulación;
4. Hipersensibilidad conocida a los materiales utilizados para la fabricación de este implante.

ADVERTENCIAS (véase también la sección Información de asesoramiento para pacientes)
- La sobrecarga mecánica extrema, la movilidad excesiva y la inestabilidad articular pueden conducir a un desgaste acelerado y a un fallo eventual por aflojamiento, fractura o dislocación del implante. Deberá explicarse a los pacientes que el riesgo de fallo del dispositivo aumenta si éste es sometido a una sobrecarga mecánica excesiva.
- Los implantes son dispositivos mecánicos susceptibles de desgaste, fatiga de material o fractura. El sitio de implantación puede presentar infección, dolor, hinchazón o inflamación. La calidad del hueso y de los tejidos blandos adyacentes puede ser inadecuada para proporcionar sustentación al implante, o puede deteriorarse con el tiempo, pudiendo producirse inestabilidad, deformidad o ambas complicaciones. Los beneficios de la cirugía implantatoria pueden no satisfacer las expectativas del paciente o pueden aminorarse con el tiempo, haciendo necesaria la cirugía de revisión para sustituir el implante o para efectuar procedimientos alternativos. Las intervenciones de revisión de implantes no son infrecuentes.

PRECAUCIONES
1. El implante se suministra estéril en un envase intacto. No utilizar el producto si el implante o el envase están dañados, si la fecha de validez se ha sobrepasado, o si, por cualquier otra razón, se duda de la esterilidad. **No reesterilizar el producto.**
2. Los implantes deberán manipularse con instrumentos romos para evitar las rayaduras, los cortes o las melladuras, y para no alterar su funcionamiento. Las superficies pulimentadas de sostén o ahusadas no deben entrar en contacto con superficies duras ni abrasivas.
3. La cabeza y el vástago no deberán implantarse si se sospecha que sus superficies articulares puedan estar dañadas. Esto incluye el caso de su inserción y extracción reiteradas.
4. La cabeza de la prótesis se impacta sobre la esfera del vástago. Antes del montaje, comprobar que las superficies articulares estén secas y libres de sustancias contaminantes.

POSIBLES EVENTOS ADVERSOS
Entre las posibles eventos adversos observados en caso de implantación de artículaciones protésicas incluyen dolor, aflojamiento, fractura, dislocación o infección. Se han documentado algunos casos de pacientes con reacciones de hipersensibilidad al metal después de la sustitución articular. La implantación de materiales tales como el cobalto-cromo y/o el titanio puede traer como consecuencia una reacción ante un cuerpo extraño alrededor del sitio de implantación. Pueden producirse lesiones de los nervios, los vasos sanguíneos, los tendones o los tejidos blandos circundantes como consecuencia de la implantación de este dispositivo.

PROCEDIMIENTOS QUIRÚRGICOS
Se suministra una descripción del procedimiento quirúrgico a aplicar para la implantación del producto. El cirujano tiene la responsabilidad de familiarizarse con el procedimiento quirúrgico antes de usar estos productos. Él tiene, además, la responsabilidad de mantenerse informado de las publicaciones científicas relevantes al respecto y de consultar a expertos acerca del procedimiento, antes de la aplicación clínica del producto.

INFORMACIÓN DE ASESORAMIENTO PARA PACIENTES (véase también la sección Advertencias)
Antes de la intervención, es indispensable asegurarse que todo paciente que haya de someterse a la cirugía de implantación reciba una documentada asesoría acerca de las complicaciones potenciales y sobre las posibles intervenciones alternativas, las cuales pueden incluir procedimientos sin implante, tales como la reconstrucción de tejidos blandos o la artrodesis. Además de la información contenida en los apartados "Advertencias" y "Eventos adversos", debe proporcionarse al paciente la siguiente información: 1) Las reacciones adversas pueden hacer necesaria la reoperación, la revisión o eventualmente la fusión de la articulación comprometida, y 2) Si bien la vida útil que cabe esperar de los componentes articulares protésicos es difícil de estimar, ésta no es infinita. Estos componentes están hechos de materiales extraños al organismo y se colocan para restablecer la movilidad o para reducir el dolor. En todo caso, debido a la gran cantidad de factores biológicos, mecánicos y fisicoquímicos que afectan a estos dispositivos, no puede esperarse que resistan el mismo nivel de actividad y las sobrecargas mecánicas que el hueso normal sano durante un período de tiempo ilimitado.

ESTERILIZACIÓN
Este componente ha sido esterilizado con óxido de etileno o por rayos gamma. El implante se suministra esterilizado y en un envase intacto. No utilizar el producto si el implante o el envase están dañados, si la fecha de validez se ha sobrepasado, o si, por cualquier otra razón, se duda de la esterilidad. **No reesterilizar el producto.** Se dispone de componentes de prueba para que el cirujano no tenga que abrir el envase estéril hasta el momento mismo de implantar la prótesis. El implante deberá sacarse de su envase estéril solamente después de que el sitio de implantación haya sido completamente preparado y después de haber determinado apropiadamente el tamaño requerido.

GARANTÍA LIMITADA
Avanta Orthopaedics, Inc. garantiza que, en el momento de su entrega, este producto cumple las especificaciones del fabricante y está libre de defectos de fabricación. La presente garantía excluye específicamente los fallos que resulten como consecuencia del uso indebido, del abuso o de la manipulación incorrecta del producto, con posterioridad a su recepción por parte del comprador. Avanta Orthopaedics, Inc. no garantiza el resultado del procedimiento quirúrgico.

REPRESENTANTE EN LA UE
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Países Bajos
31 (0) 416 563754

NEDERLANDS

BESCHRIJVING
De rHead Recon prothese bestaat uit een steel van kobaltchroom en een kop van kobaltchroom met een articulerend inzetstuk van polyethyleen. De steel van het implantaat dient om te worden ingebracht in de schacht van de proximale radius. De kop van het implantaat articuleert met het capitulum. Het implantaat is in verschillende maten verkrijgbaar, die elk in de rechter- of linkerhand kunnen worden toegepast. Voor elk type implantaat is een reeks proefonderdelen voor dimensionering verkrijgbaar als hulp bij de botpreparatie.

Materiaal:
- ASTM F-1537 gesmede legering van kobalt, chroom en molybdeen voor chirurgische implantaten
- ASTM F-1580 titaanpoeders voor het coaten van chirurgische implantaten
- ASTM F-648 UHMWP (ultra-high molecular weight polyethylene) vervaardigd in de vorm van een poeder voor chirurgische implantaten

INDICATIES
Het rHead Recon implantaat dient voor de vervanging van het proximale uiteinde van de radius:
1. Vervanging van de radiuskop vanwege degeneratieve of posttraumatische invaliditeit die gepaard gaat met pijn, crepitatie en verminderde beweeglijkheid van het radiusnumerale en/of proximale radio-ulnare gewricht en tevens:
   a. Gewrichtafbraak of subluxatie die zichtbaar is op een röntgenopname
   b. Ongeschiktheid voor een conservatieve behandeling
2. Primaire vervanging na een fractuur van de radiuskop
3. Symptomatische sequelae na resectie van de radiuskop

CONTRA-INDICATIES
1. Onvoldoende beschikbare huid of spieren/pezen
2. Patiënten in de groei met open epifysen
3. Een eerdere open fractuur of infectie in of rond het gewricht
4. Bekende overgevoeligheid voor in de prothese gebruikt materiaal

WAARSCHUWINGEN (zie ook het hoofdstuk Informatie voor patiëntvoorlichting)
- Zware belasting, overmatige mobiliteit en articulaire instabiliteit kunnen allemaal leiden tot versnelde slijtage en uiteindelijk falen door losraken, breuk of dislocatie van de prothese. Patiënten moet duidelijk worden gemaakt dat er een verhoogde kans op defect zaken van de prothese bestaat als deze wordt overbelast.
- Implantaten zijn mechanische hulpmiddelen die kunnen afsllten, onderworpen zijn aan materiaalmoeheid en kunnen breken. Een implantatieplaats kan geïnfecteerd, pijnlijk, gezwollen of ontstoken raken. Het nabuurige bot en de naastliggende weke delen kunnen onvoldoende steun geven aan het implantaat of kunnen in de loop der tijd achteruitgaan, waardoor instabiliteit kan ontstaan of kunnen in de loop der tijd achteruitgaan, waardoor revisie ter vervanging van het implantaat of alternatieve ingrepen noodzakelijk kunnen worden. Revisies van implantaties zijn niet ongebruikelijk.

VOORZORGSMAATREGELEN
1. Het implantaat wordt steriel in een onbeschadigde verpakking geleverd. Als het implantaat of de verpakking beschadigd lijkt of de vervaldatum is verstreken, of als de steriliteit om enige reden wordt betwijfeld, dan mag het implantaat niet worden gebruikt. **Niet opnieuw steriliseren.**
2. Implantaten moeten gehanteerd met stompe instrumenten om te voorkomen dat krassen, sneden of kerven op de prothese ontstaan die het functioneren ervan nadelig kunnen beïnvloeden. Gepolijste lageroppervlakken en taps toelopende vlakken mogen niet in aanraking komen met harde of schurende oppervlakken.
3. De kop en steel mogen niet worden geïmplanteerd als de articulerende oppervlakken mogelijk beschadigd zijn; dit is ook het geval bij herhaald aanbrengen en wegnemen.
4. De kop van de prothese wordt op de bal van de steel geïmpacteerd. Controleer, alvorens de groep samen te stellen, of de articulaire vlakken droog en vrij van verontreinigingen zijn.

MOGELIJKE BIJWERKINGEN
Potentiële complicaties beschreven met gewrichtsimplantaten zijn onder meer pijn, losraken, breuk, dislocatie of infectie. Er zijn patiënten beschreven met metaalovergevoeligheid na een gewrichtsvervanging. Implantatie van materialen als kobaltchroom en/of titaan kunnen een reactie op lichaamsvreemde voorwerpen naast de implantatieplaats tot gevolg hebben. Er kan letsel van de omringende zenuwen, bloedvaten, pezen of weke delen optreden als gevolg van implantatie van deze prothese.

CHIRURGISCHE PROCEDURES
Er is een chirurgische procedure voor gebruik van dit implantaat beschikbaar. Het valt onder de verantwoordelijkheid van de chirurg om, voorafgaand aan gebruik van deze producten, vertrouwd te zijn met de procedure. Daarnaast valt het onder de verantwoordelijkheid van de chirurg om vertrouwd te zijn met de relevante publicaties en voorafgaand aan gebruik advies te vragen aan ervaren collegae omtrent de procedure.

INFORMATIE VOOR PATIËNTVOORLICHTING (zie ook Waarschuwingen)
Het is noodzakelijk om elke patiënt die implantatie zal ondergaan, tevoren documentalie en advies te geven betreffende de potentiële complicaties en alternatieven, waaronder andere dan implantatie-ingrepen, zoals de reconstructie van weke delen of artrodese. Naast de patiëntgerelateerde informatie in het onderdeel Waarschuwingen en het onderdeel Complicaties moet de volgende informatie aan de patiënt kenbaar worden gemaakt: 1) Complicaties kunnen een nieuwe ingreep, revisie of fusie van het betreffende gewricht noodzakelijk maken. 2) Hoewel de verwachte levensduur van de onderdelen van de gewrichtsvervanging moeilijk is te schatten, is deze eindig. Deze onderdelen zijn gemaakt van lichaamsvreemd materiaal en worden in het lichaam ingebracht om, waar mogelijk, de mobiliteit te herstellen of de pijn te verminderen. Als gevolg van de diverse biologische, mechanische en fysiochemische factoren die invloed hebben op een dergelijke prothese, kan van de onderdelen niet worden verwacht dat ze gedurende onbeperkte tijd de mate van activiteit en de belasting van normaal gezond bot kunnen weerstaan.

STERILISATIE
De onderdeel is gesteriliseerd door middel van ethyleenoxide of gammastraling. Het implantaat wordt steriel en in een onbeschadigde verpakking geleverd. Als het implantaat of de verpakking beschadigd lijkt of de vervaldatum is verstreken, of als de steriliteit om enige reden wordt betwijfeld, dan mag het implantaat niet worden gebruikt. **Niet opnieuw steriliseren.** Er zijn proefonderdelen verkrijgbaar, zodat de steriele verpakking voorafgaand aan de prothese-implantatie niet hoeft te worden geopend. Het implantaat mag uitsluitend uit de steriele verpakking worden genomen nadat de implantatieplaats is voorbereid en het implantaat is gedimensioneerd.

BEPERKTE GARANTIE
Avanta Orthopaedics, Inc. garandeert dat dit product ten tijde van de levering voldoet aan de specificaties van de fabrikant en vrij is van productiefouten. Deze garantie sluit specifiek defecten uit die het gevolg zijn van verkeerd gebruik, misbruik of verkeerde omgang met het product na ontvangst door de koper. Avanta Orthopaedics, Inc. geeft geen garanties omtrent de uitkomst van de chirurgische ingreep.

EU-VERTEGENWOORDIGER
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Nederland
31 (0) 416 563754

ITALIANO

DESCRIZIONE
La presente protesi rHead Recon è costituita da uno stelo e da una testa in lega di cobalto-cromo con inserto articolare in polietilene. Lo stelo dell'impianto è stato progettato per l'inserimento nel fusto del radio prossimale. La testa dell'impianto si articola nel capitello. L'impianto è disponibile in varie misure, ciascuna delle quali può essere utilizzata per la mano destra o sinistra. Inoltre, a ogni tipo viene abbinata una serie di calibratori di prova, che possono fornire un ausilio per la preparazione dell'osso.

Materiali:
- Lega ASTM F-1537 di cobalto-cromo-molibdeno per la lavorazione plastica di impianti chirurgici
- Polveri di titanio ASTM F-1580 per il rivestimento di impianti chirurgici
- Componenti in polvere di polietilene ASTM F-648 ad altissimo peso molecolare per la realizzazione di impianti chirurgici

INDICAZIONI
L'impianto rHead Recon è destinato alla sostituzione dell'estremità prossimale del radio.
1. Sostituzione della testa radiale in seguito a disabilità degenerative o post-traumatiche caratterizzate da dolore, crepitazione o mobilità ridotta dell'articolazione radio-omerale e/o radio-ulnare prossimale con:
   a. distruzione o sublussazione dell'articolazione visibile ai raggi x
   b. resistenza al trattamento conservativo
2. Sostituzione primaria dopo la frattura della testa radiale
3. Sequele sintomatiche dopo la resezione della testa radiale

CONTROINDICAZIONI
1. Apparato cutaneo o muscolo-tendineo inadeguato
2. Pazienti in crescita con epifisi aperte
3. Frattura aperta o infezione pregressa all'interno o intorno all'articolazione
4. Accertata ipersensibilità ai materiali impiegati in questo dispositivo

AVVERTENZE (Si veda anche la sezione Informazioni per la consulenza ai pazienti)
- I carichi particolarmente pesanti, la mobilità eccessiva e l'instabilità articolare possono accelerare l'usura e determinare l'eventuale danno della protesi per allentamento, frattura o dislocazione. Si raccomanda di informare i pazienti sulla maggiore probabilità che si verifichi tale evenienza, se gli impianti vengono sottoposti a sollecitazioni eccessive.
- Gli impianti sono dispositivi meccanici esposti a usura, sforzo o rottura. Il sito di un impianto potrebbe essere colpito da infezione, procurare dolore, gonfiarsi o infiammarsi. Lo stato dell'osso e dei tessuti molli adiacenti potrebbe risultare inadeguato a sostenere l'impianto, oppure potrebbe deteriorarsi nel corso del tempo evidenziando instabilità, deformità o entrambi i problemi. I benefici della chirurgia implantologica potrebbero non soddisfare le aspettative del paziente o deteriorarsi nel corso del tempo, richiedendo un intervento di revisione per sostituire l'impianto o l'esecuzione di procedure alternative. Le operazioni chirurgiche di revisione non sono infrequenti.

PRECAUZIONI
1. L'impianto viene fornito sterile in confezione integra. Non utilizzarlo se il dispositivo stesso o la confezione sembrano danneggiati, se è superata la data di scadenza o se si dubita della sterilità per qualsiasi motivo. **Non risterilizzare.**
2. Manipolare gli impianti con strumenti smussati per evitare graffi, tagli o incisioni che ne comprometterebbero il funzionamento. Le superfici lucidate del cono e del supporto non devono venire a contatto con parti dure o abrasive.
3. Non impiantare la testa e lo stelo, qualora le superfici di articolazione dovessero presentare danni dovuti anche al ripetuto attacco e distacco.
4. La testa della protesi s'incastra sulla sfera dello stelo. Prima dell'assemblaggio, accertarsi che le superfici di articolazione siano asciutte e prive di contaminanti.

EVENTI AVVERSI
I potenziali eventi avversi resi noti in merito alle protesi articolari comprendono dolore, perdita, lussazione o infezione. Alcuni pazienti hanno riportato reazioni di ipersensibilità ai metalli dopo la sostituzione dell'articolazione. L'impianto di materiali come le leghe di cobalto-cromo e/o il titanio può determinare una reazione al corpo estraneo in prossimità del sito dell'impianto. In seguito, all'introduzione del presente dispositivo possono verificarsi lesioni ai nervi ai vasi sanguigni, ai tendini o ai tessuti circostanti.

PROCEDURE CHIRURGICHE
È disponibile una procedura chirurgica destinata all'uso del presente dispositivo per impianto. E' responsabilità del chirurgo acquisire famigliarità con tale procedura prima di utilizzare questi prodotti. Il chirurgo è altresì tenuto a conoscere la documentazione sull'argomento e a consultarsi con colleghi esperti in merito alla procedura prima di eseguire l'intervento.

INFORMAZIONI PER LA CONSULENZA AI PAZIENTI (Si vedano anche le Avvertenze)
Prima di effettuare l'intervento, ogni paziente in lista d'attesa per la chirurgia impiantologica deve ricevere una consulenza documentata sulle potenziali complicanze e sulle alternative, che potrebbero comprendere procedure diverse dall'impianto come la ricostruzione dei tessuti molli o l'artrodesi. Oltre alle informazioni specifiche, riportate nelle Avvertenze e negli Eventi avversi, si raccomanda di comunicare al paziente anche quanto segue: 1) l'eventuale insorgenza di eventi avversi potrebbe richiedere un secondo intervento, la revisione o la fusione dell'articolazione coinvolta. 2) i componenti sostitutivi dell'articolazione hanno una durata limitata che, purtroppo, risulta di difficile stima. Essi sono realizzati con materiali estranei, che vengono introdotti nel corpo per ripristinare la mobilità o ridurre il dolore. Tuttavia, considerando i molti fattori biologici, meccanici e fisicochimici legati a questi dispositivi, non si può partire dal presupposto che siano in grado di sostenere il livello di attività e i carichi di un osso sano per un periodo di tempo illimitato.

STERILIZZAZIONE
Il presente componente è stato sterilizzato con ossido di etilene o raggi gamma. L'impianto risulta sterile nella confezione integra. Non utilizzarlo se il dispositivo stesso o la confezione sembrano danneggiati, se è trascorsa la data di scadenza o se si dubita della sterilità per qualsiasi motivo. **Non risterilizzare.** Sono disponibili dei calibratori di prova per evitare l'apertura della confezione sterile prima d'impiantare la protesi. Prelevare l'impianto dalla confezione sterile solo dopo aver preparato e correttamente dimensionato il sito dell'impianto.

GARANZIA LIMITATA
Avanta Orthopaedics, Inc. garantisce che il presente prodotto risponde alle specifiche del fabbricante e non presenta difetti di lavorazione al momento della consegna. La presente garanzia esclude specificamente i difetti risultanti da uso improprio, abuso o manipolazione scorretta del prodotto dopo il ricevimento da parte dell'acquirente. Avanta Orthopaedics, Inc. non risponde dell'esito della procedura chirurgica.

RAPPRESENTANTE PER L'UE
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Paesi Bassi
31 (0) 416 563754

CE 0123

AVANTA
ORTHOPAEDICS
8399 Camino Del Oro, Suite A, San Diego, CA 92121 USA
(858)452-8580 | (858)452-9945 (fax)

PRODUCT INSERT

Avanta CMC Prosthesis
Avanta CMC Prothese
Prothese Avanta CMC
Protesis Avanta CMC
Avanta CMC prothese
Protesi Avanta CMC

ENGLISH

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
The Avanta CMC Trapezio-metacarpal joint prosthesis consists of an ultra-high molecular weight polyethylene (UHMWPe) component which is cemented to the prepared trapezium, and a titanium alloy stem component with integral head which is inserted into the shaft of the first metacarpal. The titanium head articulates with the UHMWPe component to form a snap-fit constrained prosthetic replacement for the basal thumb joint. The implant is available in three sizes, each of which can be used in right or left hands. A range of trial sizes for each type of implant is available to aid in bone preparation.

Materials:
- ASTM F-136 Titanium 6AL-4V ELI alloy metacarpal stem/head
- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) trapezial component
- ASTM F-75 cobalt chromium radiographic marker wire

INDICATIONS
The Avanta CMC Trapezio-metacarpal prosthesis is indicated for total joint replacement in skeletally mature patients with pain or instability of the trapezio-metacarpal joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

CONTRAINDICATIONS
- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation which cannot provide adequate support or fixation for the prosthesis.
- Any active or suspected infection in or around the thumb joint.
- Skeletal immaturity.

WARNINGS (See also the Patient Counseling Information Section)
- This device is for cemented use only.
- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.

PRECAUTIONS
- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.

ADVERSE EVENTS
- Adverse events in a published series of 50 patients included loosening, transient radial neuritis, cement extrusion injury to the palmar digital nerves and de Quervain's tendinitis'.

Event	Number of events (n=50)
Loosening	5 (10,0 %)
Transient radial neuritis	2 (4,0 %)
Cement extrusion injury	1 (2,0 %)
De Quervain's tendinitis	6 (12,0 %)

- Potential adverse events reported with other finger joint prostheses include loosening, fracture dislocation, or infection of the implant. No additional significant adverse events have been reported to date during the marketing period of this device.
- Injury to the surrounding nerves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device.
- Metal sensitivity reaction have been reported following joint replacement.

CLINICAL RESULTS
Results of twenty-nine patients implanted with this device were reported'. Replacement was performed for arthritis, failure of attempted arthrodesis, previous Silastic or basal joint arthroplasty failure, or postparalytic fibrous ankylosis of the joint. Twenty-two patients had achieved a good range of painless motion at the time of publication up to 7 years follow-up). Seven cases failed to achieve normal ROM due to significant muscle imbalance or soft tissue scarring and contracture. There were no reported cases of implant fracture or infection, but three cases demonstrated loosening at the cement-bone interface.

In a subsequent expanded publication including an additional 21 cases in the series', most of the 50 patients showed a full range of motion within four weeks of suture removal and continued to demonstrate good long-term results. Full range of asymptomatic motion was achieved in 26 osteoarthritic patients with articular derangement. Five patients showed clinical or radiographic evidence of loosening. No cases of implant fracture, surface wear, fragmentation or infection were seen.

SURGICAL PROCEDURES
A manual is available describing detailed surgical procedure for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings)
In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

- While the expected life of total joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time. The reported rate of loosening in a clinical study of this device was 10% at up to 10 years follow-up. (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985;195:161-7.)
- Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION
- This componens has been sterilized by ethylene oxide or gamma radiation.
- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize.
- Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile packages only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics Corporation warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985 May;(195):161-7
Braun RM. Total joint replacement at the base of the thumb--preliminary report. Br J Hand Surg [Am] 1982 May; 7(1):45-51

DEUTSCH

BESCHREIBUNG
Die Trapezio-Metacarpal-Gelenkprothese Avanta CMC hat eine Komponente aus ultrahochmolekularem Polyethylen (UHMWPe), die in den präparierten Trapezknochen einzementiert ist, und eine Schaftkomponente aus Titanlegierung mit integriertem Kopf, die in den Schaft des ersten Metacarpal-Knochens zementiert verankert ist. Zwischen Titankopf und der UHMWPe-Komponente besteht eine gelenkige Verbindung (Artikulation), um einen gekoppelten prothetischen Ersatz mit einem „Snap-Fit"-Mechanismus für das Daumengrundgelenk zu bilden. Das Implantat ist in drei Größen verfügbar, die alle an der rechten oder linken Hand eingesetzt werden können. Für jeden Implantattyp gibt es eine Palette von Probeprothesen, die als Hilfsmittel für die Präparation des Knochens verwendet werden.

Materialien:
- Metacarpal-Schaft/Kopf aus Titanlegierung 6AL-4V ELI gemäß ASTM F-136
- Trapezialskomponente aus ultrahochmolekularem Polyethylen (UHMWPe) gemäß ASTM F-648
- Radiologischer Markierungsdraht aus Kobaltchrom gemäß ASTM F-75

ANWENDUNGSGEBIETE
Die Trapezio-Metacarpal-Prothese Avanta CMC ist indiziert als Totalgelenkersatz bei Personen mit ausgereifter Skelettentwicklung, die infolge von Traumen, entzündlicher oder degenerativer Erkrankung oder Revision früherer Prothesen an Schmerzen oder Instabilität des Trapezio-Metacarpal-Gelenkes leiden, und stellt eine Alternative zu Arthrodese oder rekonstruktiver Chirurgie dar.

GEGENANZEIGEN
- Durch Krankheit, Infektion oder früherem Implantation angegriffene Knochen, Muskulatur, Sehnen oder angrenzende Weichteile, die keine sichere Unterlage oder Fixierung für die Prothese bieten können.
- Aktive oder vermutete Infektion in oder an dem Daumengelenk.
- Unreife in der Skelettentwicklung.

WARNHINWEISE (siehe auch Abschnitt „Informationen zur Patientenberatung")
- Dieses Gerät ist nur zur zementierten Anwendung bestimmt.
- Starke Belastung, übermäßige Mobilität und Gelenkinstabilität können alle zu beschleunigtem Verschleiß und eventuellem Versagen durch Lockerung, Fraktur oder Dislokation der Prothese führen. Die Patienten sind auf das erhöhte Potenzial des Versagens der Prothese bei übermäßiger Belastung hinzuweisen.

VORSICHTSMAßNAHMEN
- Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn eine Beschädigung des Implantates oder der Verpackung vorzuliegen scheint, das Verfallsdatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden. Nicht resterilisieren.
- Sorgfältige Vorbereitung des Implantatlagers und die Wahl der richtigen Größe des Implantates erhöhen die Erfolgsaussichten der Implantation.
- Das Implantat ist erst aus seiner sterilen Verpackung zu entnehmen, wenn das Implantatlager vorbereitet und für die Größe des Implantats richtig dimensioniert ist.
- Bei der Handhabung des Implantats sind stumpfe Instrumente zu verwenden, um Kratzer, Schnitte oder Kerben auf dem Implantat zu vermeiden.

NEBENWIRKUNGEN
- Zu den Nebenwirkungen, die von 50 Patienten veröffentlicht wurden, gehörten Lockerung, transiente Neuritis des Nervus radialis, Verletzung der palmaren Fingernerven infolge von Zementextrusion und De-Quervain-Tendinitis':

Nebenwirkung	Anzahl der Nebenwirkungen (n = 50)
Lockerung	5 (10,0 %)
Transiente Neuritis des Nervus radialis	2 (4,0 %)
Verletzung durch Zementextrusion	1 (2,0 %)
De-Quervain-Tendinitis	6 (12,0 %)

- Zu den potenziellen Nebenwirkungen, über die bei anderen Fingergelenkprothesen berichtet wurde, gehören Lockerung des Implantats, Dislokation der Fraktur oder Infektion des Implantats. Seit der Markteinführung des Gerätes gab es bisher keine Berichte über weitere signifikante Nebenwirkungen.
- Verletzungen an den umgebenden Nerven, Blutgefäßen, Sehnen oder Weichteilen können infolge der Implantation dieses Gerätes auftreten.
- Nach Gelenkersatz wurde über Überempfindlichkeitsreaktionen auf Metall berichtet.

KLINISCHE ERGEBNISSE
Es gab Berichte über die Ergebnisse bei neunundzwanzig Patienten, denen das Gerät implantiert wurde'. Der Ersatz erfolgte wegen Arthritis, fehlgeschlagener versuchter Arthrodese, vorheriger fehlgeschlagener Arthroplastik mit Silastikprothese oder Totalgelenkersatz oder überser Ankylose des Gelenks nach Lähmung. Zweundzwanzig Patienten hatten zum Zeitpunkt der Veröffentlichung (Nachuntersuchungen bis zu 7 Jahre) einen zufriedenstellenden schmerzfreien Bewegungsspielraum erreicht. In sieben Fällen wurde wegen signifikanter Muskelunbalance, Weichteilvernarbungen oder -kontrakturen kein normaler Bewegungsspielraum (ROM) erreicht. Es gab keine Berichte über Fraktur- oder Infektionsfälle des Implantats, aber in drei Fällen kam es zu einer Lockerung an der Zement-Knochen-Grenze.

Im Rahmen einer späteren größeren Veröffentlichung, die 21 weitere Fälle umfasste', erreichten die meisten der 50 Patienten innerhalb von vier Wochen nach Nahtentfernung den vollen Bewegungsspielraum und zeigten gute Langzeitergebnisse. Bei 26 osteoarthritischen Patienten mit Gelenkverschiebung wurde der vollständige symptomfreie Bewegungsspielraum erreicht. Bei fünf Patienten zeigte sich klinisch oder radiologisch eine Lockerung des Implantats. Es waren keine Fälle von Implantatfraktur, Oberflächenverschleiß, Fragmentation oder Infektion festzustellen.

CHIRURGISCHE VERFAHREN
Ein Handbuch mit einer genauen Beschreibung des chirurgischen Verfahrens für den Einsatz dieser Implantatprothese ist verfügbar. Der Chirurg ist dafür verantwortlich, sich vor Anwendung dieses Medizinproduktes mit dem Verfahren vertraut zu machen. Der Chirurg ist weiterhin dafür verantwortlich, die einschlägigen Publikationen sorgfältig zu lesen und sich mit Berufskollegen zu beraten, die Erfahrung in der Anwendung dieses Verfahrens gesammelt haben.

INFORMATIONEN ZUR PATIENTENBERATUNG (Siehe auch Warnhinweise)
Neben den Patienteninformationen in den Abschnitten Warnhinweise und Nebenwirkungen sind den Patienten die nachfolgenden Informationen zu vermitteln:

- Die erwartete Lebensdauer der Komponenten des Totalgelenkersatzes ist zwar schwer zu bestimmen, aber bis ist begrenzt. Diese Komponenten sind aus Fremdstoffen gefertigt, die zur potenziellen Wiederherstellung der Mobilität und zur Verringerung der Schmerzen in den Körper implantiert werden. Aufgrund einer Vielzahl biologischer, mechanischer und physikalisch-chemischer Faktoren, die diese Prothesen beeinflussen, kann jedoch nicht erwartet werden, dass die Komponenten auf unbegrenzte Zeitdauer demselben Aktivitätsgrad und derselben Belastung standhalten wie der normale gesunde Knochen. Die in einer klinischen Studie über dieses Implantat ermittelte Lockerungsrate betrug 10 % nach einer Kontrolle von bis zu 10 Jahren. (Braun, RM, Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985; 195: 161-7.)
- Nebenwirkungen dieser Prothese können möglicherweise Reoperation, Revision oder Fusion des betroffenen Gelenkes erforderlich machen.

STERILISATION
- Diese Komponente wurde mit Ethylenoxid oder Gammabestrahlung sterilisiert.
- Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn eine Beschädigung des Implantats oder der Verpackung vorzuliegen scheint, das Verfallsdatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden. Nicht resterilisieren.
- Probeprothesen, sind verfügbar, um zu vermeiden, dass die sterile Verpackung vor der Implantation der Prothese geöffnet werden muss. Das Implantat darf erst aus der sterilen Verpackung entnommen werden, wenn das Implantatlager vorbereitet und für die Größe des Implantats richtig dimensioniert ist.

EINGESCHRÄNKTE GEWÄHRLEISTUNG
Avanta Orthopaedics Corporation gewährleistet, dass dieses Medizinprodukt die Spezifikationen des Herstellers erfüllt und bei der Lieferung keine Herstellungsfehler aufweist. Diese Gewährleistung schließt speziell Fehler aus, die auf nicht-bestimmungsgemäßen Gebrauch, Abusus oder unsachgemäße Handhabung des Medizinproduktes nach Eingang bei dem Käufer zurückzuführen sind. Avanta Orthopaedics übernimmt keine Gewährleistung für das Resultat der chirurgischen Methode.

EU-VERTRETER:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Die Niederlande
31 (0) 416 563754

Braun, RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop [Mai 1985]; (195):161-7
Braun, RM. Total joint replacement at the base of the thumb - preliminary report. Br J Hand Surg [Am] Mai 1982; 7(1): 45-51

FRANÇAIS

DESCRIPTION
La prothèse pour articulation trapézo-métacarpienne Avanta CMC est composée d'un matériau à base de polyéthylène à ultra haute masse moléculaire (UHMWPe) qui est cimenté sur le trapèze préalablement préparé, et d'un composant postérieur en alliage de titane avec tête intégrée qui est introduit dans le creux du premier metacarpe. La tête en titane est reliée à la pièce en UHMWPe de façon à former un substitut systématiquement adapté à l'articulation basale du pouce. L'implant existe en trois tailles, toutes utilisables sur la main gauche comme sur la main droite. Une gamme de calibreurs tests est proposée pour chaque type d'implant afin de contribuer à la préparation de l'os.

Matériaux :
- Tige/tête métacarpiennes en alliage de titane 6AL-4V ELI ASTM F-136
- Composant trapézien en polyéthylène à ultra haute masse moléculaire (UHMWPe) ASTM F-648
- Câble de marquage radiographique en chrome-cobalt ASTM F-75

INDICATIONS
La prothèse trapézio-métacarpienne Avanta CMC est indiquée pour le remplacement articulaire total chez les patients dont le développement osseux est arrivé à maturité et présentant une douleur ou une instabilité au niveau de l'articulation trapézio-métacarpienne en raison d'un traumatisme, d'une maladie inflammatoire ou dégénérative, ou en cas de renouvellement d'implantations antérieures. Il s'agit d'une solution alternative à l'arthrodèse ou à la chirurgie reconstructrice.

CONTRE-INDICATIONS
- La désintégration d'os, de muscles, de tendons ou de tissus mous voisins due à une maladie, une infection ou une implantation antérieure et empêchant d'obtenir un maintien ou une fixation satisfaisante de la prothèse.
- Toute infection active ou suspectée au niveau ou aux alentours de l'articulation du pouce.
- Une maturité osseuse non atteinte.

MISES EN GARDE (voir aussi la section Conseils donnés au patient)
- Ce dispositif est à utiliser uniquement dans le cadre d'une application cimentée.
- Les charges imposantes, les mouvements excessifs et l'instabilité articulaire sont tous susceptibles de provoquer le desserrement, la rupture ou la dislocation du dispositif et d'en précipiter ainsi l'usure et l'éventuel défaillance. Les patients doivent être avertis qu'il existe un risque accru de défaillance du dispositif en cas de sollicitations excessives.

PRÉCAUTIONS
- L'implant est fourni stérile, tant que l'emballage est intact. En cas de détérioration apparente de l'implant ou de son emballage, de dépassement de la date de péremption ou de doute sur la stérilité du dispositif pour quelque raison que ce soit, l'implant ne doit pas être utilisé. Ne pas re-stériliser.
- La préparation méticuleuse du site d'implantation et le choix d'une taille d'implant adéquate augmentent les chances de réussite de l'intervention.
- L'implant doit être sorti de son emballage stérile uniquement une fois le site d'implantation préparé et convenablement calibré.
- L'implant doit être manipulé à l'aide d'instruments arrondis afin d'éviter toute gerçure, coupure ou entaille.

EFFETS INDÉSIRABLES
- Les effets indésirables relevés chez une série de 50 patients ont publiée étaient notamment le desserrement, la névrite passagère du nerf radial, la lésion des nerfs digitaux palmaires liée à l'expulsion du ciment et la ténosynovite chronique sténosante du pouce de De Quervain'.

Événement	Nombre d'occurrences (n = 50)
Desserrement	5 (10,0 %)
Névrite passagere du nerf radial	2 (4,0 %)
Lésion liée à l'expulsion du ciment	1 (2,0 %)
Ténosynovite de De Quervain	6 (12,0 %)

- Les éventuels effets indésirables observés avec les autres prothèses articulaires des doigts sont, notamment, le desserrement, la rupture, la dislocation ou l'infection de l'implant. Aucun autre événement indésirable significatif n'a été rapporté à ce jour depuis le début de la période de commercialisation de ce dispositif.
- L'implantation de ce dispositif peut entraîner des lésions au niveau des nerfs, vaisseaux, tendons ou tissus mous environnants.
- Des cas de réaction allergique au métal suite à la substitution articulaire ont été relevés.

RÉSULTATS CLINIQUES
Les résultats de l'implantation de ce dispositif ont été observés chez vingt-neuf patients'. La substitution a été pratiquée en raison d'une arthrite, de l'échec d'une arthrodèse préalable, de l'échec de l'utilisation d'un implant en Silastic ou d'une arthroplastie articulaire totale, ou encore d'une ankylose fibreuse post-paralytique de l'articulation. À l'heure de la publication (après jusque 7 années de suivi), vingt-deux patients étaient en mesure d'accomplir sans douleur une palette satisfaisante de mouvements. Dans sept cas, le jeu de l'articulation demeurait anormal en raison d'un déséquilibre musculaire significatif ou de la cicatrisation des tissus mous et de contractures. Aucun cas de rupture ou d'infection de l'implant n'a été rapporté mais, dans trois cas, un desserrement a été noté au niveau de la jonction ciment/os.

À l'occasion d'un rapport publié ultérieurement, portant sur cette même série de cas auxquels s'ajoutaient 21 cas supplémentaires', il est apparu que la plupart des 50 patients étaient en mesure de faire jouer parfaitement leur articulation dans les quatre semaines suivant le retrait des fils de suture et présentaient toujours de bons résultats à long terme. Une marge complète de mouvement asymptomatique de l'articulation a été obtenue chez 26 patients arthritiques atteints de dérèglements articulaires. Dans cinq cas, l'examen clinique ou radiographique a fait apparaître un desserrement de l'implant. Aucun cas de rupture de l'implant, d'usure de surface, de morcellement ou d'infection n'a été relevé.

PROCÉDURES CHIRURGICALES
Il existe un manuel décrivant en détail l'intervention chirurgicale à pratiquer pour l'implantation de ces dispositifs. Le chirurgien est seul chargé de se familiariser avec l'intervention avant utilisation de ces produits, ainsi que de se tenir au courant des publications sur le sujet et de consulter des collègues expérimentés ayant de procéder à ces interventions.

CONSEILS DONNÉS AU PATIENT (voir aussi la section Mises en garde)
Les informations suivantes, en plus de celles communes dans les sections « Mises en garde » et « Effets indésirables », doivent être transmises au patient :

- La durée de vie des pièces de substitution articulaires totale est difficile à évaluer mais n'est, quoi qu'il en soit, pas éternelle. Ces pièces sont composées de matériaux étrangers à l'organisme et placés à l'intérieur de ce dernier en vue de rétablir la mobilité du membre ou de réduire la douleur. Cependant, étant donnés les nombreux facteurs biologiques, mécaniques et physiochimiques auxquels sont soumis les implants, il ne faut pas attendre des dispositifs qu'ils peuvent indéfiniment le même niveau d'activité et supportent le même niveau de charge qu'un os sain et normal. Lors d'un essai clinique de ce dispositif, le taux de cas de desserrement des implants après une période de suivi allant jusqu'à 10 ans était de 10 % (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985 ; 195 : 161-7).
- La survenue d'effets indésirables peut rendre nécessaire de réopérer, corriger l'opération ou procéder à la fusion de l'articulation concernée.

STÉRILISATION
- Ce dispositif a été stérilisé à l'oxyde d'éthylène ou aux rayons gamma.
- L'implant est fourni stérile tant que son emballage est intact. En cas de détérioration apparente de l'implant ou de son emballage, de dépassement de la date de péremption ou de doute sur la stérilité du dispositif pour quelque raison que ce soit, l'implant ne doit pas être utilisé. Ne pas re-stériliser.
- Des pièces de calibrage test sont mises à votre disposition afin de vous éviter d'avoir à ouvrir l'emballage stérile avant l'implantation de la prothèse. L'implant doit être sorti de son emballage stérile uniquement une fois le site d'implantation préparé et convenablement calibré.

GARANTIE LIMITÉE
Avanta Orthopaedics Corporation garantit que ce produit répond aux caractéristiques décrites par le fabricant et ne présente pas de défauts de fabrication au moment de la livraison. Cette garantie exclut spécifiquement les défauts provoqués par la mauvaise utilisation, l'utilisation excessive ou la manipulation inconsidérée du produit suite à sa réception par l'acquéreur. Avanta Orthopaedics n'offre aucune garantie quant aux résultats de l'intervention chirurgicale.

REPRÉSENTANT POUR L'UE :
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Pays-Bas
+31 (0) 416 563754

Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. In: Clin Orthop Mai 1985 ; 195: 161-7
Braun RM. Total joint replacement at the base of the thumb - preliminary report. Br J Hand Surg [Am] Mai 1982 ; 7(1) : 45-51

ESPAÑOL

DESCRIPCIÓN
La prótesis para la articulación trapeciometacarpiana Avanta CMC consta de un componente de polietileno de peso molecular ultra alto (UHMWPe), que se cementa al trapecio preparado, y un componente de vástago de aleación de titanio con una cabeza integral que se inserta dentro del eje del primer metacarpo. La cabeza de titanio se articula con el componente de UHMWPe formando un reemplazo protésico de ajuste exacto para la articulación de la base del pulgar. El implante se presenta en tres tamaños, cada uno de los cuales puede usarse en la mano derecha o en la mano izquierda. Para ayudar a preparar el hueso existe una serie de medidores de prueba para cada tipo de implante.

Materiales:
- Vástago/cabeza metacarpianos de aleación de titanio 6AL-4V ELI ASTM F-136
- Componente de trapecio de polietileno de peso molecular ultra alto, ASTM F-648
- Alambre marcador radiográfico de cobalto-cromo, ASTM F-75

INDICACIONES
La prótesis trapeciometacarpiana Avanta CMC está indicada para el reemplazo articular total en pacientes con estructura ósea madura, que presenten dolor o inestabilidad en la articulación trapeciometacarpiana debido a traumatismo, enfermedades inflamatorias o degenerativas o revisión de procedimientos anteriores, como alternativa a la artrodesis o a la cirugía reconstructiva.

CONTRAINDICACIONES
- Compromiso de los huesos, músculos, tendones o tejido blando adyacentes a causa de patologías, infección o implante previo, que no ofrezcan con una sustentación o fijación adecuadas para la prótesis.
- Toda infección activa o sospecha de infección en la articulación del pulgar o alrededor de la misma.
- Inmadurez ósea.

ADVERTENCIAS (véase también la sección sobre información de asesoramiento para pacientes)
- Este dispositivo es sólo para uso cementado.
- La carga y la movilidad excesivas y la inestabilidad articular pueden acelerar el desgaste y eventualmente provocar el fracaso del procedimiento por aflojamiento, fractura o dislocación del dispositivo. Se debe informar a los pacientes que una demanda excesiva sobre el dispositivo puede aumentar las posibilidades de fracaso.

PRECAUCIONES
- El implante se presenta estéril en un envase estéril. Si el implante o el envase están dañados, si ha transcurrido el período de validez o si por cualquier motivo se duda de su esterilidad, el implante no debería utilizarse. No volver a esterilizar.
- La preparación minuciosa de la zona de implantación y la elección de un implante del tamaño adecuado aumentan las probabilidades de éxito.
- El implante debe sacarse de su envase estéril sólo después de haber concluido la preparación de la zona de implantación y de haber determinado el tamaño correcto.
- Los implantes deben manipularse utilizando instrumentos romos para evitar rayaduras, cortes o marcas en el dispositivo.

EVENTOS ADVERSOS
- Los eventos adversos que se han informado en una serie publicada de 50 pacientes incluyen aflojamiento, neuritis radial transitoria, lesión por extrusión del cemento hacia los nervios digitales palmares y tendinitis de de Quervain[1].

Evento	Número de casos (n=50)
Aflojamiento	5 (10,0 %)
Neuritis radial transitoria	2 (4,0 %)
Lesión por extrusión del cemento	1 (2,0 %)
Tendinitis de Quervain	6 (12,0 %)

- Los potenciales eventos adversos que se han documentado con otras prótesis de articulación de dedos incluyen aflojamiento, fractura, dislocación o infección del implante. Hasta la fecha no se han documentado otros eventos adversos significativos durante el período de comercialización de este dispositivo.
- Como consecuencia del implante de este dispositivo se puede producir una lesión de los nervios, vasos sanguíneos, tendones y tejidos blandos que lo rodean.
- Se han documentado casos de reacción de sensibilidad al metal como consecuencia del reemplazo articular.

RESULTADOS CLÍNICOS
Se presentaron los resultados obtenidos con veintinueve pacientes a los cuales se les implantó el dispositivo[2]. Los reemplazos se realizaron a causa de artritis, fracaso del interno de artrodesis, fracaso de la artroplastia con prótesis de Silastic o articular total previa o anquilosis fibrosa postartrítica de la articulación. En artritis pacientes se había alcanzado un buen rango de movimiento sin dolor en el momento de la publicación (con un seguimiento de hasta 7 años). Siete de los pacientes no lograron alcanzar un rango de movimiento normal debido a un desequilibrio muscular significativo o a cicatrización y contractura del tejido blando. No se documentaron casos de fractura o infección del implante, pero hubo tres casos de aflojamiento en la unión entre el cemento y el hueso.

En una publicación posterior más extensa que incluyó otros veintiuno casos adicionales de la serie[3], la mayoría de los 50 pacientes alcanzó un rango de movimiento completo dentro de las cuatro semanas después de retirar los puntos de sutura y continuó demostrando buenos resultados a largo plazo. Se alcanzó un rango completo de movimiento asintomático en 26 pacientes osteoartríticos con trasfondo articular. En cinco pacientes se observaron evidencias clínicas o radiográficas de aflojamiento. No se observaron casos de fractura del implante, desgaste superficial, fragmentación o infección.

PROCEDIMIENTOS QUIRÚRGICOS
Existe un manual que describe en detalle el procedimiento quirúrgico para el uso de estos implantes. El cirujano familiarizar con el procedimiento antes de usar estos productos. También es responsabilidad del cirujano familiarizarse con las publicaciones relevantes y consultar con colegas experimentados acerca del procedimiento antes del empleo de estos implantes.

INFORMACIÓN DE ASESORAMIENTO PARA PACIENTES (véase también Advertencias)
Además de la información relativa al paciente que incluyen las secciones Advertencias y Eventos Adversos, se debe transmitir al paciente la siguiente información:

- Si bien resulta difícil estimar la duración prevista de los componentes del reemplazo articular total, ésta es finita. Estos componentes están realizados con materiales extraños que se colocan dentro del cuerpo para la potencial restauración de la movilidad o la reducción del dolor. No obstante, debido a múltiples factores biológicos, mecánicos y físicoquímicos que afectan a estos dispositivos, no es de aspirar que los componentes retengan el nivel de actividad y de carga que resulta un hueso normal sano durante un período ilimitado de tiempo. La tasa de aflojamiento que se documentó en un estudio clásico de este dispositivo fue del 10% en un seguimiento de hasta 10 años. (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985;195;161-7).
- Los efectos adversos pueden requerir una nueva operación, revisión o la fusión de la articulación afectada.

ESTERILIZACIÓN
- Este componente ha sido esterilizado con óxido de etileno y radiación gamma.
- El implante se presenta estéril en un envase intacto. Si el implante o el envase están dañados, si ha transcurrido el período de validez o si se duda de su esterilidad por alguna razón, no debe usarse el implante. No volver a esterilizar.
- Existen componentes medidores de prueba para evitar tener que abrir el envase estéril antes de implantar la prótesis. El implante debe extraerse de su envase estéril sólo después de que se haya preparado el lugar de colocación del implante y de que se haya determinado adecuadamente su tamaño.

GARANTÍA LIMITADA
Avanta Orthopaedics Corporation garantiza que este producto cumple con las especificaciones del fabricante y no contiene defectos de fabricación en el momento de su entrega. Esta garantía excluye específicamente los defectos que surjan de uso indebido, abuso o manipulación incorrecta del producto una vez recibido por el comprador. Avanta Orthopaedics no garantiza el resultado de la intervención quirúrgica.

REPRESENTANTE EN LA UNIÓN EUROPEA:
Medical Products International Europe, BV
Schurweg 13a
5145 NP Waalwijk, Países Bajos
31 (0) 416 563754

[1] Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop (1985 May)(195):161-7
[2] Braun RM. Total joint replacement at the base of the thumb - preliminary report. J Hand Surg [Am] (1982 May);7(3):245-51

DE DEUTSCH

BESCHRIJVING
De Avanta CMC trapeziometacarpale gewrichtsprothese bestaat uit een component van ultrahoog molecuulair gewicht polyethyleen (UHMWP), welke aan het voorbereide trapezium wordt gelijmd, en een uit een titaniumlegering bestaande steelcomponent met geïntegreerde kop welke in de achterlijf van de eerste metacarpals wordt gebracht. De titanium kop is door een gewricht verbonden met de component van UHMWP om zo een snap-fit constrained prothetische vervanging van het basisduimgewricht te vormen. Het implantaat is verkrijgbaar in drie maten, die allemaal kunnen worden gebruikt in de rechter- of linkerhand. Voor alle type implantaat is een serie proefmaten verkrijgbaar als hulp bij het voorbereiden van het bot.

Materialen:
- ASTM F-136 titanium 6AL-4V ELI legering metacarpale steel/kop
- ASTM F-648 trapezale component van ultrahoog molecular gewicht polyethyleen (UHMWP)
- ASTM F-75 kobalt/chroomen radiografische markeringsdraad

INDICATIES
De Avanta CMC trapeziometacarpale prothese is bestemd voor vervanging van het complete gewricht in patiënten met een volgroeid skelet met pijn of instabiliteit in het trapeziometacarpale gewricht door trauma, inflammatoire of degeneratieve aandoeningen of voor revisie van eerdere ingrepen, als alternatief voor artrodese of reconstructieve chirurgie.

CONTRA-INDICATIES
- Door ziekte, infectie of eerdere implantatie aangetast bot, musculatuur, pezen, of omliggend zacht weefsel, welke niet genoeg steun of bevestiging voor de prothese kunnen bieden.
- Actieve of vermoede infecties in of rond het duimgewricht.
- Onvolgroeidheid van het skelet.

WAARSCHUWINGEN (zie ook het hoofdstuk Informatie voor patiëntvoorlichting)
- Dit instrument is uitsluitend voor gelijmd gebruik.
- Zware belasting, overmatige beweeglijkheid en gewrichtsinstabiliteit kunnen aleraal leiden tot vervroegde slijtage en uiteindelijk kan het instrument het begeven door loslaten, breken of dislokatie. Patiënten dienen te worden gewezen op de verhoogde kans dat het instrument het begeeft wanneer er te hoge eisen aan worden gesteld.

VOORZORGSMAATREGELEN
- Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien ofwel het implantaat ofwel de verpakking beschadigd blijkt te zijn, de vervaldatum is overschreden, of om welke reden dan ook aan de sterliteit wordt getwijfeld, mag het implantaat niet worden gebruikt. Niet hersterliseren.
- Een nauwkeurige voorbereiding van de implantatieplaats en de keuze van de juiste maat implantaat vergroten de kans op een succesvol resultaat.
- Het implantaat mag pas uit zijn steriele verpakking worden gehaald zodra de implantatieplaats is voorbereid en de juiste afmetingen heeft.
- Om te voorkomen dat er in het instrument wordt gekrast, gesneden of gekerfd moeten implantaten met stompe instrumenten worden gehanteerd.

MOGELIJKE BIJWERKINGEN
- Bijwerkingen in een beschreven serie van 50 patiënten omvatten losgaan van het implantaat, tijdelijke radiale neuritis, letsel aan de vingerzenuwen in de handpalm door extrusie van het kleefmiddel en De Quervains tendinitis[1].

Bijwerking	Aantal gevallen (n = 50)
Losgaan van het implantaat	5 (10,0 %)
Tijdelijke radiale neuritis	2 (4,0 %)
Letsel door extrusie van het kleefmiddel	1 (2,0 %)
De Quervains tendinitis	6 (12,0 %)

- Mogelijke bijwerkingen die in combinatie met andere vingergewrichtsprotheses zijn gemeld omvatten losgaan, fractuurdislokatie, of infectie van het implantaat. Gedurende de periode dat dit instrument op de markt is zijn er geen verdere significante bijwerkingen gerapporteerd.
- Letsel aan de omliggende zenuwen, bloedvaten, pezen of zacht weefsel kan optreden als gevolg van de implantatie van het instrument
- Metaalgevoeligheidsreacties zijn gerapporteerd na vervanging van het gewricht.

KLINISCHE RESULTATEN
Er zijn resultaten van negenentwintig patiënten gerapporteerd die het instrument geïmplanteerd hebben gekregen[2]. Vervanging is uitgevoerd voor artritis, mislukte poging tot artrodese, eerdere mislukte elastische of totale gewrichtsartroplastiek, of postparalytische fibreuze ankylose van het gewricht. Op het moment van publicatie (tot 7 jaar follow-up) hadden tweeëntwintig patiënten een goed bereik van pijnloze beweging bereikt. In zeven gevallen werd geen normaal bewegingsbereik vanwege aanwezige significante ontsteking van de spieren of littekenvorming en contractuur van zacht weefsel. Er zijn geen gevallen gerapporteerd van breuk of infectie van het implantaat, maar drie gevallen vertoonden loslating van het implantaat op het grensvlak kleefmiddel-bot.

In een latere uitgebreidere publicatie, waarin nog eens 21 gevallen in de serie zijn opgenomen vertoonden de meeste van de 50 patiënten binnen vier weken na verwijdering van de hechtdraden een volledig bewegingsbereik en feiten ook daarna goede langetermijnresultaten zien. Een volledig bereik van asymptomatische beweging werd bereikt bij 26 osteoartritische patiënten met een gewrichtsstoornis. Vijf patiënten vertoonden klinisch of radiografisch bewijs van loslating. Er zijn geen gevallen van breuk van het implantaat, oppervlakslijtage, verschilmering of infectie geconstateerd.

CHIRURGISCHE PROCEDURES
Er is een handleiding verkrijgbaar waarin gedetailleerd de chirurgische procedure voor het gebruik van deze implantate-instrumenten wordt beschreven. Het is de verantwoordelijkheid van de chirurg dat hij vertrouwd is met de procedure voordat hij deze producten gebruikt. Daarnaast is het de verantwoordelijkheid van de chirurg dat hij voorafgaand aan het gebruik op de hoogte is van relevante publicaties en dat hij bij ervaren collega's advies inwint met betrekking tot de procedure.

INFORMATIE VOOR PATIËNTVOORLICHTING (zie ook Waarschuwingen)
Naast de patiëntgerelateerde informatie in de hoofdstukken Waarschuwingen en Bijwerkingen dient de volgende informatie te worden medegedeeld aan de patiënt:

- Hoewel de verwachte levensduur van componenten voor een complete gewrichtsvervanging moeilijk te schatten is, is deze beperkt. Deze componenten zijn gemaakt van vreemde materialen, die in het lichaam worden geplaatst voor mogelijk herstel van de mobiliteit of vermindering van pijn. Vanwege de vele biologische, mechanische en fysicochemische factoren die invloed op deze instrumenten uitoefenen, kan echter niet van deze componenten worden verwacht dat zij gedurende onbeperkte tijd bestand zijn tegen het activiteitenniveau en de belasting van normaal gezond bot. Het gerapporteerde percentage van loslatingen in een klassieke studie van dit instrument bedroeg 10% bij tot 10 jaar follow-up. (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985; 195: 161-7.)
- Door nadelige effecten kan heroperatie, revisie of fusie van het betreffende gewricht nodig zijn.

STERILISATIE
- Deze component is gesteriliseerd door middel van ethyleenoxide of gammastraling.
- Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien ofwel het implantaat ofwel de verpakking beschadigd blijkt te zijn, de vervaldatum is overschreden, of om welke reden dan ook aan de sterliteit wordt getwijfeld, mag het implantaat niet worden gebruikt. Niet hersterliseren.
- Proefmaatcomponenten zijn verkrijgbaar om te voorkomen dat de steriele verpakking voor de implantatie van de prothese moet worden geopend. Het implantaat mag pas uit zijn steriele verpakking worden gehaald zodra de implantatieplaats is voorbereid en de juiste afmetingen heeft.

BEPERKTE GARANTIE
Avanta Orthopaedics Corporation garandeert dat dit product beantwoordt aan de specificaties van de fabrikant en op het moment van levering geen productiefouten bevat. Uitgesloten van deze garantie zijn met name gebreken als gevolg van verkeerd gebruik, misbruik of een onjuiste bediening van het product nadat het door de koper is ontvangen. Avanta Orthopaedics geeft geen garantie op het resultaat van de chirurgische procedure.

EU-VERTEGENWOORDIGER:
Medical Products International Europe BV
Schurweg 13A
5145 NP Waalwijk, Nederland
+31 (0) 416 563754

[1] Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. In: Clin Orthop (mei) 1985(195):161-7
[2] Braun RM. Total joint replacement at the base of the thumb--preliminary report. In: J Hand Surg [Am] (mei 1982) 7(3): 245-51

ITALIANO

DESCRIZIONE
La protesi trapezio-metacarpale Avanta CMC è costituita da un elemento in polietilene ad altissimo peso molecolare (UHMWPe) cementato al trapezio preparato, e da uno stelo in lega di titanio con testa integrata, inserito nel fusto del primo metacarpo. La testa in titanio si articola con l'elemento in UHMWPe formando una sostituzione protesica vincolata "snap-fit" per l'articolazione basale del pollice. L'impianto è disponibile in tre misure, ciascuna delle quali può essere utilizzata per la mano destra o sinistra. Inoltre, per ogni tipo di impianto è disponibile una serie di calibratori di prova, che possono essere d'aiuto per la preparazione dell'osso.

Materiali:
- Testa/stelo metacarpale in lega di titanio 6AL-4V ELI ASTM F-136
- Elemento trapeziale in polietilene ad altissimo peso molecolare (UHMWPe) ASTM F-648
- Filo marcatore radiografico in cromo-cobalto ASTM F-75.

INDICAZIONI
La protesi trapezio-metacarpale Avanta CMC è indicata per la sostituzione totale dell'articolazione in pazienti con sviluppo scheletrico completo, che accusano dolore o instabilità dell'articolazione trapezio-metacarpale in seguito a trauma, patologia infiammatorie o degenerative oppure revisione di procedure precedenti, in alternativa all'artrodesi o alla chirurgia ricostruttiva.

CONTROINDICAZIONI
- Ossa, muscolatura, tendini o tessuti molli adiacenti alterati da patologie, infezioni o precedenti impianti, che non sono in grado di fornire supporto o fissaggio adeguato per la protesi.
- Infezioni in atto o sospette nell'area interessata o circostante l'articolazione del pollice.
- Immaturità scheletrica.

AVVERTENZE (Si veda anche la sezione relativa alle informazioni per la consulenza al paziente)
- Questo presidio è destinato esclusivamente all'uso cementato.
- I carichi particolarmente pesanti, l'eccessiva mobilità e l'instabilità articolare possono accelerare l'usura e provocare eventuali danni alla protesi per distacco, frattura o lussazione. Si raccomanda di informare i pazienti sulla maggiore probabilità che si verifichi tale evenienza, se gli impianti vengono sottoposti a sollecitazioni eccessive.

PRECAUZIONI
- L'impianto risulta sterile nella confezione integra. Non utilizzarlo se l'impianto stesso o la confezione sembrano danneggiati, se è trascorsa la data di scadenza o se si dubita della sterilità per qualsiasi motivo. Non risterilizzare.
- Una preparazione meticolosa del sito d'impianto e la scelta della misura adeguata dell'impianto aumentano le probabilità di esito positivo dell'intervento.
- Prelevare l'impianto dalla confezione sterile solo dopo aver preparato e correttamente misurato il sito dell'impianto.
- Manipolare gli impianti con strumenti smussati per evitare che sublecano graffi, tagli o incisioni.

EVENTI AVVERSI
- Gli eventi avversi pubblicati per un campione rappresentativo di 50 pazienti comprendono il distacco, la neurite radiale transitoria, la lesione per l'estrusione di cemento ai nervi digitali palmari e la tendinite di de Quervain[1].

Evento	Numero di eventi (n=50)
Distacco	5 (10,0 %)
Neurite radiale transitoria	2 (4,0 %)
Lesione per l'estrusione di cemento	1 (2,0 %)
Tendinite di de Quervain	6 (12,0 %)

- I potenziali eventi avversi resi noti in relazione ad altre protesi per articolazioni falangee comprendono il distacco, la frattura, la lussazione o infezione dell'impianto. Non sono stati resi noti ulteriori effetti avversi rilevanti durante tutto il periodo di commercializzazione di questo presidio.
- In seguito all'inserimento di questo impianto possono verificarsi lesioni ai nervi circostanti, ai vasi sanguigni, ai tendini o ai tessuti molli.
- Sono stati riportati casi di ipersensibilità ai metalli dopo la sostituzione dell'articolazione.

RISULTATI CLINICI
Sono stati resi noti i risultati di ventinove pazienti a cui è stato impiantato questo presidio[2]. La sostituzione è stata effettuata a causa di artrite, insuccesso di una fusione artrodesi, precedente sinuccesso dell'artroplastica totale o in Silastic, oppure anchilosi articolare fibrosa post-cerattica. Ventidue pazienti avevano raggiunto una buona mobilità indolore al momento della pubblicazione (fino a 7 anni di follow-up). Sette pazienti non sono riusciti a raggiungere l'articolarità normale (ROM) a causa di un notevole squilibrio muscolare e della contrattura e della scarring del tessuto molle. Non sono stati riferiti casi di frattura o infezione dell'impianto, ma in tre casi si è verificato il distacco in corrispondenza dell'interfacce osteo-cemento.

In una successiva pubblicazione estesa, comprendente ulteriori 21 casi della fattispecie[3], la maggior parte dei 50 pazienti ha mostrato un'articolarità completa entro quattro settimane dalla rimozione della sutura e ha continuato a mostrare buoni risultati a lungo termine. Una completa articolarità asintomatica è stata raggiunta da 26 pazienti osteoartritici con fusazione articolare. In cinque casi si è verificato il distacco dimostrato clinicamente o radiograficamente. Non sono stati osservati casi di frattura dell'impianto, usura superficiale, frammentazione o infezione.

PROCEDURE CHIRURGICHE
È disponibile una procedura chirurgica destinata all'uso del presente dispositivo per impianto. È responsabilità del chirurgo acquisire familiarità con tale procedura prima di utilizzare questi prodotti. Il chirurgo è altresì tenuto a conoscere la documentazione sull'argomento e a consultarsi con colleghi esperti in merito alla procedura prima di eseguire l'intervento.

INFORMAZIONI PER LA CONSULENZA AI PAZIENTI (Si vedano anche le Avvertenze)
Oltre alle informazioni specifiche, riportate nelle sezioni Avvertenze ed Eventi avversi, si raccomanda di comunicare ai pazienti anche quanto segue:

- I componenti sostitutivi dell'articolazione hanno una durata limitata che, purtroppo, risulta difficile da stimare. Questi componenti sono realizzati con materiali estranei, che vengono inseriti nel corpo per ripristinare una potenziale mobilità o ridurre il dolore. Tuttavia, considerando i numerosi fattori biologici, meccanici e fisicochimici legati a questi dispositivi, non si può certo dal presupposto che sano in grado di sostenere il livello di attività e i carichi di un normale osso sano per un periodo di tempo illimitato. La percentuale di casi di distacco riferita in uno studio classico relativo a questo dispositivo è stata del 10% in un periodo di 10 anni di follow-up. (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985; 195;161-7).
- L'eventuale insorgenza di eventi avversi potrebbe richiedere un secondo intervento, la revisione o la fusione dell'articolazione convolta.

STERILIZZAZIONE
- Il presente impianto è stato sterilizzato con ossido di etilene o raggi gamma.
- L'impianto fornito è sterile se la confezione è integra. Non utilizzarlo se l'impianto stesso o la confezione sembrano danneggiati, se è trascorsa la data di scadenza o se si dubita della sterilità per qualsiasi motivo. Non risterilizzare.
- Sono disponibili calibratori di prova per evitare l'apertura della confezione sterile prima d'impiantare la protesi. Prelevare l'impianto dalla confezione sterile solo dopo aver preparato e correttamente misurato il sito dell'impianto.

GARANZIA LIMITATA
Avanta Orthopaedics Corporation garantisce che il presente prodotto è conforme alle specifiche del produttore e che è esente da difetti di fabbricazione al momento della consegna. La presente garanzia esclude specificamente i difetti derivanti da uso improprio, abuso o scorretto o da errori di manipolazione del prodotto successivamente al ricevimento da parte dell'acquirente. Avanta Orthopaedics non garantisce l'esito della procedura chirurgica.

RAPPRESENTANTE PER L'UE:
Medical Products International Europe, BV
Schurweg 13a
5145 NP Waalwijk, Paesi Basei
31 (0) 416 563754

[1] Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. In: Clin Orthop (maggio 1985)(195):161-7
[2] Braun RM. Total joint replacement at the base of the thumb - relazione preliminare. In: J. Hand Surg (Am)(maggio 1982

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19-0353 Rev. D

AVANTA
ORTHOPAEDICS
9389 Carroll Park Drive Suite A, San Diego, CA 92121 USA
(858)452-8580 / (858)452-9945 (fax)

PRODUCT INSERT

AVANTA WRIST IMPLANT
AVANTA HANDGELENKIMPLANTAT
IMPLANT DE POIGNET AVANTA
IMPLANTE DE MUÑECA AVANTA
AVANTA POLSIMPLANTAAT
IMPIANTO DEL POLSO AVANTA

ENGLISH

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
This semi constrained wrist joint prostheses consists of a cobalt chromium radial component, a cobalt chromium carpal component, two (2) cobalt chromium carpal screws, and an UHMWPe carpal ball component. The UHMWPe carpal ball component articulates with the radial and cerpal components. The proximal aspect of the implant is designed to be inserted into the shaft of the radius bone and the distal aspect is designed to be fastened to the carpal bones of the hand. The device is intended to replace the wrist. The implant is available in several sizes in right and left hand configurations. A range of trial sizers for each type of implant is available to aid in bone preparation.

Materials:
- ASTM F-648 ultra-high molecular weight polyethylene powder fabricated form for surgical implants
- ASTM F-1537 wrought cobalt chromium molybdenum alloy for surgical implants
- ASTM F-1580 titanium powders for coatings of surgical implants

INDICATIONS
The Avanta Orthopaedics Wrist implant is intended for replacement of the painful wrist joint due to rheumatoid arthritis (RA), osteo-arthritis (OA), or traumatic arthritis (TA).

CONTRAINDICATIONS
- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Known sensitivity to materials used in this device
- Skeletal immaturity.

WARNINGS (See also the Patient Counseling Information Section)
- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure when excessive demands are made upon it.
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

PRECAUTIONS
- Do not resterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.

ADVERSE EVENTS
Potential adverse events reported with joint prostheses include pain, loosening, fracture, transient radial neuritis, tendinitis, dislocation, or infection. There have been some reports of patients with metal sensitivity reactions following joint replacement. Implantation of materials such as cobalt chrome and/or titanium may result in foreign body reaction adjacent to the implant site. Injury to the surrounding nerves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device. Surgical intervention may be required to treat adverse effects. This may involve arthrodesis or amputation of the involved appendage.

SURGICAL PROCEDURES
A manual is available describing detailed surgical procedures for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the implant procedures before use.

PATIENT COUNSELING INFORMATION (See also Warnings)
A patient brochure is available for use in counseling the patient.

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

- While the expected life of total joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.
- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION
- This component has been sterilized by ethylene oxide or gamma radiation.
- Do not resterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics Inc., warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

19-0382 rev. A

DEUTSCH

ACHTUNG
Laut US Bundesgesetz darf dieses Produkt nur von einem Arzt oder in dessen Auftrag verkauft, vertrieben und eingesetzt werden.

BESCHREIBUNG
Diese halbgeführte Handgelenkprothese besteht aus einer radialen Komponente aus Cobalt-Chrom, einer Karpalkomponente aus Cobalt-Chrom, zwei (2) Karpalschrauben aus Cobalt-Chrom und einer Karpalkugelkomponente aus ultrahochmolekularem Polyethylen (UHMW-PE). Die UHMW-PE-Karpalkugelkomponente artikuliert mit der Radial- und der Karpalkomponente. Der proximale Teil des Implantats ist zum Einsetzen in den Schaft des Radius bestimmt und der distale Teil zum Befestigen an den Handwurzelknochen. Das Implantat ist als Handgelenkersatz konzipiert. Es ist in mehreren Größen für die rechte und die linke Hand erhältlich. Zur Erleichterung der Knochenpräparation ist ein Satz Probeimplantate für jeden Implantattyp erhältlich.

Werkstoffe:
- ASTM F-648: Ultrahochmolekulares Polyethylenpulver für chirurgische Implantate
- ASTM F-1537: Cobalt- Chrom-Molybdän-Knetlegierung für chirurgische Implantate
- ASTM F-1580 Titanpulver für Beschichtungen von chirurgischen Implantaten

INDIKATIONEN
Das Avanta Orthopaedics Handgelenk-Implantat ist zum Ersatz des schmerzhaften Handgelenks bei rheumatoider Arthritis (RA), Osteoarthritis (OA) oder traumatischer Arthritis(TA) bestimmt.

KONTRAINDIKATIONEN
- Durch Krankheiten, Infektionen oder frühere Implantationen geschädigte Knochen, Muskulatur, Sehnen oder umgebende Weichteile bieten keinen ausreichenden Halt oder Fixierung für die Prothese
- Aktive Infektion oder Verdacht auf Infektion im Gelenk oder im Umkreis des Gelenks
- Bei im Wachstum begriffenen Patienten mit offenen Epiphysen.
- Bekannte Überempfindlichkeit gegenüber den Implantatwerkstoffen

WARNUNGEN (Siehe auch den Abschnitt Patienteninformationen)
Extreme Belastungen, große Mobilität und Gliedmaßeninstabilität können zu frühzeitigem
Verschleiß und eventuellem Versagen der Prothese durch Lockern, Brechen oder Verrutschen führen. Der Patient sollte über das erhöhte Risiko eines Versagens der Prothese bei Überbeanspruchung aufgeklärt werden. Mitteilung gemäß California Safe Drinking Water and Toxic Enforcement Act von 1986 (Proposition 65): Dieses Produkt enthält einen chemischen Stoff, der nach Kenntnis des State of California Krebs und/oder kongenitale Defekte oder andere reproduktionstoxikologische Wirkungen hervorrufen kann..

ACHTUNG
Die Prothese wird steril in einer unbeschädigten Verpackung geliefert. Sollte entweder die Prothese oder die Verpackung beschädigt, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grunde zweifelhaft sein, sollte die Prothese nicht verwendet werden. **Nicht erneut sterilisieren.** Nach dem Entfernen der sterilen Verpackung die Prothese bis zum Zeitpunkt der Implantation in ein Bad mit steriler Salzlösung legen. Die Prothesen sollten ausschließlich mit stumpfen Instrumenten gefasst werden, um Kratzer, Schnitte und Kerben auf der Prothese zu vermeiden. Eine gründliche Vorbereitung der Implantationsstelle und die Wahl der richtigen Prothesengröße erhöhen die Chance eines erfolgreichen Eingriffs. Zur Erleichterung der Knochenvorbereitung ist eine große Auswahl von Musterprothesen erhältlich. Die Prothese in der richtigen Größe erst aus der sterilen Packung nehmen, wenn die Implantationsstelle ausreichend vorbereitet wurde.

KOMPLIKATIONEN
Bekannte mögliche Komplikationen mitGelenkprothesen sind Schmerzen, Zementextrusionsschädigung, Lockerung, Transiente Radialisneuritis, Tendinitis, Fraktur, Verrutschen oder Infektionen. Bei einigen Patienten traten Überempfindlichkeiten gegen Metall nach dem Gelenkersatz auf. Darüber hinaus können Verletzungen der umgebenden Nerven, Blutgefäße, Bänder oder der Weichteile auftreten. Ein chirurgischer Eingriff kann zur Behandlung von unerwünschten Wirkungen notwendig sein. Dies kann eine Arthrodese oder Amputation des betroffenen Anhangsgebildes bedeuten.

OPERATIONSVERFAHREN
Eine Operationsanweisung zur Verwendung dieser Prothese ist erhältlich. Der Chirurg hat sich vor der Verwendung dieser Produkte mit den Operationsverfahren vertraut zu machen. Darüber hinaus liegt es in der Verantwortung des Chirurgen, vor Verwendung dieser Produkte die relevanten Publikationen zur Kenntnis zu nehmen und sich mit in dieser Angelegenheit erfahrenen Kollegen auszutauschen.

PATIENTEN INFORMATIONEN (Siehe auch Warnung)
Es steht eine Patientenbroschüre zur Information des Patienten zur Verfügung.
Warnung und Komplikationen sollte der Patient über Folgendes informiert werden:
1) Komplikationen können eine neue Operation, eine neue Begutachtung oder Fusion des betreffenden Gelenks erfordern, 2) Die Lebensdauer der Gelenkersatz-Komponenten ist begrenzt, ihre Lebensdauer lässt sich nur schwer voraussagen. Die Komponenten sind aus körperfremdem Material hergestellt, die in den Körper eingepflanzt werden, um möglichst die Mobilität wiederherzustellen und Schmerzen zu verringern. Aufgrund zahlreicher biologischer, mechanischer und physiologischer Faktoren, die diese Komponenten beeinflussen, können die Komponenten das Aktivitätsniveau und die Belastung eines normalen gesunden Knochens nicht über einen unbegrenzten Zeitraum aushalten.

STERILISATION
Dieses Produkt wurde mit Ethylenoxid oder mithilfe von Gammastrahlen sterilisiert. Es wird steril in einer unbeschädigten Verpackung geliefert. Sollte entweder die Prothese oder die Verpackung beschädigt sein, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grunde zweifelhaft sein, sollte die Prothese nicht verwendet werden. **Nicht erneut sterilisieren.** Um die sterile Verpackung nicht nur wegen der Feststellung der richtigen Größe der Prothese vor der Implantation öffnen zu müssen, stehen Größenmuster zur Verfügung. Die Prothese erst aus der sterilen Verpackung entfernen, nachdem die Implantationsstelle ausreichend vorbereitet und die richtige Größe der Prothese ermittelt wurde.

BEGRENZTE GARANTIE
Avanta Orthopaedics, Inc. garantiert, dass dieses Produkt den Spezifikationen des Herstellers entspricht und zum Zeitpunkt der Lieferung keine Herstellungsfehler aufweist. Diese Garantie bezieht sich nicht auf Schäden, die auf unsachgerechte Behandlung, Missbrauch oder falsche Verwendung des Produkts durch den Benutzer zurückzuführen sind. Avanta Orthopaedics gewährleistet nicht den Erfolg des chirurgischen Eingriffs.

EU REPRÄSENTANT
Medical Products International Europe
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

FRANÇAIS

MISE EN GARDE
La législation fédérale (des États-Unis d'Amerique) émet la restriction que cet appareil doit être vendu, distribue et utilise par et sur ordre d'un médecin.

DESCRIPTION
Cette prothèse de poignet semi-contrainte se compose d'une pièce radiale cobalt-chrome, d'une pièce carpienne cobalt-chrome, de deux (2) vis carpiennes cobalt-chrome et d'une bille carpienne en UHMWPE (polyéthylène à poids moléculaire ultra élevé). La bille carpienne en UHMWPE s'articule sur les pièces radiale et carpienne. L'aspect proximal de l'implant doit être inséré dans le corps du radius ; l'aspect distal doit être fixé sur les os carpiens de la main. Cette prothèse s'utilise en remplacement du poignet. L'implant est disponible en plusieurs tailles, dans des configurations de main droite et main gauche. Une série de calibreurs d'essai pour chaque type d'implant est disponible, pour aider à la préparation osseuse.

Matériaux:
- ASTM F-648 : forme de poudre de polyéthylène à poids moléculaire ultra élevé traitée pour enplants chirurgicaux
- ASTM F-1537 : alliage de cobalt-chrome-molybdène façonné pour implants chirurgicaux
- Poudres de titane conformes à la norme ASTM F-1580 pour enrobages d'implants chirurgicaux

INDICATIONS
L'implant de poignet d'Avanta Orthopaedics est prévu pour remplacer l'articulation douloureuse du poignet en cas d'arthrite rhumatoïde, d'ostéoarthrite ou d'arthrite traumatique.

CONTRE-INDICATIONS
- Os, musculature, tendons ou tissus mous adjacents endommagés par une maladie, une infection ou une précédente implantation et incapables d'offrir un support ou une fixation adéquats à la prothèse
- Jeunes patients en cours de croissance présentant des épiphyses ouvertes
- Sensibilité connue aux matériaux utilisés dans la prothèse

MISES EN GARDE (Voir aussi la partie relative à l'information et conseils destinés au patient).
Contraintes importantes, mobilité excessive et instabilité articulaire peuvent toutes accélérer l'usure et aboutir à une éventuellement défaillance par détachement, fracture ou dislocation de l'appareil. Les patients doivent être conscients du risque potentiel de la défaillance de l'appareil si ce dernier subit des contraintes excessives. Notification en conformité avec le California Safe Drinking Water and Toxic Enforcement Act de 1986 (Proposition 65) : ce produit contient un agent chimique connu dans l'État de Californie pour causer le cancer et/ou des malformations néonatales et autre toxicité liée à la reproduction.

PRÉCAUTIONS
L'implant est fourni stérile dans un emballage intact. Si l'implant ou son emballage apparaît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en doute pour une raison quelconque, il faut proscrire l'emploi de cet implant. **Ne pas re-stériliser.** Les implants doivent être gardés dans une solution saline stérile après qu'ils ont été retirés de leur emballage stérile avant implantation.
Il convient de manipuler les implants uniquement avec des instruments émoussés pour éviter de rayer, de couper ou d'entailler l'appareil. Une préparation méticuleuse du site d'implantation et le choix de la taille appropriée de l'implant augmentent la chance de succès de l'implantation. Il existe une gamme complète de gabarits pour aider à la préparation de l'os. On recommande de retirer l'implant de taille appropriée de son emballage stérile seulement après que le site d'implantation a été préparé et correctement dimensionné.

EFFETS INDESIRABLES
Parmi les effets indésirables potentiels des prothèses on a signalé la douleur, blessure par extrusion de ciment, névrite radiale passagère, tendinite, le détachement, la fracture, la dislocation ou l'infection. On a signalé quelques cas de patients qui ont manifesté des réactions de sensibilité au métal après remplacement de l'articulation. La lésion des nerfs, vaisseaux sanguins, tendons ou tissus mous environnants peut survenir suite à l'implantation de cet appareil. Une intervention chirurgicale peut être requise pour traiter les effets contraires. Elle peut comprendre l'arthrodèse ou l'amputation de l'appendice impliqué.

PROCEDURES CHIRURGICALES
Il existe une procédure chirurgicale à suivre dans la mise en oeuvre de cette prothèse. Il est de la responsabilité du chirurgien de bien prendre connaissance de cette procédure avant d'utiliser ces produits. De plus, le chirurgien est tenu de prendre des connaissances des publications utiles et de consulter des confrères expérimentés quant à cette procédure avant qu'il utilise ces prothèses.

INFORMATION ET CONSEILS DESTINES AU PATIENT (Voir également la partie Mises en garde)
Une brochure à l'attention du patient, contenant des conseils, a été réalisée. En plus de l'information relative au patient, contenue dans les parties Mises en garde et Effets indésirables, il convient de faire savoir au patient que:
1) Les effets secondaires peuvent nécessiter une nouvelle operation, une correction ou une fusion de l'articulation concernée. 2) Comme la longévité des composants de remplacement de l'articulation est difficile a estimer, elle est limitée. Ces composants sont constitues de matériaux étrangers qui sont placés à l'intérieure de l'organisme en vue de la restauration potentielle de la mobilité ou de la réduction de la douleur. Toutefois, en raison des nombreux facteurs biologiques, mécaniques et physicochimiques intérents à ces appareils, les composants ne peuvent pas résister indéfiniment au niveau d'activité et aux contraintes d'un os sain normal.

STERILISATION
Ce composant a été stérilisé à l'oxyde d'éthylène ou aux rayons gamma. L'implant est fourni stérile dans un emballage intact. Si l'implant ou son emballage apparaissent endommagés, si la date de péremption est dépassée ou si la stérilité est mise en doute pour une raison quelconque, il faut proscrire l'emploi de cet implant. **Ne pas re-stériliser.** Il existe des gabarits d'eassai pour vous éviter d'ouvrir un emballage stérile avant l'implantation de la prothèse. Il faut retirer l'implant de son emballage stérile seulement après que le site d'implantation a été préparé et correctement dimensionné.

GARANTIE LIMITEE
Avanta Orthopaedics, Inc. garantit que ce produit satisfait aux spécifications du fabricant et qu'il est dénué de défauts de fabrication au moment de sa livraison. Cette garantie exclue expressément les défauts résultant d'une mauvaise utilisation, d'un de l'usage abusif ou d'une manipulation incorrecte du produit après que ce dernier a été réceptionné par l'acheteur. Avanta Orthopaedics décline toute responsabilité quant à l'issue de l'intervention chirurgicale.

REPRÉSENTANT EU
Medical Products International Europe
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

ESPAÑOL

CUIDADADO
La legislación federal de los Estados Unidos restringe la venta, la distribución y el uso de este producto, autorizándolos solamente cuando sean efectuados por un médico o por orden de un médico.

DESCRIPCIÓN
Esta prótesis semiconstreñida para la articulación de la muñeca consta de un componente radial de cromo-cobalto, un componente carpiano de cromo-cobalto, dos (2) tornillos carpianos de cromo-cobalto y una esfera carpiana de polietileno de peso ...cular ultra-alto (UHMWPe). La esfera carpiana de UHMWPe articula con los ...mentes radial y carpiano. La parte proximal del implante está diseñada para su ...ón en la diáfisis del radio, mientras que la parte distal está diseñada para su ...ión a los huesos del carpo. El dispositivo está provisto para sustituir la articulación de la muñeca. El implante está disponible en varios tamaños, para mano derecha y mano izquierda. Para ayudar a la preparación del hueso existe una gama de calibradores de prueba para cada tipo de implante.

Materiales:
- ASTM F-648: forma fabricada con polvo de polietileno de peso molecular ultra-alto para implantes quirúrgicos
- ASTM F-1537: aleación forjada de cobalto-cromo-molibdeno para implantes quirúrgicos
- ASTM F-1580: polvos de titanio para revestimientos de implantes quirúrgicos

INDICACIONES
El implante de muñeca de Avanta Orthopaedics está previsto para la sustitución de la articulación carpiana dolorosa en caso de artritis reumatoide, artrosis o artritis traumática.

CONTRAINDICACIONES
- Huesos, musculatura, tendones o tejidos blandos adyacentes afectados por una enfermedad, una infección o un implante previo, de manera que no pueden proporcionar un soporte o fijación adecuados para la prótesis.
- Sensibilidad conocida a los materiales utilizados en este dispositivo
- Pacientes en desarrollo con epífisis abiertas

ADVERTENCIAS (Véase también el Párrafo Informativo sobre Asistencia al Paciente)
Cargas agotadoras, movilidad excesiva y inestabilidad articular pueden conducir a un desgaste acelerado y con el tiempo a fallos causados por soltarse, quebrarse o dislocarse el dispositivo. Los pacientes deben ser conscientes de la posibilidad a un fallo de un dispositivo aumenta significativamente si se le imponen exigencias excesivas. Notificación de acuerdo al Acta de Seguridad del agua potable y de aplicación de sustancias tóxicas del Estado de California, de 1986 (Proposición 65): "Este producto contiene una sustancia química(s) que de acuerdo a la información del Estado de California reconocidamente causa cancer y/o malformaciones congenitas, además de ejercer otras formas de toxicidad sobre las funciones reproductoras".

PRECAUCIONES
El implante se entrega estéril en un paquete intacto. Si bien el implante o el paquete suele estar dañado, ha caducado la fecha de expiracion o si por cualquier motivo existen dudas sobre la esterilidad, el implante no se debe usar. **No lo esterilice nuevamente.** Antes de la implantación y después de sacar la envoltura estéril se deben guardar los implantes inmersos en una solución salina estéril. Los implantes se deben manejar unicamente con instrumentos contundentes para evitar que se rayen, corte o melle el dispositivo. Una preparacion meticulosa de la zona del implante y la selección de la medida correcta del implante aumentará la posibilidad de un resultado exitoso. Hay disponible una gama completa de calibradores de prueba para facilitar la preparacion del hueso. Se recomienda mantener el implante de la medida apropiada en el paquete estéril hasta que la zona de implantación se haya preparado y calibrado apropiadamente.

EVENTOS ADVERSOS
Eventos adversos potenciales registrados con prótesis para la articulación de un dedo del pie incluyen dolor, soltura, Neuritis radial transitoria, tendinitis, lesión por extrusión del cemento, fracción, dislocación o infección. Existen ciertos informes de pacientes con reacciones sensitivas componentes de metal seguidas de una sustitución de la articulacion. La implantación de este dispositivo puede causar lesiones en ...s nervios circundantes, vasos sanguíneos, tendones o tejidos suaves. Puede ser ...saria una intervención quirurgica para tratar los efectos secundarios. Esto puede ...ar la artrodesis o amputación de la extremidad afectada.

PROCEDIMIENTOS QUIRÚRGICOS
Hay disponible un procedimiento quirurgico para el uso de este dispositivo de implantacion. Es la responsabilidad del quirófano familiarizarse con el procedimiento antes de utilizar estos productos. Antes de usar dicho dispositivo, el quirófano es, además, responsable de familiarizarse con las publicaciones pertinentes y mantener contacto con asociados experimentados respecto al procedimiento.

INFORMACIÓN SOBRE ASISTENCIA AL PACIENTE (Véase también Advertencias)
Se suministra una monografia informativa para dar consejo y explicación a los pacientes. Ademas de la información relacionada al paciente que se describe en los párrafos de Advertencias y Eventos Adversos, se ha de informar al paciente sobre lo siguiente:
1) Efectos adversos pueden requerir operación repetida, revision o fusion de la articulacion en cuestion. 2) A pesar de que es difícil estimar la vida supuesta de los componentes sustitutivos de una articulación, ésta es finita. Dichos componentes son de materiales extraños al cuerpo y se han colocado dentro del cuerpo para la restauración potencial de la movilidad o la reducción de dolor. No obstante y debido a numerosos factores biológicos, mecánicos y fisioquímicos que pueden afectar estos dispositivos, no se puede esperar de los componentes que resistan por un período limitado el nivel de actividad y la carga de los huesos normales y sanos.

ESTERILIZACIÓN
Este componente ha sido esterilizado por oxido de etileno o radiacion gamma. El implante se entrega esteril en un paquete intacto. Si bien el implante o el paquete suele estar dañado, ha caducado la fecha de expiracion o si por cualquier motivo existen dudas sobre la esterilidad, el implante no se debe usar. No lo esterilice nuevamente. Hay disponible calibradores de prueba para evitar que se haya de abrir el paquete esteril previamente a la implantación de la prótesis. El implante solamente se ha de sacar del paquete estéril cuando la zona de implantacion se ha preparado y calibrado apropiadamente.

GARANTÍA LIMITADA
Avanta Orthopaedics, Inc. garantiza que este producto cumple con las especificaciones del fabricante y que en el momento de entrega está libre de defectos de fabricación. Dicha garantía excluye específicamente defectos causados por mal uso, abuso o manejo impropio del producto posterior al recibo del comprador. Avanta Orthopaedics no garantiza el resultado de un procedimiento quirurgico.

REPRESENTANTE EU
Medical Products International Europe
Schutweg 13a
5145 NP Waalwijk. The Netherlands
31 (0) 416 563754

NEDERLANDS

OPGELET
Krachtens de federale wetgeving (VS) mag dit medische hulpmiddel uitsluitend door of op voorschrift van een arts worden verkocht.

BESCHRIJVING
Deze polsgewrichtprothese met beperkte bewegingsvrijheid bestaat uit een kobalt-chroom radiusdeel, een kobalt-chroom carpaal deel, twee (2) carpale schroeven van kobalt-chroom en een carpaal kopdeel van UHMWPe. Het carpale kopdeel van UHMWPe articuleert met het radiusdeel en carpale deel. Het proximale gedeelte van het implantaat is ontworpen om te worden ingebracht in de schacht van de radius en het distale gedeelte om te worden bevestigd aan de carpale botten van de hand. De prothese dient ter vervanging van de pols. Het implantaat is verkrijgbaar in verschillende maten en in rechter en linker handconfiguraties. Er is een reeks proefpassers voor elk type implantaat verkrijgbaar als hulp bij het gereedmaken van het bot.

Materialen:
- ASTM F-648: Een vorm van UHMWPe (Ultra High Molecular Weight Polyethylene) op poederbasis voor chirurgische implantaten
- ASTM F-1537: gesmede legering van kobalt-chroom en molybdeen voor chirurgische implantaten
- ASTM F-1580 titaanpoeders voor deklagen op chirurgische implantaten

INDICATIES
Het Avanta orthopedische polsimplantaat dient voor de vervanging van een pijnlijk polsgewricht als gevolg van reumatoide artritis (RA), osteoartritis (OA) of traumatische artritis (TA).

CONTRA-INDICATIES
- Bot, spier, pees of andere weke delen afwijkingen veroorzaakt door ontstekingen of voorgaande gewrichts vervangende prothesen die een goede plaatsing en of hechting van het implantaat in de weg staan
- Bekende overgevoeligheid voor materialen die in dit product worden gebruikt.
- Patiënten in de groei met open epifysen

WAARSCHUWINGEN (Zie ook het gedeelte over informatie over counseling van de patiënt)
Sterke belasting, overmatige mobiliteit en articulaire instabiliteit kunnen alle leiden tot verspilde slijtage en uiteindelijk falen door loslating, fractuur of dislocatie van het implantaat. Patiënten moeten bewust gemaakt worden van de verhoogde kans op falen van het implantaat als hier overmatige veel van gevergd wordt. Verklaring in overeenstemming met de California Safe Drinking Water and Toxic Enforcement Act van 1986 (Proposition 65): Dit product bevat een chemische stof, waarvan bij de Staat California bekend is dat deze kanker en/of geboortedefecten en andere reproductietoxiciteit veroorzaakt.

VOORZORGSMAATREGELEN
Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Als het implantaat of de verpakking beschadigd lijken te zijn, als de uiterste gebruiksdatum is overschreden of als om de een of andere reden twijfel bestaat over de steriliteit, mag het implantaat niet gebruikt worden. **Niet opnieuw steriliseren.** Vóór het implanteren moeten implantaten in steriele zoutoplossing ondergedompeld blijven nadat zij uit de steriele verpakking gehaald zijn.
Voor implantaten mogen uitsluitend stompe instrumenten gebruikt worden, om krassen, snijden of kraakjes van het implantaat te voorkomen. Zeer nauwgezette voorbereiding van de plaats van het implantaat en de keuze van de juiste maat implantaat verhogen de kans op een succesvol resultaat. Een volledig assortiment proefcomponenten is verkrijgbaar ter ondersteuning van de botvoorbereiding. Geadviseerd wordt om het implantaat met de juiste maat pas uit de steriele verpakking te halen nadat de plaats van het implantaat is voorbereid en de juiste maat heeft.

BIJWERKINGEN
De mogelijke bijwerkingen die gemeld zijn bij het gebruik van vinger gewrichtsprothe pijn, loslating, letsel door cementextrusie, transitoire radiale neuritis, tendinitis, fractuur, dislocatie en infectie. Er is ook een aantal meldingen van patiënten die na gewrichtsvervanging overgevoelig bleken te zijn voor metaal. Letsel aan de/het omringende zenuwen, bloedvaten, pezen en zachte weefsel kunnen optreden als gevolg van het toepassen van dit implantaat. Complicaties kunnen chirurgische interventie noodzakelijk maken. Dit kan artrodese of amputatie van de betrokken ledemaat omvatten.

CHIRURGISCHE PROCEDURES
Een chirurgische procedure voor het gebruik van dit implantaat is beschikbaar. Het is de verantwoordelijkheid van de chirurg om op de hoogte te zijn van de procedure voordat hij deze producten gebruikt. Het is ook zijn verantwoordelijkheid om op de hoogte te zijn van relevante publicaties en ervaren collega's te raadplegen over de procedure voordat hij deze verricht.

PATIËNTINFORMATIE (Zie ook Waarschuwingen)
Er is een patiëntenbrochure verkrijgbaar voor gebruik bij het counselen van de patiënt. Naast de informatie die betrekking heeft op de patiënt zoals deze is opgenomen onder Waarschuwingen en Bijwerkingen moet de volgende informatie aan de patiënt worden meegedeeld:
1) Bijwerkingen kunnen heroperatie, revisie of fusie van het betrokken gewricht noodzakelijk maken. 2) De verwachte levensduur van gewrichtsvervangingscomponenten is moeilijk te schatten, maar is eindig. Deze componenten zijn vervaardigd van lichaamsvreemde materialen die in het lichaam worden geplaatst voor potentieel herstel van mobiliteit of voor potentiële pijnverlichting. Door de vele biologische, mechanische en fysiochemische factoren die deze implantaten beinvloeden, kan echter niet verwacht worden dat deze componenten voor onbepaalde tijd bestand zijn tegen het activiteitsniveau en de belastingen van normaal gezond bot.

STERILISATIE
Deze component is gesteriliseerd met ethyleenoxide of gammastralen. Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Als het implantaat of de verpakking beschadigd lijken te zijn, als de uiterste gebruiksdatum is overschreden of als om de een of andere reden twijfel bestaat over de steriliteit, mag het implantaat niet gebruikt worden. **Niet opnieuw steriliseren.**
Proefcomponenten zijn verkrijgbaar om te voorkomen dat de steriele verpakking vóór het implanteren van de prothese geopend moet worden. Het implantaat met de juiste maat mag pas uit de steriele verpakking gehaald worden nadat de plaats van het implantaat is voorbereid en de juiste maat heeft.

BEPERKTE GARANTIE
Avanta Orthopaedics, Inc. garandeert dat dit product voldoet aan de specificaties van de fabrikant en ten tijde van de levering vrij is van fabricagegebreken. Deze garantie sluit uitdrukkelijk gebreken uit die het gevolg zijn van verkeerd gebruik, misbruik of onjuiste behandeling van het product na ontvangst door de koper. Avanta Orthopaedics geeft geen garantie op het resultaat van de chirurgische ingreep.

EU AFGEVAARDIGDE
Medical Products International Europe
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

ITALIANO

ATTENZIONE
La legge federale (Stati Uniti) limita la vendita, la distribuzione e l'uso di questo dispositivo ai soli medici o previa prescrizione degli stessi.

DESCRIZIONE
Questa protesi semi vincolata dell'articolazione del polso è costituita da un componente radiale in cromo-cobalto, un componente carpale in cromo-cobalto, due (2) viti carpali in cromo-cobalto e un componente a sfera carpale in UHMWPe, quest'ultimo articolato con i componenti radiale e carpale. L'aspetto prossimale dell'impianto è progettato per essere inserito nel corpo dell'osso radiale, mentre l'aspetto prossimale prevede l'inserimento nelle ossa carpali della mano. Il dispositivo è concepito per sostituire il polso. L'impianto è disponibile in numerose misure in configurazioni per la mano destra e sinistra. Per ogni tipo d'impianto è disponibile una vasta gamma di calibratori di prova, che rappresentano un valido ausilio nella preparazione dell'osso.

Materiali:
- ASTM F-648 componente articolare a sfera in polietilene a peso molecolare ultra-elevato (UHMWPe)
- ASTM F-1537 lega lavorata in molibdeno-cromo-cobalto per impianti chirurgici
- ASTM F-1580 titanio allo stato commercialmente puro (CPTi)

INDICAZIONI
L'impianto del polso Avanta Orthopaedics è previsto per la sostituzione del polso dolorante a causa di artrite reumatoide (RA), di osteoartrite (OA) o di artrite traumatica.

CONTROINDICAZIONI
- Ossa, muscolatura, tendini o tessuti molli adiacenti compromessi da malattie, infezioni o precedenti impianti che non forniscono il supporto o il fissaggio adeguato per la protesi
- Accertata sensibilità nei confronti dei materiali utilizzati nel presente dispositivo
- Pazienti in crescita con epifisi aperta.

AVVERTENZE (si rimanda al paragrafo relativo alle informazioni per la Consulenza al Paziente)
I carichi estenuanti, una mobilità eccessiva e l'instabilità articolare costituiscono fattori in grado di accelerare l'usura e l'eventuale danno del dispositivo attraverso un processo di allentamento, frattura o dislocazione. I pazienti devono essere avvertiti del fatto che il rischio di danni al dispositivo aumenta in caso di utilizzo poco moderato dello stesso. Notifica ai sensi della Legge d'Applicazione in materia di Prodotti Tossici e Acqua Potabile Sicura dello Stato della California del 1986 (Dichiarazione 65): Questo prodotto contiene una sostanza chimica(i) nota allo Stato della California come cancerogena e/o in grado di provocare malformazioni congenite e diversa tossicità a livello riproduttivo.

PRECAUZIONI
La protesi viene fornita in condizioni sterili, all'interno di una confezione integra. Evitare di procedere all'utilizzo della protesi nei casi in cui si constati un danno alla stessa o alla confezione, oppure in caso di superamento della data di scadenza o di dubbi di qualsiasi natura sull'effettiva condizione di sterilità. **Non ripetere la sterilizzazione.** Dopo la rimozione dell'involucro sterile e prima dell'intervento di impianto, le protesi devono essere conservate in una soluzione salina sterile. Le protesi vanno maneggiate esclusivamente con l'ausilio di strumenti smussati, per evitare di graffiarle. Una preparazione accurata del sito di impianto ed una corretta scelta delle dimensioni della protesi aumentano le probabilità di successo dell'intervento. Una gamma completa di dispositivi di prova è disponibile per la predisposizione dimensionale dell'osso. Si consiglia di estrarre la protesi dalla giuste dimensioni dalla sua confezione sterile soltanto dopo aver predisposto e dimensionato adeguatamente il sito di impianto.

EVENTI NEGATIVI
Alcuni potenziali eventi negativi riportati in seguito all'impianto di protesi dell'alluce includono dolore, allentamento, neurite radiale transitoria, tendinite, lesione per estrusione del cemento, frattura, dislocazione o infezione. Sono stati riportati dei casi di pazienti che hanno manifestato delle reazioni di sensibilità ai al metalli in seguito alla sostituzione dell'articolazione. In seguito all'impianto di questo dispositivo, si possono verificare dei danni a nervi, vasi sanguigni, tendini e tessuti molli situati nell'area circostante al sito di impianto. Può rendersi necessario un intervento chirurgico per contrastare eventuali effetti indesiderati, che possono includere artrodesi o amputazione degli annessi coinvolti.

PROCEDURA CHIRURGICA
E' disponibile un protocollo di procedura chirurgica per l'impiego di questa protesi. E' responsabilità del chirurgo acquisire familiarità con tale protocollo prima di procedere all'utilizzo di questi prodotti. Lo stesso chirurgo ha la responsabilità di acquisire conoscenza delle principali pubblicazioni del settore e di consultarsi con colleghi esperti in relazione alla procedura, prima di eseguire l'intervento.

INFORMAZIONI PER LA CONSULENZA AL PAZIENTE (si rimanda alle Avvertenze)
E' disponibile una brochure che riporta importanti consigli per il paziente. Oltre alle informazioni per il paziente riportate ai paragrafi "Avvertenze" e "Eventi negativi", è indispensabile fornire al paziente le seguenti informazioni:
1) l'eventuale insorgenza di eventi negativi può rendere necessario un secondo intervento chirurgico, una revisione o la fusione dell'articolazione in questione; 2) La durata dei componenti sostitutivi dell'articolazione è difficile da prevedere ma, in ogni caso, avrà un termine. Questi componenti sono realizzati in materiali non fisiologici e collocati all'interno dell'organismo per il potenziale ripristino della mobilità o per la riduzione del dolore. Ciononostante, per via dei diversi fattori di natura biologica, meccanica e fisico-chimica che influenzano questi dispositivi, non ci si può aspettare che i componenti siano resistenti, per un tempo limitato, al livello di attività e alle sollecitazioni da carico ai quali sono sottoposte le normali ossa sane.

STERILIZZAZIONE
Questo articolo è stato sterilizzato con ossido di etilene o con radiazioni gamma. La protesi è fornita in condizioni sterili all'interno di una confezione integra. Evitare di procedere all'utilizzo della protesi nei casi in cui si constati un danno alla stessa o alla confezione, oppure in caso di superamento della data di scadenza o di dubbi di qualsiasi natura sull'effettiva condizione di sterilità. **Non ripetere la sterilizzazione.**
Dei dispositivi di prova sono disponibili per evitare che si debba aprire la confezione sterile prima dell'effettivo impianto della protesi. La protesi va estratta dalla sua confezione sterile soltanto dopo aver predisposto e dimensionato adeguatamente il sito di impianto.

GARANZIA LIMITATA
Avanta Orthopaedics, Inc. garantisce che questo prodotto soddisfa le specifiche della casa produttrice e non presenta difetti di produzione al momento della consegna. Questa garanzia esclude espressamente qualsiasi difetto derivante da utilizzo errato, abuso o maneggiamento improprio del prodotto avvenuti successivamente all'arrivo dello stesso presso il recapito dell'acquirente. Avanta Orthopaedics non garantisce l'esito positivo della procedura chirurgica.

RAPPRESENTANTE EU
Medical Products International Europe
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

CE 0123

AVANTA
ORTHOPAEDICS
9369 Carroll Park Drive, Suite A, San Diego, CA 92121 USA
(858)452-8580 / (858)452-9945 (fax)

PRODUCT INSERT

CARPAL FUSION PLATE

ENGLISH

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
The Avanta Carpal Fusion Plate is designed for fusion of the carpal bones of the hand including; capitate, hamate, lunate, and triquetrum. The fusion plate is a low profile single piece construct designed to fit over the dorsal aspect of the carpal bones in the hand. The plate has spherical holes or slots that accommodate screws for fixation. The fusion plate and screws are fabricated from implantable grade stainless steel.

Materials:
- Stainless Steel ASTM F-138 or ASTM F-139

INDICATIONS
The Avanta Carpal Fusion Plate is designed for fusion of the carpal bones of the hand including; capitate, lunate, hamate, and triquetrum. The fusion plate is intended for use in patients suffering from pain and/or loss of function due to osteoarthritis, post-traumatic arthritis, fractures, revision of failed partial wrist fusions, carpal instability, or rheumatoid arthritis. The fusion plate is used in conjunction with screws that fix the plate to the carpal bones of the hand.

CONTRAINDICATIONS
- Active or latent infection
- Osteoporosis, insufficient quantity or quality of bone/soft tissue
- Material sensitivity - if suspected perform tests prior to surgery
- Sepsis
- Patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions

WARNINGS (See also the Patient Counseling Information and Adverse Events Section)
- This device is intended for the uses described in this insert only.
- Careful patient selection, education and counseling by the surgeon and rehabilitation care provider is important.
- Strenuous loading, excessive mobility, may lead to failure of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
- Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing.
- Improper insertion of the device during implantation can increase the possibility of loosening and migration.
- A poor result may be obtained if the fracture is not properly reduced or the device is not properly assembled.
  Explantation of this device may be necessary.
  Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the state of California to cause cancer, and/or birth defects and other reproductive toxicity.

PRECAUTIONS
- An implant should never be reused. Previous stresses may have created imperfections which may lead to device failure.
- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. This is a single use device it is not intended for re-use. Re-sterilization is not recommended for the implant.
- Meticulous preparation of the implant site and proper implant positioning increase the potential for a successful outcome.
- The sterile products should be removed from its sterile package only after it is determined that the implant will be used on the patient.

ADVERSE EVENTS
- Adverse events published in the literature should be reviewed prior to using this device.
- Metal sensitivity reactions have been reported following metal implantation.
- Injury to surrounding nerves, blood vessels, tendons, or soft tissues.
- Additional possible adverse events may include fracture of the bone, infection, pain and soft tissue irritation.

SURGICAL PROCEDURES
A manual is available describing the detailed surgical procedure for use of this device. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings and Adverse Events Section)
In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:
- While the expected life of this device is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body to facilitate the healing process. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

STERILIZATION
- This product is sterilized by ethylene oxide (EO) gas or gamma radiation.
- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. This is a single use device.

LIMITED WARRANTY
Avanta Orthopaedics Corporation warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

DEUTSCH

BESCHREIBUNG
Die Platte zur karpalen Fusion von Avanta dient zur operativen Versteifung der Karpalknochen der Hand, einschließlich Capitatum, Hamatum, Lunatum und Triquetrum. Die Fusionsplatte ist eine einteilige Niederprofil-Konstruktion, die über dem dorsalen Bereich der Karpalknochen in der Hand eingesetzt wird. Die Platte hat runde Löcher oder Schlitze für die Schrauben zur Fixierung. Fusionsplatte und Schrauben sind aus rostfreiem Stahl mit Implantatqualität hergestellt.

Werkstoffe:
- Rostfreier Stahl ASTM F-138 oder ASTM F-139

ANWENDUNGSGEBIETE
Die Platte zur karpalen Fusion von Avanta dient zur operativen Versteifung der Karpalknochen der Hand, einschließlich Capitatum, Hamatum, Lunatum und Triquetrum. Die Fusionsplatte wird bei Patienten angewandet, die auf Grund von Osteoarthritis, posttraumatischer Arthritis, Frakturen, Revision am Handgelenk bei ausgeblieberen Teillusionen, karpaler Instabilität oder rheumatoider Arthritis an Schmerzen und/oder Funktionsverlust leiden. Die Anwendung der Fusionsplatte erfolgt in Verbindung mit Schrauben, die die Platte an den Karpalknochen der Hand fixieren.

GEGENANZEIGEN
- Aktive oder latente Infektion
- Osteoporose, unzureichende Menge oder Qualität des Knochens/Weichgewebes
- Empfindlichkeit gegenüber dem Material - wenn ein diesbezüglicher Verdacht besteht, sind vor dem chirurgischen Eingriff entsprechende Tests durchzuführen
- Sepsis
- Patienten mit mentalen oder neurologischen Erkrankungen, die nicht gewillt oder nicht fähig sind, die postoperativen Behandlungsanweisungen zu befolgen

WARNHINWEISE (Siehe auch die Abschnitte Informationen zur Patientenberatung sowie Nebenwirkungen)
- Dieses Medizinprodukt ist nur für den in dieser Packungsbeilage beschriebenen Verwendungszweck bestimmt.
- Sorgfältige Patientenauswahl, Edukation sowie Beratung durch den Chirurgen und den Leistungsanbieter für Rehabilitation sind besonders wichtig.
- Starke Belastung und übermäßige Mobilität können zum Ausfall des Medizinproduktes (Implantatversagen) führen. Die Patienten sind darauf hinzuweisen, dass sich das Ausfallrisiko des Medizinproduktes bei übermäßiger Beanspruchung erhöht.
- Bruch oder Beschädigung des Medizinproduktes können eintreten, wenn das Implantat bei verzögerter Frakturheilung, Pseudarthrose oder unvollständiger Heilung einer erhöhten Belastung ausgesetzt wird.
- Unsachgemäßige Insertion des Medizinproduktes während der Implantation kann das Lockerungs- oder Migrationsrisiko des Implantats erhöhen.
- Ein schlechtes Ergebnis kann erzielt werden, wenn die Fraktur nicht korrekt eingerichtet oder das Medizinprodukt nicht ordnungsgemäß zusammengesetzt wird.
- Es kann erforderlich sein, dieses Implantat zu entfernen.
- Warnhinweis: Dieses Medizingerät ist nicht zur Verschraubung oder Fixierung an posterioren Elementen (Pedikel) der Halswirbel-, Brustwirbel- oder Lendenwirbelsäule zugelassen.
- Mitteilung gemäß dem Gesetz für sauberes Trinkwasser und zur Bekämpfung toxischer Stoffe des Bundesstaates Kalifornien (California Safe Drinking Water and Toxic Enforcement Act) von 1986 (Proposition 65): Dieses Produkt enthält eine Chemikalie/Chemikalien, von der/denen dem Bundesstaat von Kalifornien bekannt ist, dass sie Krebs und/oder Geburtsschäden und/oder andere Reproduktionstoxizität erzeugt/erzeugen.

VORSICHTSMASSNAHMEN FÜR DIE ANWENDUNG
- Das Implantat darf nie wiederverwendet werden. Durch frühere Beanspruchungen können Störungen und Defekte entstanden sein, die zum Ausfall des Medizinproduktes führen können.
- Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn eine Beschädigung des Implantates oder der Verpackung vorzuliegen scheint, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden. Bei diesem Implantat handelt es sich um ein Medizinprodukt für einmaligen Gebrauch; es ist nicht zur Wiederverwendung bestimmt. Die Resterilisation des Implantates wird nicht empfohlen.
- Sorgfältige Vorbereitung der Implantationsstelle und korrekte Positionierung des Implantates erhöhen die Erfolgsaussichten der Implantation.
- Das sterile Produkt ist erst aus seiner sterilen Verpackung zu entnehmen, wenn entschieden ist, dass das Implantat bei dem Patienten eingesetzt wird.

NEBENWIRKUNGEN
- Die in der Literatur veröffentlichten Nebenwirkungen sind vor Anwendung dieses Medizinproduktes zu beachten.
- Empfindlichkeitsreaktionen auf Metall wurden nach Metallimplantation gemeldet.
- Verletzung der umgebenden Nerven, Blutgefäße, Sehnen oder Weichteile.
- Als weitere Nebenwirkungen können Knochenfrakturen, Infektionen, Schmerzen und Weichteilreflektion auftreten.

CHIRURGISCHE VERFAHREN
Ein Handbuch mit einer genauen Beschreibung des chirurgischen Verfahrens zur Anwendung dieses Medizinproduktes ist verfügbar. Der Chirurg ist dafür verantwortlich, sich vor Anwendung dieses Medizinproduktes mit dem Verfahren vertraut zu machen. Der Chirurg ist weiterhin dafür verantwortlich, die einschlägigen Publikationen sorgfältig zu lesen und erfahrene Mitarbeiter über das Verfahren vor der Anwendung zu konsultieren.

INFORMATIONEN ZUR PATIENTENBERATUNG (Siehe auch die Abschnitte Warnhinweise sowie Nebenwirkungen)
Neben den Patienteninformationen in den Abschnitten Warnhinweise und Nebenwirkungen sind dem Patienten die nachfolgenden Informationen zu vermitteln:
- Die erwartete Lebensdauer dieses Medizinproduktes ist zwar schwer zu bestimmen, aber sie ist begrenzt. Die Bestandteile sind aus Fremdstoffen gefertigt, die zur Erleichterung des Heilungsprozesses in den Körper implantiert werden. Auf Grund einer Vielzahl biologischer, mechanischer und physikalisch-chemischer Faktoren, die diese Medizinprodukte beeinträchtigen, kann jedoch nicht erwartet werden, dass diese Bestandteile auf unbegrenzte Zeitdauer derselben Aktivitätsstufe und Belastung wie der normale gesunde Knochen standhalten.

STERILISATION
- Dieses Produkt wird durch Ethylenoxid (EO)-Gas oder Gammabestrahlung sterilisiert.
- Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn das Implantat oder die Verpackung beschädigt zu sein scheinen, das Verfalldatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden. Dies ist ein Medizinprodukt für einmaligen Gebrauch.

EINGESCHRÄNKTE GARANTIE
Avanta Orthopaedics Corporation gewährleistet, dass dieses Produkt die Spezifikationen des Herstellers erfüllt und bei der Lieferung keine Herstellungsfehler aufweist. Ausgeschlossen von dieser Garantie sind speziell Fehler, die auf nicht-bestimmungsgemäßen Gebrauch, Abusus oder unsachgemäße Handhabung des Medizinproduktes nach Eingang bei dem Käufer zurückzuführen sind. Für das Ergebnis des chirurgischen Verfahrens übernimmt Avanta Orthopaedics keine Garantie.

EU-VERTRETER
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Niederlande
31 (0) 416 563754

FRANÇAIS

DESCRIPTION
La plaque de fusion carpienne Avanta a été conçue pour la fusion des os du carpe, incluant : grand os, os crochu, semi-lunaire et pyramidal. La plaque de fusion est composée d'une unique pièce à profil bas, qui a été conçue pour recouvrir la face dorsale des os du carpe. La plaque a des trous sphériques ou des fentes par où passent les vis de fixation. La plaque de fusion et les vis sont fabriqués en acier inoxydable de qualité médicale implantable.

Matériaux:
- Acier inoxydable ASTM F-138 ou ASTM F-139

INDICATIONS
- La plaque de fusion carpienne Avanta a été conçue pour la fusion des os du carpe, incluant : grand-os, os crochu, semi-lunaire et pyramidal. La plaque de fusion est prévue pour être utilisée sur les patients souffrant de douleurs et/ou d'une perte fonctionnelle due à l'ostéoarthrite, l'arthrite post-traumatique, les fractures, la révision chirurgicale postérieure à l'échec d'une fusion partielle du poignet, l'instabilité carpienne ou l'arthrite rhumatoïde. La plaque de fusion s'utilise conjointement avec des vis qui la fixent aux os carpiens.

CONTRE-INDICATIONS
- Infection active ou latente
- Ostéoporose, quantité ou qualité insuffisante d'os/de tissu osseux
- Allergie au matériau - en cas de suspicion d'allergie, faire des tests avant la chirurgie
- Sepsis
- Patients qui, du fait de leur état mental ou neurologique, n'ont pas la volonté suffisante ou sont incapables de suivre les instructions relatives aux soins post-opératoires.

AVERTISSEMENTS (Voir aussi les sections Conseils donnés au patient et Effets indésirables)
- Ce dispositif est uniquement prévu pour les utilisations décrites dans cet encart.
- La sélection rigoureuse des patients, l'information et les conseils donnés au patient par le chirurgien et le prestataire de soins de réhabilitation sont importants.
- De fortes charges et une mobilité excessive peuvent entraîner l'échec du dispositif. Il faut informer le patient de l'augmentation du risque d'échec du dispositif en cas de sollicitations excessives.
- Une rupture ou un dommage du dispositif peut se produire si l'implant est soumis à une augmentation de charge associée à un retard de consolidation, une pseudarthrose ou une guérison incomplète.
- L'insertion incorrecte du dispositif pendant l'implantation peut augmenter la possibilité de relâchement et de migration.
- Le résultat obtenu peut être insatisfaisant en cas de réduction de fracture incorrecte ou d'assemblage incorrect du dispositif.
- Il peut être nécessaire d'explanter le dispositif.
- Avertissement : Ce dispositif n'a pas reçu d'approbation pour l'attachement par vis ou la fixation aux éléments postérieurs (pédicules) de la colonne vertébrale (cervicale, thoracique ou lombaire).
- Notification conforme à la Proposition 65 de Californie (California Safe Drinking Water and Toxic Enforcement Act, acte exécutoire de la protection de l'eau potable contre les produits toxiques, approuvé en 1986) : ce produit contient un agent chimique connu dans l'Etat de Californie pour causer le cancer et/ou des malformations néonatales et autre toxicité liée à la reproduction.

PRÉCAUTIONS
- Il ne faut jamais réutiliser un implant. Les tensions précédentes peuvent avoir créé des imperfections risquant d'entraîner l'échec du dispositif.
- L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en cause pour telle ou telle raison, il ne faut pas utiliser l'implant. C'est un dispositif à usage unique qui n'est pas prévu pour la réutilisation. Il n'est pas recommandé de restériliser l'implant.
- Une préparation méticuleuse du site de l'implant et un positionnement correct augmentent le potentiel de réussite.
- Les produits stériles ne doivent être enlevés de leur emballage stérile que si la décision d'implantation a été prise.

EFFETS INDÉSIRABLES
- Les effets indésirables publiés dans la littérature doivent être revus avant l'utilisation du dispositif.
- Des réactions d'allergie au métal ont été rapportées suite à l'implantation du dispositif.
- Lésion traumatique des nerfs, vaisseaux sanguins, tendons ou du tissu mou environnants.
- Les éventuels effets indésirables supplémentaires sont notamment : fracture osseuse, infection, douleur et irritation des tissus mous.

PROCÉDURES CHIRURGICALES
Un manuel est disponible ; il décrit en détail la procédure chirurgicale permettant d'utiliser l'implant. La connaissance de cette procédure est de la responsabilité du chirurgien. Il incombe également au chirurgien de se tenir au courant des publications pertinentes et de consulter des confrères expérimentés au sujet de la procédure à utiliser.

CONSEILS DONNÉS AU PATIENT (Voir aussi les sections Avertissements et Effets indésirables)
Outre l'information relative au patient qui est contenue dans les sections Avertissements et Effets indésirables, le patient doit recevoir l'information suivante :
- Il est difficile d'estimer la durée de vie prévue de ce dispositif, mais elle n'est pas illimitée. Ces composants sont en effet fabriqués dans des matériaux étrangers au corps humain et implantés afin de faciliter le processus de guérison. Toutefois, en raison des nombreux facteurs biologiques, mécaniques et physio-chimiques qui affectent ces dispositifs, les composants ne peuvent pas supporter le même niveau d'activité et les mêmes charges qu'un os sain pendant une période illimitée.

STÉRILISATION
- Ce composant est stérilisé par oxyde d'éthylène ou rayons gamma.
- L'implant est fourni stérile dans un emballage scellé. Si l'implant ou l'emballage paraît endommagé, si la date de péremption est dépassée ou si la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant. C'est un dispositif à usage unique.

GARANTIE LIMITÉE
Avanta Orthopaedics Corporation garantit que ce produit est conforme aux spécifications du fabricant et qu'il est livré sans défaut de fabrication. Cette garantie exclut spécifiquement les défauts résultant d'une utilisation incorrecte ou abusive, ou d'une manipulation incorrecte du produit postérieure à la réception par l'acheteur. Avanta Orthopaedics ne garantit pas l'issue de la chirurgie.

REPRÉSENTANT EN EUROPE :
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Pays-Bas
31 (0) 416 563754

ESPAÑOL

DESCRIPCIÓN
La placa para fusión carpiana Avanta está diseñada para la fusión de los huesos carpianos de la mano, que incluyen el hueso grande del carpo, el hueso ganchoso, el semilunar y el piramidal. La placa para fusión es una construcción de un solo componente, de perfil bajo, diseñada para encajar sobre la cara dorsal de los huesos carpianos de la mano. La placa tiene ranuras u orificios estériles donde se alojan los tornillos de fijación. La placa para fusión y los tornillos están fabricados en acero inoxidable apto para implantes.

Materiales:
- Acero inoxidable ASTM F-138 o ASTM F-139

INDICACIONES
- La placa para fusión carpiana Avanta está diseñada para la fusión de los huesos carpianos de la mano, que incluyen el hueso grande del carpo, el hueso ganchoso, el semilunar y el piramidal. La placa para fusión está prevista para su empleo en pacientes que presenten dolor o pérdida funcional debidos a artrosis, artritis postraumática, fracturas, revisión de fusiones parciales fallidas de la articulación carpiana, inestabilidad carpiana o artritis reumatoide. La placa para fusión se emplea en combinación con tornillos destinados a fijarla a los huesos carpianos de la mano.

CONTRAINDICACIONES
- Infección activa o latente
- Osteoporosis; cantidad o calidad insuficiente del hueso o los tejidos blandos
- Hipersensibilidad al material: en caso de sospecha debe realizarse una prueba antes de la cirugía
- Septicemia
- Pacientes con trastornos mentales o neurológicos que no estén dispuestos a seguir las instrucciones para los cuidados posoperatorios o no sean capaces de hacerlo

ADVERTENCIAS (Véanse también los apartados "Información para el paciente" y "Efectos adversos")
- Este producto está previsto exclusivamente para los usos descritos en el presente prospecto.
- Es importante una selección cuidadosa de los pacientes, así como una apropiada información y asesoramiento por parte del cirujano y el responsable de la rehabilitación.
- Los esfuerzos intensos o la movilidad excesiva pueden provocar el fracaso del dispositivo. Debe informarse a los pacientes de que las probabilidades de fracaso del dispositivo aumentan si se somete a una carga excesiva.
- El dispositivo puede romperse o deformarse si el implante se somete a un esfuerzo adicional asociado a una consolidación diferida, una seudoartrosis o una consolidación incompleta.
- La inserción inadecuada del dispositivo durante la implantación puede aumentar la posibilidad de su aflojamiento y migración.
- Puede obtenerse un resultado insatisfactorio si la fractura no se reduce correctamente o el dispositivo no se monta correctamente.
- Puede ser necesaria una explantación del dispositivo.
- Advertencia: este producto no está autorizado para su fijación o unión mediante tornillos a los elementos posteriores (pedículos) de la columna cervical, dorsal o lumbar.
- Notificación de acuerdo con lo establecido en la California Safe Drinking Water and Toxic Enforcement Act de 1986 [Ley sobre Seguridad del Agua Potable y Agentes Tóxicos del estado de California, conocida también como Proposición 65]: Este producto contiene uno o más productos químicos de los que el estado de California sabe que provocan cáncer o defectos congénitos y otros efectos de toxicidad reproductiva.

PRECAUCIONES
- Nunca debe reutilizarse un implante. Los esfuerzos anteriores pueden haber provocado imperfecciones que podrían llevar a un fracaso del dispositivo.
- El implante se suministra estéril en un envase intacto. Si el implante o el envase aparecen dañados, ha transcurrido la fecha de caducidad, o existe alguna duda sobre la esterilidad, el implante no debe utilizarse. Se trata de un producto desechable no previsto para su reutilización. No se recomienda resterilizar el implante.
- La preparación meticulosa de la zona de implantación y la colocación correcta del implante aumentan las posibilidades de éxito.
- Los productos estériles sólo deben extraerse de su envase estéril una vez que se determine que el implante va a utilizarse en el paciente.

EFECTOS ADVERSOS
- Antes de utilizar este dispositivo deben estudiarse los efectos adversos descritos en la literatura.
- Se han descrito reacciones de hipersensibilidad a los metales tras la implantación de materiales metálicos.
- Existe posibilidad de lesionar los nervios, vasos sanguíneos, tendones o tejidos blandos circundantes.
- Entre otros posibles efectos adversos figuran fracturas óseas, infección, dolor e irritación de los tejidos blandos.

TÉCNICAS QUIRÚRGICAS
Existe un manual donde se describe detalladamente la técnica quirúrgica para el uso de este dispositivo. Es responsabilidad del cirujano familiarizarse con la técnica antes de utilizar estos productos. También es responsabilidad del cirujano estar familiarizado con las publicaciones relevantes y consultar sobre la técnica con colegas experimentados antes del empleo de estos productos.

INFORMACIÓN PARA EL PACIENTE (Véanse también los apartados "Advertencias" y "Efectos adversos")
Además de la información relacionada con los pacientes que figura en los apartados "Advertencias" y "Efectos adversos", debe transmitirse al paciente la siguiente información:
- Si bien resulta difícil estimar la expectativa de vida de este dispositivo, ésta no es ilimitada. Los componentes están fabricados con materiales ajenos al organismo que se introducen en el mismo para facilitar el proceso de consolidación ósea. Sin embargo, debido a los numerosos factores biológicos, mecánicos y fisioquímicos que afectan a estos dispositivos, no es posible esperar que los componentes resistan durante un periodo ilimitado el nivel de actividad y los esfuerzos a los que está sometido un hueso normal sano.

ESTERILIZACIÓN
- Este producto está esterilizado por óxido de etileno o radiación gamma.
- El implante se suministra estéril en un envase intacto. Si el implante o el envase aparecen dañados, ha transcurrido la fecha de caducidad, o existe alguna duda sobre la esterilidad, el implante no debe utilizarse. Este producto es de un solo uso.

GARANTÍA LIMITADA
Avanta Orthopaedics Corporation garantiza que este producto cumple las especificaciones del fabricante y no presenta defectos de fabricación en el momento de su entrega. Esta garantía excluye específicamente los defectos derivados del uso incorrecto, abuso o manejo inadecuado del producto tras su recepción por el comprador. Avanta Orthopaedics no garantiza el resultado de la operación quirúrgica.

REPRESENTANTE EN LA UE:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Países Bajos
31 (0) 416 563754

NEDERLANDS

BESCHRIJVING
De Avanta carpale fusieplaat is ontworpen voor fusie van de carpale botten van de hand waaronder: capitatum, hamatum, lunatum en triquetrum. De fusieplaat is een constructie uit één stuk met een geringe bouwhoogte, ontworpen om over het dorsale deel van de carpale botten in de hand te passen. De plaat heeft sleuven of sleuven die plaats bieden aan schroeven voor fixatie. De fusieplaat en schroeven zijn gemaakt van implanteerbaar roestvrij staal.

Materialen:
- Roestvrij staal ASTM F-138 of ASTM F-139

INDICATIES
- De Avanta carpale fusieplaat is ontworpen voor fusie van de carpale botten van de hand waaronder: capitatum, lunatum, hamatum en triquetrum. De fusieplaat is bedoeld voor gebruik in patiënten die lijden aan pijn en/of functieverlies wegens osteoartritis, posttraumatische artritis, fracturen, correctie van misvormde partiële pseudosis, carpale instabiliteit of reumatoide artritis. De fusieplaat wordt gebruikt in combinatie met schroeven die de plaat aan de carpale botten van de hand bevestigen.

CONTRA-INDICATIES
- Actieve of latente infectie
- Osteoporose, onvoldoende kwantiteit of kwaliteit van bot/zacht weefsel
- Materiaalgevoeligheid - voer bij verdenking hiervan vóór de chirurgische ingreep tests uit
- Sepsis
- Patiënten met mentale of neurologische afwijkingen die instructies voor postoperatieve zorg niet willen of kunnen opvolgen

WAARSCHUWINGEN (Zie ook de paragrafen Informatie voor patiëntadvisering en Mogelijke complicaties)
- Dit toestel is uitsluitend bedoeld voor gebruik zoals beschreven in deze bijlage.
- Een zorgvuldige patiëntselectie, voorlichting en advisering door de chirurg en de verlener van revalidatiezorg is belangrijk.
- Zware belasting, overmatige mobiliteit, kan ertoe leiden dat het toestel het begeeft. Patiënten dienen erop te worden geattendeerd dat er een verhoogde kans bestaat dat het toestel het begeeft wanneer er te veel van wordt gevergd.
- Wanneer het implantaat wordt blootgesteld aan een verhoogde belasting, kan het toestel kapot gaan of beschadigd raken, gepaard gaand met vertraagd aaneengroeien, niet aaneengroeien of onvolledige genezing.
- Onjuist inbrengen van het toestel tijdens de implantatie kan de kans op losgaan en migratie vergroten.
- Een slecht resultaat kan worden behaald wanneer de fractuur niet goed wordt gezet of het toestel niet goed wordt geïmanteerd.
- Explantatie van dit toestel kan noodzakelijk zijn.
- Waarschuwing: Dit toestel is niet goedgekeurd voor aanhechting of fixatie met behulp van schroeven aan de achterelementen (pediculi) van de cervicale, thoracale of lumbale wervelkolom.
- Notificatie conform de wet van de Amerikaanse deelstaat Californië inzake veilig drinkwater en toxische handhaving van 1986 (opmerking 65): Dit product bevat een chemisch product/chemische producten waarvan in de staat Californië bekend is dat dit/deze kanker en/of geboortegebreken en andere reproductieve toxiciteit veroorzaakt/veroorzaken.

VOORZORGSMAATREGELEN
- Een implantaat mag nooit worden hergebruikt. Eerdere belastingen kunnen gebreken hebben veroorzaakt die ertoe kunnen leiden dat het toestel het begeeft.
- Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien het implantaat of de verpakking beschadigd blijkt te zijn, de vervaldatum is verlopen, of om welke reden dan ook wordt getwijfeld aan de steriliteit, dient het implantaat niet te worden gebruikt. Dit is een toestel voor eenmalig gebruik en niet bedoeld voor hergebruik. Hersterilisatie wordt niet aanbevolen voor het implantaat.
- Een nauwkeurige voorbereiding van de implantatieplaats en een juiste positionering van het implantaat vergroten de kans op een succesvol resultaat.
- De steriele producten mogen pas uit de steriele verpakking worden gehaald zodra vaststaat dat het implantaat zal worden gebruikt op de patiënt.

MOGELIJKE COMPLICATIES
- Complicaties die in de literatuur bekend zijn gemaakt, dienen te worden bestudeerd voordat dit toestel wordt gebruikt.
- Metaalgevoeligheidsreacties zijn gemeld na metaalimplantatie.
- Verwonding van omringende zenuwen, bloedvaten, pezen of zacht weefsel.
- Mogelijke bijkomende complicaties kunnen botfractuur, infectie, pijn en irritatie van zacht weefsel omvatten.

CHIRURGISCHE PROCEDURES
Er is een handleiding verkrijgbaar, waarin in detail de chirurgische procedure voor het gebruik van dit toestel wordt beschreven. Het is de eigen verantwoordelijkheid van de chirurg om vóór gebruik van deze producten op de hoogte te zijn van de procedure. Daarnaast is het de verantwoordelijkheid van de chirurg om vóór gebruik op de hoogte te zijn van relevante publicaties en het advies in te winnen van ervaren collega's met betrekking tot de procedure.

INFORMATIE VOOR PATIËNTADVISERING (Zie ook de paragrafen Waarschuwingen en Mogelijke complicaties)
Naast de patiëntinformatie in de paragrafen Waarschuwingen en Mogelijke complicaties dient de volgende informatie aan de patiënt te worden verstrekt:
- Hoewel de verwachte levensduur van dit toestel moeilijk in te schatten is, is deze beperkt. Deze componenten zijn gemaakt van vreemde materialen, die in het lichaam worden geplaatst om het genezingsproces te bevorderen. Vanwege de vele biologische, mechanische en fysiochemische factoren die deze toestellen beïnvloeden, kan echter niet van de componenten worden verwacht dat ze voor onbeperkte tijd bestand zijn tegen het activiteitsniveau en de belasting van normaal gezond bot.

STERILISATIE
- Dit product wordt gesteriliseerd door ethyleenoxide (EO) gas of gammastraling.
- Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien het implantaat of de verpakking beschadigd blijkt te zijn, de vervaldatum is verlopen, of om welke reden dan ook wordt getwijfeld aan de steriliteit, dient het implantaat niet te worden gebruikt. Dit is een toestel voor eenmalig gebruik.

BEPERKTE GARANTIE
Avanta Orthopaedics Corporation garandeert dat dit product op het moment van levering voldoet aan de specificaties van de fabrikant en vrij is van fabricagefouten. Met name uitgesloten van deze garantie zijn defecten die een gevolg zijn van verkeerd gebruik, misbruik of een onjuiste behandeling van het product na ontvangstneming door de koper. Avanta Orthopaedics biedt geen garantie op het resultaat van de chirurgische procedure.

VERTEGENWOORDIGER IN DE EU:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

ITALIANO

DESCRIZIONE
La Placca per fusione carpale Avanta è progettata per la fusione delle ossa carpali, comprendenti capitato, uncinato, lunato e piramidale. La placca per fusione è una struttura a basso profilo in un unico pezzo, da adattare sulla faccia dorsale delle ossa carpali. La placca è dotata di fori sferici o asole per le viti da usare per la fissazione. La placca per fusione e le relative viti sono in acciaio inossidabile di qualità per impianti.

Materiali:
- Acciaio inox ASTM F-138 o ASTM F-139

INDICAZIONI
- La Placca per fusione carpale Avanta è progettata per la fusione delle ossa carpali, comprendenti capitato, uncinato, lunato e piramidale. L'impiego della placca per fusione è destinato a pazienti con dolori e/o perdita funzionale dovuti a osteoartrite, artrite post-traumatica, fratture, revisione di fusioni parziali del polso non riuscite, instabilità carpale o artrite reumatoide. La placca per fusione è da usarsi in associazione con viti che la fissano sulle ossa carpali.

CONTROINDICAZIONI
- Infezione in atto o latente
- Osteoporosi, tessuto osseo/molle insufficiente per quantità o qualità
- Ipersensibilità al materiale - in caso di sospetta ipersensibilità, eseguire test prima dell'intervento
- Sepsi
- Pazienti che per condizioni mentali o neurologiche non vogliono o possono seguire le istruzioni per le cure postoperatorie

AVVERTENZE (vedere anche le sezioni Informazioni per la consulenza ai pazienti ed Effetti indesiderati)
- Il presidio è destinato unicamente all'uso descritto nel presente foglio illustrativo.
- È importante che il chirurgo e l'équipe di riabilitazione provvedano a selezionare attentamente i pazienti, educarli e consigliarli.
- Un eccesso di carico o di mobilità possono comportare il fallimento del presidio. I pazienti devono essere avvertiti del maggiore potenziale di fallimento del presidio se sottoposto a sollecitazioni eccessive.
- Il presidio può rompersi o rimanere danneggiato se l'impianto viene assoggettato a carichi crescenti in associazione con ritardo di unione, mancata unione o guarigione incompleta.
- L'inserimento non corretto del presidio durante l'impianto può aumentare la possibilità di distacco e spostamento dello stesso.
- Si può ottenere un risultato insoddisfacente se la frattura non viene ridotta correttamente o il presidio non è correttamente assemblato.
- In tali casi potrebbe rendersi necessario l'espianto del presidio.
- Avvertenza importante: il presente presidio non è approvato per l'attacco o fissazione con viti degli elementi posteriori (peduncoli) delle vertebre cervicali, toraciche o lombari.
- Notifica in conformità con la Legge del 1986 dello Stato della California sulla sicurezza dell'acqua potabile e sulle sostanze tossiche (dichiarazione 65): Questo prodotto contiene uno o più sostanze chimiche note allo Stato della California come possibili cause di cancro e/o difetti neonatali e di altri effetti tossici sull'attività riproduttiva.

PRECAUZIONI
- Un impianto non deve mai essere riutilizzato. Le sollecitazioni subite in precedenza possono aver dato origine ad imperfezioni che determinerebbero il fallimento del presidio.
- L'impianto fornito è sterile se in confezione integra. Non utilizzare l'impianto se lo stesso o la confezione appaiono danneggiati, se la data di scadenza è stata superata o se per qualsiasi motivo si è indotti a dubitare della sua sterilità. Il presente presidio è monouso e non deve essere riutilizzato. Si sconsiglia la risterilizzazione dell'impianto.
- Una preparazione meticolosa del sito d'impianto e un corretto posizionamento dell'impianto stesso aumentano le probabilità di esito positivo dell'intervento.
- I prodotti sterili devono essere prelevati dalla confezione sterile solo dopo aver accertato l'uso effettivo dell'impianto sul paziente.

EVENTI INDESIDERATI
- Prima di usare il presidio, eseguire una ricerca degli eventi indesiderati pubblicati dalla letteratura.
- Sono stati riferiti casi di reazioni di sensibilizzazione ai metalli in seguito all'impianto.
- Lesioni dei nervi, vasi sanguigni, tendini o tessuti molli circostanti.
- Altri possibili effetti indesiderati: fratture ossee, infezioni, dolore e irritazione dei tessuti molli.

PROCEDURE CHIRURGICHE
È disponibile un manuale che descrive nei dettagli la procedura chirurgica da applicare a questo presidio. È responsabilità del chirurgo acquisire familiarità con la procedura prima dell'uso di questi prodotti. È inoltre responsabilità del chirurgo anche acquisire familiarità con le pubblicazioni relative e consultarsi con colleghi esperti in merito alla procedura prima dell'uso.

INFORMAZIONI PER LA CONSULENZA AI PAZIENTI (vedere anche le sezioni Avvertenze ed Effetti indesiderati)
Oltre alle informazioni relative al paziente contenute nelle sezioni Avvertenze ed Effetti indesiderati, devono essere trasmesse al paziente le seguenti informazioni:
- La durata prevista di questo presidio, sebbene sia difficile da valutare, è comunque limitata nel tempo. Si tratta infatti di elementi composti da materiali estranei all'organismo, inseriti per facilitare il processo di guarigione. A causa dei molti fattori biologici, meccanici e fisiochimici che influiscono su questi dispositivi, non si può tuttavia pensare che essi possano resistere per un periodo di tempo illimitato a livelli di attività e carico uguali a quelli del normale osso sano.

STERILIZZAZIONE
- Il prodotto è sterilizzato in ossido di etilene (ETO) o ai raggi gamma.
- L'impianto fornito è sterile se in confezione integra. Non utilizzare l'impianto se lo stesso o la confezione appaiono danneggiati, se la data di scadenza è stata superata o se per qualsiasi motivo si è indotti a dubitare della sua sterilità. Il presidio è monouso.

GARANZIA LIMITATA
La Avanta Orthopaedics Corporation garantisce che il presente prodotto è conforme alle specifiche del produttore e che è esente da difetti di fabbricazione al momento della consegna. La presente garanzia esclude specificamente i difetti derivanti da uso improprio o non corretto o da errori di manipolazione del prodotto successivamente al ricevimento da parte dell'acquirente. La Avanta Orthopaedics non garantisce l'esito della procedura chirurgica.

AGENTE PER L'UE:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Paesi Bassi
31 (0) 416 563754

19-0389 rev A

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AVANTA
ORTHOPAEDICS
9369 Carroll Park Drive, Suite A, San Diego, CA 92121 USA
(858)452-8580 / (858)452-9945 (fax)

PRODUCT INSERT

Avanta CMC Prosthesis

ENGLISH

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
The Avanta CMC Trapezio-metacarpal joint prosthesis consists of an ultra-high molecular weight polyethylene (UHMWPe) component which is cemented to the prepared trapezium, and a titanium alloy stem component with integral head which is inserted into the shaft of the first metacarpal. The titanium head articulates with the UHMWPe component to form a snap-fit constrained prosthetic replacement for the basal thumb joint. The implant is available in three sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation.

Materials:
- ASTM F-136 Titanium 6AL-4V ELI alloy metacarpal stem/head
- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) trapezial component
- ASTM F-75 cobalt chromium radiographic marker wire

INDICATIONS
The Avanta CMC Trapezio-metacarpal prosthesis is indicated for total joint replacement in skeletally mature patients with pain or instability of the trapezio-metacarpal joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

CONTRAINDICATIONS
- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation which cannot provide adequate support or fixation for the prosthesis.
- Any active or suspected infection in or around the thumb joint.
- Skeletal immaturity.

WARNINGS (See also the Patient Counseling Information Section)
- This device is for cemented use only.
- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.

PRECAUTIONS
- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.

ADVERSE EVENTS
- Adverse events in a published series of 50 patients included loosening, transient radial neuritis, cement extrusion injury to the palmar digital nerves and de Quervain's tendinitis1.

Event	Number of events (n=50)
Loosening	5 (10.0 %)
transient radial neuritis	2 (4.0 %)
cement extrusion injury	1 (2.0 %)
de Quervain's tendinitis	6 (12.0 %)

- Potential adverse events reported with other finger joint prostheses include loosening, fracture dislocation, or infection of the implant. No additional significant adverse events have been reported to date during the marketing period of this device.
- Injury to the surrounding nerves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device.
- Metal sensitivity reaction have been reported following joint replacement.

CLINICAL RESULTS
Results of twenty-nine patients implanted with the device were reported2. Replacement was performed for arthritis, failure of attempted arthrodesis, previous Silastic or total joint arthroplasty failure, or postparalytic fibrous ankylosis of the joint. Twenty-two patients had achieved a good range of painless motion at the time of publication (up to 7 years follow-up). Seven cases failed to achieve normal ROM due to significant muscle imbalance or soft tissue scarring and contracture. There was no reported cases of implant fracture or infection, but three cases demonstrated loosening at the cement—bone interface.

In a subsequent expanded publication including an additional 21 cases in the series1, most of the 50 patients showed a full range of motion within four weeks of suture removal and continued to demonstrate good long-term results. Full range of asymptomatic motion was achieved in 26 osteoarthritic patients with articular derangement. Five patients showed clinical or radiographic evidence of loosening. No cases of implant fracture, surface wear, fragmentation or infection were seen.

SURGICAL PROCEDURES
A manual is available describing detailed surgical procedure for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings)
In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

- While the expected life of total joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time. The reported rate of loosening in a clinical study of this device was 10% at up to 10 years follow-up. (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985;195:161-7.)
- Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION
- This component has been sterilized by ethylene oxide or gamma radiation.
- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize.
- Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY
Avanta Orthopaedics Corporation warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

EU REPRESENTATIVE:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

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2 Braun RM. Total joint replacement at the base of the thumb—preliminary report. In: J Hand Surg [Am](1982 May) 7(3):245-51

DEUTSCH

BESCHREIBUNG
Die Trapezio-Metacarpal-Gelenkprothese Avanta CMC ist eine Komponente aus ultrahochmolekularem Polyethylen (UHMWPe), die in den präparierten Trapezknochen zementiert ist, und eine Schaftkomponente aus Titanlegierung mit integriertem Kopf, die in dem Schaft des ersten Metacarpal-Knochens zementiert verankert ist. Zwischen Titankopf und der UHMWPe-Komponente besteht eine gelenkige Verbindung (Artikulation), um einen gekoppelten prothetischen Ersatz mit einem „Snap-Fit"-Mechanismus für das Daumengrundgelenk zu bilden. Das Implantat ist in drei Größen verfügbar, die alle an der rechten oder linken Hand eingesetzt werden können. Für jeden Implantattyps gibt es eine Palette von Probeprothesen, so genannte Sizer, die als Hilfsmittel für die Präparation des Knochens verwendet werden.

Materialien:
- Metacarpal-Schaft/Kopf aus Titanlegierung 6AL-4V ELI gemäß ASTM F 136
- Trapeziuskomponente aus ultrahochmolekularem Polyethylen (UHMWPe) gemäß ASTM F-648
- Radiologischer Markierungsdraht aus Kobaltchrom gemäß ASTM F75

ANWENDUNGSGEBIETE
Die Trapezio-Metacarpal-Prothese Avanta CMC ist indiziert als Totalgelenkersatz bei Personen mit ausgereifter Skelettentwicklung, die infolge von Trauma, entzündlicher oder degenerativer Erkrankung oder Revision früherer Prothesen an Schmerzen oder Instabilität des Trapezio-Metacarpal-Gelenkes leiden, und stellt eine Alternative zu Arthrodese oder rekonstruktiver Chirurgie dar.

GEGENANZEIGEN
- Durch Krankheit, Infektion oder frühere Implantation angegriffene Knochen, Muskulatur, Sehnen oder angrenzende Weichteile, die keine sichere Unterlage oder Fixierung für die Prothese bieten können.
- Aktive oder vermutete Infektion in oder an dem Daumengelenk.
- Unreife in der Skelettentwicklung.

WARNHINWEISE (siehe auch Abschnitt „Informationen zur Patientenberatung")
- Dieses Gerät ist nur zur zementierten Anwendung bestimmt.
- Starke Belastung, übermäßige Mobilität und Gelenkinstabilität können alle zu beschleunigtem Verschleiß und eventuellem Versagen durch Lockerung, Fraktur oder Dislokation der Prothese führen. Die Patienten sind auf das erhöhte Potenzial des Versagens der Prothese bei übermäßiger Belastung hinzuweisen.

VORSICHTSMAßNAHMEN FÜR DIE VERWENDUNG
- Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn eine Beschädigung des Implantates oder der Verpackung vorzuliegen scheint, das Verfallsdatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden. Nicht resterilisieren.
- Sorgfältige Vorbereitung des Implantatlagers und die Wahl der richtigen Größe des Implantates erhöhen die Erfolgsaussichten der Implantation.
- Das Implantat ist erst aus seiner sterilen Verpackung zu entnehmen, wenn das Implantatlager präpariert und für die Größe des Implantats richtig dimensioniert ist.
- Bei der Handhabung des Implants sind stumpfe Instrumente zu verwenden, um Kratzer, Schnitte oder Kerben auf dem Gerät zu vermeiden.

NEBENWIRKUNGEN
- Zu den Nebenwirkungen, die von 50 Patienten veröffentlicht wurden, gehörten Lockerung, transiente Neuritis des Nervus radialis, Verletzung der palmaren Fingernerven infolge von Zementextrusion und De-Quervain-Tendinitis.

Nebenwirkung	Anzahl der Nebenwirkungen (n = 50)
Lockerung	5 (10,0 %)
Transiente Neuritis des Nervus radialis	2 (4,0 %)
Verletzung durch Zementextrusion	1 (2,0 %)
De-Quervain-Tendinitis	6 (12,0 %)

- Zu den potenziellen Nebenwirkungen, über die bei anderen Fingergelenkprothesen berichtet wurde, gehören Lockerung des Implantats, Dislokation der Fraktur oder Infektion des Implantats. Seit der Markteinführung des Gerätes gab es bisher keine Berichte über weitere signifikante Nebenwirkungen.
- Verletzungen an den umgebenden Nerven, Blutgefäßen, Sehnen oder Weichteilen können infolge der Implantation dieses Gerätes auftreten.
- Nach Gelenkersatz wurde über Überempfindlichkeitsreaktionen auf Metall berichtet.

KLINISCHE ERGEBNISSE
Es gab Berichte über die Ergebnisse bei neunundzwanzig Patienten, denen das Gerät implantiert wurde.2 Der Ersatz erfolgte wegen Arthritis, fehlgeschlagener versuchter Arthrodese, vorheriger fehlgeschlagener Arthroplastik mit Silastikprothese oder Totalgelenkersatz oder fibröser Ankylose des Gelenks nach Lähmung. Zweiundzwanzig Patienten hatten zum Zeitpunkt der Veröffentlichung (Nachuntersuchungen bis zu 7 Jahre) einen zufriedenstellenden schmerzfreien Bewegungsspielraum erreicht. In sieben Fällen wurde wegen signifikanter Muskeldysbalance, Weichteilvernarbungen oder -kontrakturen kein normaler Bewegungsspielraum (ROM) erreicht. Es gab keine Berichte über Fraktur- oder Infektionsfälle des Implantats, aber in drei Fällen kam es zu einer Lockerung an der Zement-Knochen-Grenze (Interface).

Im Rahmen einer späteren größeren Veröffentlichung, die 21 weitere Fälle umfasste1, erreichten die meisten der 50 Patienten innerhalb von vier Wochen nach Nahtentfernung den vollen Bewegungsspielraum und zeigten gute Langzeitergebnisse. Bei 26 osteoarthritischen Patienten mit Gelenkverschiebung wurde der vollständige symptomfreie Bewegungsspielraum erreicht. Bei fünf Patienten zeigte sich klinisch oder radiologisch eine Lockerung des Implantats. Es waren keine Fälle von Implantatfraktur, Oberflächenverschleiß, Fragmentation oder Infektion festzustellen.

CHIRURGISCHE VERFAHREN
Ein Handbuch mit einer genauen Beschreibung des chirurgischen Verfahrens für den Einsatz dieser Implantatprothese ist verfügbar. Der Chirurg ist dafür verantwortlich, sich vor Anwendung dieses Medizinprodukts mit dem Verfahren vertraut zu machen. Der Chirurg ist weiterhin dafür verantwortlich, die einschlägigen Publikationen sorgfältig zu lesen und sich mit Berufskollegen zu beraten, die Erfahrung in der Anwendung dieses Verfahrens gesammelt haben.

INFORMATIONEN ZUR PATIENTENBERATUNG (Siehe auch Warnhinweise)
Neben den Patienteninformationen in den Abschnitten Warnhinweise und Nebenwirkungen sind den Patienten die nachfolgenden Informationen zu vermitteln:

- Die erwartete Lebensdauer der Komponenten des Totalgelenkersatzes ist zwar schwer zu bestimmen, aber sie ist begrenzt. Diese Komponenten sind aus Fremdstoffen gefertigt, die zur potenziellen Wiederherstellung der Mobilität und zur Verringerung der Schmerzen in den Körper implantiert werden. Aufgrund einer Vielzahl biologischer, mechanischer und physikalisch-chemischer Faktoren, die diese Prothesen beeinflussen, kann jedoch nicht erwartet werden, dass die Komponenten auf unbegrenzte Zeitdauer denselben Aktivitätsgrad und derselben Belastung standhalten wie der normale gesunde Knochen. Die in einer klinischen Studie über dieses Gerät gemeldete Lockerungsrate betrug 10 % nach einer Kontrolle von bis zu 10 Jahren. (Braun, RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985; 195: 161-7.)
- Nebenwirkungen dieser Prothese können möglicherweise Reoperation, Revision oder Fusion des betroffenen Gelenkes erforderlich machen.

STERILISATION
- Diese Komponente wurde mit Ethylenoxid oder Gammabestrahlung sterilisiert.
- Das Implantat wird steril in unversehrter Verpackung geliefert. Wenn eine Beschädigung des Implantats oder der Verpackung vorzuliegen scheint, das Verfallsdatum überschritten oder die Sterilität aus irgendeinem Grund in Frage gestellt ist, darf das Implantat nicht verwendet werden. Nicht resterilisieren.
- Probeprothesen, so genannte Sizer, sind verfügbar, um zu vermeiden, dass die sterile Verpackung vor der Implantation der Prothese geöffnet werden muss. Das Implantat darf erst aus der sterilen Verpackung entnommen werden, wenn das Implantatlager vorbereitet und für die Größe des Implantats richtig dimensioniert ist.

EINGESCHRÄNKTE GEWÄHRLEISTUNG
Avanta Orthopaedics Corporation gewährleistet, dass dieses Medizinprodukt die Spezifikationen des Herstellers erfüllt und bei der Lieferung keine Herstellungsfehler aufweist. Diese Gewährleistung schließt speziell Fehler aus, die auf nicht-bestimmungsgemäßen Gebrauch, Abusus oder unsachgemäße Handhabung des Medizinproduktes nach Eingang bei dem Käufer zurückzuführen sind. Avanta Orthopaedics übernimmt keine Gewährleistung für das Resultat der chirurgischen Methode.

EU-VERTRETER:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, The Netherlands
31 (0) 416 563754

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FRANÇAIS

DESCRIPTION
La prothèse pour articulation trapézo-métacarpienne Avanta CMC est composée d'un matériau à base de polyéthylène à ultra haute masse moléculaire (UHMWPE) qui est cimenté sur le trapèze préalablement préparé, et d'un composant postérieur en alliage de titane avec tête intégrée qui est introduit dans le creux du premier métacarpe. La tête en titane est reliée à la pièce en UHMWPE de façon à former un substitut instantanément adapté à l'articulation basale du pouce. L'implant existe en trois tailles, toutes utilisables sur la main gauche comme sur la main droite. Une gamme de calibreurs tests est proposée pour chaque type d'implant afin de contribuer à la préparation de l'os.

Composants:
- Tige/tête métacarpiennes en alliage de titane 6AL-4V ELI ASTM F 136
- Composant trapézien en polyéthylène à ultra haute masse moléculaire (UHMWPE) ASTM F-648
- Câble de marquage radiographique en chrome-cobalt ASTM F75

INDICATIONS
La prothèse trapézo-métacarpienne Avanta CMC est indiquée pour le remplacement articulaire total chez les patients dont le développement osseux est arrivé à maturité et présentant une douleur ou une instabilité au niveau de l'articulation trapézo-métacarpienne en raison d'un traumatisme, d'une maladie inflammatoire ou dégénérative, ou en cas de renouvellement d'implantations antérieures. Il s'agit d'une solution alternative à l'arthrodèse ou à la chirurgie reconstructrice.

CONTRE-INDICATIONS
- La détérioration d'os, de muscles, de tendons ou de tissus mous voisins dus à une maladie, une infection ou une implantation antérieure et empêchant d'obtenir un maintien ou une fixation satisfaisants de la prothèse.
- Toute infection active ou suspectée au niveau ou aux alentours de l'articulation du pouce.
- Une maturité osseuse non atteinte.

MISES EN GARDE (Voir également la partie intitulée « Informations à porter à l'attention du patient »)
- Ce dispositif est à utiliser uniquement dans le cadre d'une application cimentée.
- Les charges imposantes, les mouvements excessifs et l'instabilité articulaire sont tous susceptibles de provoquer le desserrement, la rupture ou le dislocation du dispositif et d'ou précipiter ainsi l'usure et l'éventuel défaillance. Les patients doivent être avertis qu'il existe un risque accru de défaillance du dispositif en cas de sollicitations excessives.

PRÉCAUTIONS
- L'implant est fourni stérile, tant que l'emballage est intact. En cas de détérioration apparente de l'implant ou de son emballage, de dépassement de la date de péremption ou de doute sur la stérilité du dispositif pour quelque raison que ce soit, l'implant ne doit pas être utilisé. Ne pas re-stériliser.
- La préparation méticuleuse du site d'implantation et le choix d'une taille d'implant adéquate augmentent les chances de réussite de l'intervention.
- L'implant doit être sorti de son emballage stérile uniquement une fois le site d'implantation préparé et convenablement calibré.
- L'implant doit être manipulé à l'aide d'instruments arrondis afin d'éviter toute griffure, coupure ou entaille.

ÉVÉNEMENTS INDÉSIRABLES
- Les événements indésirables relevés chez une série de 50 patients (et publiés) étaient notamment le desserrement, la névrite passagère du nerf radial, le lésion des nerfs digitaux palmaires liée à l'expulsion du ciment et la ténosynovite chronique sténosante du pouce de De Quervain1.

Événement	Nombre d'occurrences (n = 50)
Desserrement	5 (10,0 %)
Névrite passagère du nerf radial	2 (4,0 %)
Lésion liée à l'expulsion du ciment	1 (2,0 %)
Ténosynovite de De Quervain	6 (12,0 %)

- Les événements relatifs indésirables observés avec les autres prothèses articulaires des doigts sont, notamment, le desserrement, le rupture, le dislocation ou l'infection de l'implant. Aucun autre événement indésirable significatif n'a été rapporté à ce jour depuis le début de la période de commercialisation de ce dispositif.
- L'implantation de ce dispositif peut entraîner des lésions au niveau des nerfs, vaisseaux, tendons ou tissus mous environnants.
- Des cas de réaction allergique au métal suite à la substitution articulaire ont été relevés.

RÉSULTATS CLINIQUES
Les résultats de l'implantation de ce dispositif ont été observés chez vingt-neuf patients.2 Le substitution a été pratiquée en raison d'une arthrite, l'échec d'une arthrodèse préalable, l'échec de l'utilisation d'un implant en Silastic ou d'une arthroplastie articulaire totale, ou encore d'une ankylose fibreuse post-paralytique de l'articulation. À l'heure de la publication (après jusque 7 années de suivi), 22 patients étaient en mesure d'accomplir sans douleur une palette satisfaisante de mouvements. Dans sept cas, le jeu de l'articulation demeurait anormal en raison d'un déséquilibre musculaire significatif ou de la cicatrisation des tissus mous et de contractures. Aucun cas de rupture ou d'infection de l'implant n'a été rapporté mais, dans trois cas, un desserrement a été noté au niveau de la jonction ciment/os.

À l'occasion d'un rapport publié ultérieurement, portant sur cette même série de cas auxquels s'ajoutaient 21 cas supplémentaires1, il est apparu que la plupart des 50 patients étaient en mesure de faire jouer parfaitement leur articulation dans les quatre semaines suivant le retrait des fils de suture et présentaient toujours de bons résultats à long terme. Une marge complète de mouvement asymptomatique de l'articulation a été obtenue chez 26 patients arthritiques atteints de dérèglements articulaires. Dans cinq cas, l'examen clinique ou radiographique a fait apparaître un desserrement de l'implant. Aucun cas de rupture de l'implant, d'usure de surface, de morcellement ou d'infection n'a été relevé.

INTERVENTIONS CHIRURGICALES
Il existe un manuel décrivant en détail l'intervention chirurgicale à pratiquer pour l'implantation de ces dispositifs. La chirurgien est seul chargé de se familiariser avec l'intervention avant utilisation de ces produits, ainsi que de se tenir au courant des publications sur le sujet et de consulter des collègues expérimentés avant de procéder à ces interventions.

INFORMATIONS À PORTER À L'ATTENTION DES PATIENTS (Voir également les Mises en garde.)
Les informations suivantes, en plus de celles contenues dans les parties « Mises en garde » et « Événements indésirables », doivent être transmises au patient :

- La durée de vie des pièces de substitution articulaire totale est difficile à évaluer mais n'est, quoi qu'il en soit, pas éternelle. Ces pièces sont composées de matériaux étrangers à l'organisme et placés à l'intérieur de ce dernier en vue de rétablir la mobilité du membre ou de réduire la douleur. Cependant, étant données les nombreux facteurs biologiques, mécaniques et physicochimiques auxquels sont soumis les implants, il ne faut pas attendre des dispositifs qu'ils assurent indéfiniment le même niveau d'activité et supportent le même niveau de charge qu'un os sain et normal. Lors d'un essai clinique de ce dispositif, le taux de desserrements des implants après une période de suivi allant jusqu'à 10 ans était de 10 % (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985 ; 195 : 161-7)
- La survenue d'événements indésirables peut rendre nécessaire de finalement réopérer, corriger l'opération ou procéder à la fusion de l'articulation concernée.

STÉRILISATION
- Ce dispositif a été stérilisé à l'oxyde d'éthylène ou aux rayons gamma.
- L'implant est fourni stérile tant que son emballage est intact. En cas de détérioration apparente de l'implant ou de son emballage, de dépassement de la date de péremption ou de doute sur la stérilité du dispositif pour quelque raison que ce soit, l'implant ne doit pas être utilisé. Ne pas re-stériliser.
- Des pièces de calibrage test sont mises à votre disposition afin de vous éviter d'avoir à ouvrir l'emballage stérile avant l'implantation de la prothèse. L'implant doit être sorti de son emballage stérile uniquement une fois le site d'implantation préparé et convenablement calibré.

GARANTIE LIMITÉE
Avanta Orthopaedics Corporation garantit que ce produit répond aux caractéristiques décrites par le fabricant et ne présente pas de défauts de fabrication au moment de la livraison. Cette garantie exclue spécifiquement les défauts provoqués par la mauvaise utilisation, l'utilisation excessive ou la manipulation incorrecte du produit suite à sa réception par l'acquéreur. Avanta Orthopaedics n'offre aucune garantie quant aux résultats de l'intervention chirurgicale.

REPRÉSENTANT POUR L'UE:
Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Pays-Bas
Tél. : +31 (0) 416 563754

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ESPAÑOL

DESCRIPCIÓN

La prótesis para la articulación trapecio-metacarpiana Avanta CMC consta de un componente de polietileno de peso molecular ultra alto (UHMWPe), que se cementa al trapecio preparado, y un componente de vástago de aleación de titanio con una cabeza integral que se inserta dentro del eje del primer metacarpo. La cabeza de titanio se articula con el componente de UHMWPe formando un reemplazo protésico de ajuste exacto para la articulación de la base del pulgar. El implante se presenta en tres tamaños, cada uno de los cuales puede usarse en la mano derecha o en la mano izquierda. Para ayudar a preparar el hueso existe una serie de medidores de prueba para cada tipo de implante.

Materiales

- Vástago/cabeza metacarpianos de aleación de titanio 6AL-4V ELI, ASTM F136
- Componente de trapecio de polietileno de peso molecular ultra alto, ASTM F-648
- Alambre marcador radiográfico de cromo-cobalto, ASTM F75

INDICACIONES

La prótesis trapecio-metacarpiana Avanta CMC está indicada para el reemplazo articular total en pacientes con estructura ósea madura, que sienten dolor o inestabilidad en la articulación trapecio-metacarpiana debido a traumatismo, enfermedades inflamatorias o degenerativas o revisión de procedimientos anteriores, como alternativa a la artrodesis o la cirugía reconstructiva.

CONTRAINDICACIONES

- Compromiso de los huesos, músculos, tendones o tejido blando adyacentes a causa de patologías, infección o implante previo, que no permitan contar con un apoyo o fijación adecuados para la prótesis.
- Toda infección activa o sospecha de infección activa en la articulación del pulgar o alrededor de la misma.
- Inmadurez ósea.

ADVERTENCIAS (véase también la sección sobre información de asesoramiento para pacientes)

- Este dispositivo es sólo para uso cementado.
- La carga y la movilidad excesivas y la inestabilidad articular pueden acelerar el desgaste y eventualmente provocar el fracaso del procedimiento debido a que se puede aflojar, fracturar o dislocar el dispositivo. Se debe informar a los pacientes que una demanda excesiva sobre el dispositivo puede aumentar las posibilidades de tal caso.

PRECAUCIONES

- El implante se presenta estéril en un envase intacto. Si el implante o el envase están dañados, si ha transcurrido el período de validez o si se duda de su esterilidad por alguna razón, no debe usarse el implante. No volver a esterilizar.
- Una preparación minuciosa del lugar de colocación del implante y la elección de un implante de tamaño adecuado aumentan las posibilidades de obtener un resultado exitoso.
- El implante debe extraerse de su envase estéril sólo después de que se haya preparado el lugar de colocación del implante y de que se haya determinado adecuadamente su tamaño.
- Los implantes deben manipularse con instrumentos sin puntas para evitar rayaduras, cortes o marcas en el dispositivo.

EVENTOS ADVERSOS

- Los eventos adversos que se han informado en una serie publicada de 50 pacientes incluyen aflojamiento, neuritis radial transitoria, lesión por extrusión del cemento hacia los nervios digitales palmares y tendinitis de de Quervain.

Evento	Número de casos (n=50)
Aflojamiento	5 (10.0%)
Neuritis radial transitoria	2 (4.0%)
Lesión por extrusión del cemento	1 (2.0%)
Tendinitis de de Quervain	6 (12.0%)

- Los potenciales eventos adversos que se han informado con otras prótesis de articulación de dedos incluyen aflojamiento, fractura, dislocación o infección del implante. No se han informado otros eventos adversos significativos hasta la fecha durante el período de comercialización de este dispositivo.
- Como consecuencia del implante de este dispositivo se puede producir una lesión de los nervios, vasos sanguíneos, tendones y tejidos blandos que lo rodean.
- Se ha informado reacción de sensibilidad al metal como consecuencia del reemplazo articular.

RESULTADOS CLÍNICOS

Se informaron los resultados obtenidos con 29 pacientes a los cuales se les implantó el dispositivo. Los reemplazos se realizaron a causa de artritis, fracaso del injerto de artrodesis, fracaso de la artroplastia con prótesis de Silastic o articular total previa o anquilosis fibrosa posparalítica de la articulación. En 22 pacientes se había alcanzado un buen rango de movimiento sin dolor al momento de la publicación (con un seguimiento de hasta 7 años). Siete de los pacientes no lograron alcanzar un rango de movimiento normal debido a un desequilibrio muscular significativo o a cicatrización y contractura del tejido blando. No se informaron casos de fractura o infección del implante, pero hubo tres casos de aflojamiento en la unión entre el cemento y el hueso.

En una publicación posterior más extensa, que incluyó otros 21 casos de la serie[1], la mayoría de los 50 pacientes alcanzó un rango de movimiento completo dentro de las cuatro semanas posteriores a la retirada de los puntos de sutura y continuó demostrando buenos resultados a largo plazo. Se alcanzó un rango completo de movimiento asintomático en 26 pacientes osteoartríticos con trastorno articular. En cinco pacientes se observaron evidencias clínicas o radiográficas de aflojamiento. No se observaron casos de fractura del implante, desgaste superficial, fragmentación o infección.

PROCEDIMIENTOS QUIRÚRGICOS

Existe un manual que describe en detalle el procedimiento quirúrgico para el uso de estos implantes. Es responsabilidad del cirujano familiarizarse con el procedimiento antes de usar estos productos. Además, es responsabilidad del cirujano familiarizarse con las publicaciones pertinentes y consultar con colegas experimentados acerca del procedimiento antes de usar estos implantes.

INFORMACIÓN DE ASESORAMIENTO PARA EL PACIENTE (véase también Advertencias)

Además de la información relativa al paciente que incluyen las secciones Advertencias y Eventos adversos, se deberá transmitir al paciente la siguiente información.

- Si bien resulta difícil estimar la duración prevista de los componentes del reemplazo articular total, ésta es finita. Estos componentes están realizados con materiales extraños que se colocan dentro del cuerpo para la potencial restauración de la movilidad o la reducción del dolor. No obstante, debido a múltiples factores biológicos, mecánicos y fisicoquímicos que afectan a estos dispositivos, no es de esperar que los componentes resistan el nivel de actividad y de carga que resiste un hueso normal sano durante un período ilimitado de tiempo. La tasa de aflojamiento que se informó en un estudio clínico de este dispositivo fue del 10% en un seguimiento de hasta 10 años. (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985;195;161-7).
- Los efectos adversos pueden requerir una nueva operación, revisión o fusión de la articulación afectada.

ESTERILIZACIÓN

- Este componente ha sido esterilizado con óxido de etileno y radiación gamma.
- El implante se presenta estéril en un envase intacto. Si el implante o el envase están dañados, si ha transcurrido el período de validez o si se duda de su esterilidad por alguna razón, no debe usarse el implante. No volver a esterilizar.
- Existen componentes medidores de prueba para evitar tener que abrir el envase estéril antes de implantar la prótesis. El implante debe extraerse de su envase estéril sólo después de que se haya preparado el lugar de colocación del implante y de que se haya determinado adecuadamente su tamaño.

GARANTÍA ILIMITADA

Avanta Orthopaedics Corporation garantiza que este producto cumple con las especificaciones del fabricante y no contiene defectos de fabricación al momento de su entrega. Esta garantía excluye específicamente los defectos que surjan de mal uso, abuso o manipulación incorrecta del producto una vez recibido por el comprador. Avanta Orthopaedics no garantiza el resultado del procedimiento quirúrgico.

REPRESENTANTE EN LA UNIÓN EUROPEA

Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Países Bajos
31 (0) 416 563754

[1] Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop (1985 May);195:161-7

[2] Braun RM. Total joint replacement at the base of the thumb - preliminary report. J Hand Surg [Am] (1982 May);7(3):245-51

NEDERLANDS

BESCHRIJVING

De Avanta CMC trapeziometacarpale gewrichtsprothese bestaat uit een component van ultrahoog molecuulair gewicht polyethyleen (UHMWPE), welke aan het voorbereide trapezium wordt gelijmd, en een uit een titaniumlegering bestaande steelcomponent met geïntegreerde kop welke in de achterkant van de eerste metacarpale wordt gebracht. De titanium kop is door een gewricht verbonden met de component van UHMWP om zo een snap-fit constrained prothetische vervanging van het basisduimgewricht te vormen. Het implantaat is verkrijgbaar in drie maten, die allemaal kunnen worden gebruikt in de rechter- of linkerhand. Voor elk type implantaat is een serie proefmeten verkrijgbaar als hulp bij het voorbereiden van het bot.

Materialen

- ASTM F 136 titanium 6AL-4V ELI legering metacarpale steel/kop
- ASTM F-648 trapeziale component van ultrahoog molecuulair gewicht polyethyleen (UHMWP)
- ASTM F75 kobaltchromen radiografische markeringsdraad

INDICATIES

De Avanta CMC trapeziometacarpale prothese is bestemd voor vervanging van het complete gewricht in patiënten met een volgroeid skelet met pijn of instabiliteit in het trapeziometacarpale gewricht door trauma, inflammatoire of degenerative aandoeningen of voor revisie van eerdere ingrepen, als alternatief voor artrodese of reconstructieve chirurgie.

CONTRA-INDICATIES

- Door ziekte, infectie of eerdere implantatie aangetast bot, musculatuur, pezen, of omliggend zacht weefsel, welke niet genoeg steun of bevestiging voor de prothese kunnen bieden.
- Actieve of vermoede infecties in of rond het duimgewricht.
- Onvolgroeid skelet.

WAARSCHUWINGEN (zie ook het hoofdstuk Informatie voor patiëntvoorlichting)

- Dit instrument is uitsluitend voor gelijmd gebruik.
- Zware belasting, overmatige beweeglijkheid en gewrichtsinstabiliteit kunnen aanmaat leiden tot vervroegde slijtage en uiteindelijk kan het instrument het begeven door loslaten, breken of dislokatie. Patiënten dienen te worden gewaarschuwd voor de verhoogde kans dat het instrument het begeeft wanneer er te hoge eisen aan worden gesteld.

VOORZORGSMAATREGELEN

- Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien öfwel het implantaat öfwel de verpakking beschadigd blijkt te zijn, de vervaldatum is overschreden, of om welke reden dan ook aan de sterliteit wordt getwijfeld, mag het implantaat niet worden gebruikt. Niet hersteriliseren.
- Een nauwkeurige voorbereiding van de implantatieplaats en de keuze van de juiste maat implantaat vergroten de kans op een succesvol resultaat.
- Het implanteat mag pas uit zijn steriele verpakking worden gehaald zodra de implantatieplaats is voorbereid en de juiste afmetingen heeft.
- Om te voorkomen dat er in het instrument wordt gekrast, geneiden of gekerfd moeten implantaten met stompe instrumenten worden geïnspecteerd.

MOGELIJKE BIJWERKINGEN

- Bijwerkingen in een bekendgemaakte serie van 50 patiënten omvatten losgaan van het implantaat, tijdelijke radiale neuritis, letsel aan de vingerzenuwen in de handpalm door extrusie van het kleefmiddel en De Quervains tendinitis[1].

Bijwerking	aantal gevallen (n = 50)
losgaan van het implantaat	5 (10,0%)
tijdelijke radiale neuritis	2 (4,0%)
letsel door extrusie van het kleefmiddel	1 (2,0%)
De Quervains tendinitis	6 (12,0%)

- Mogelijke bijwerkingen die in combinatie met andere vingergewrichtsprotheses zijn gemeld omvatten losgaan, fractuurdislokatie, of infectie van het implantaat. Gedurende de periode dat dit instrument op de markt is zijn er geen verdere significante bijwerkingen gerapporteerd.
- Letsel aan de omliggende zenuwen, bloedvaten, pezen of zacht weefsel kan optreden als gevolg van de implantatie van het instrument.
- Metaalgevoeligheidsreacties zijn gerapporteerd na vervanging van het gewricht.

KLINISCHE RESULTATEN

Er zijn resultaten van negenentwintig patiënten gerapporteerd die het instrument geïmplanteerd hebben gekregen2. Vervanging is uitgevoerd voor artritis, mislukte poging tot artrodese, eerdere mislukte silastische of totale gewrichtsartroplastie, of postparalytische fibreuze ankylose van het gewricht. Op het moment van publicatie (tot 7 jaar follow-up) hadden tweeëntwintig patiënten een goed bereik van pijnloze beweging bereikt. In zeven gevallen werd geen normaal bewegingsbereik verkregen vanwege significante ontbrekens van de spieren of littekenvorming en contractuur van zacht weefsel. In zijn geen gevallen gerapporteerd van breuk of infectie van het implantaat, maar in drie gevallen vertoonden loslating van het implantaat op het grensvlak kleefmiddel-bot.

In een latere uitgebreidere publicatie, waarin nog eens 21 gevallen in de serie zijn opgenomen vertoonden de meeste van de 50 patiënten binnen vier weken na verwijdering van de hechtdraden een volledig bewegingsbereik en lieten ook daarna goede langetermijnresultaten zien. Een volledig bereik van asymptomatische beweging werd bereikt bij 26 osteoarthritische patiënten met een gewrichtsaandoening. Vijf patiënten vertoonden klinisch of radiografisch bewijs van loslating. Er zijn geen gevallen van breuk van het implantaat, oppervlakslijtage, versplintering of infectie geconstateerd.

CHIRURGISCHE PROCEDURES

Er is een handleiding verkrijgbaar waarin gedetailleerd de chirurgische procedure voor het gebruik van deze implantatie instrumenten wordt beschreven. Het is de verantwoordelijkheid van de chirurg dat hij vertrouwd is met de procedure voordat hij deze producten gaat gebruiken. Daarnaast is het de verantwoordelijkheid van de chirurg dat hij voorafgaand aan het gebruik op de hoogte is van relevante publicaties en dat hij bij ervaren collega's advies inwint met betrekking tot de procedure.

INFORMATIE VOOR PATIËNTVOORLICHTING (zie ook Waarschuwingen)

Naast de patiëntgerelateerde informatie in de hoofdstukken Waarschuwingen en Bijwerkingen dient de volgende informatie te worden medegedeeld aan de patiënt:

- Hoewel de verwachte levensduur van componenten voor een complete gewrichtsvervanging moeilijk te schatten is, is deze beperkt. Deze componenten zijn gemaakt van vreemde materialen, die in het lichaam worden geplaatst voor mogelijk herstel van de mobiliteit of vermindering van pijn. Vanwege de vele biologische, mechanische en fysiochemische factoren die invloed op deze instrumenten uitoefenen, kan echter niet van deze componenten worden verwacht dat zij gedurende onbeperkte tijd bestand zijn tegen het activiteitsniveau en de belasting van normaal gezond bot. Het gerapporteerde percentage van loslatingen in een klinische studie van dit instrument bedroeg 10% bij tot 10 jaar follow-up. (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985; 195: 161-7.)
- Door nadelige effecten kan heroperatie, revisie of fusie van het betreffende gewricht nodig zijn

STERILISATIE

- Deze component is gesteriliseerd door middel van ethyleenoxide of gammastraling.
- Het implantaat wordt steriel geleverd in een onbeschadigde verpakking. Indien öfwel het implantaat öfwel de verpakking beschadigd blijkt te zijn, de vervaldatum is overschreden, of om welke reden dan ook aan de sterliteit wordt getwijfeld, mag het implantaat niet worden gebruikt. Niet hersteriliseren.
- Proefmaatcomponenten zijn verkrijgbaar om te voorkomen dat de steriele verpakking vóór de implantatie van de prothese moet worden geopend. Het implantaat mag pas uit zijn steriele verpakking worden gehaald zodra de implantatieplaats is voorbereid en de juiste afmetingen heeft.

BEPERKTE GARANTIE

Avanta Orthopaedics Corporation garandeert dat dit product beantwoordt aan de specificaties van de fabrikant en op het moment van levering geen productiefouten bevat. Uitgesloten van deze garantie zijn met name gebreken als gevolg van verkeerd gebruik, misbruik of een onjuiste toediening van het product nadat het door de koper is ontvangen. Avanta Orthopaedics geeft geen garantie op het resultaat van de chirurgische procedure.

EU-VERTEGENWOORDIGER:

Medical Products International Europe BV
Schutweg 13A
5145 NP Waalwijk, Nederland
++31 (0) 416 563754

[1] Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. In: Clin Orthop (mei 1985);195): 161-7

[2] Braun RM. Total joint replacement at the base of the thumb-preliminary report. In: J Hand Surg (Am) (mei 1982) 7(3): 245-51

ITALIANO

DESCRIZIONE

La protesi trapezio-metacarpale Avanta CMC è costituita da un elemento in polietilene ad altissimo peso molecolare (UHMWPe) cementato al trapezio preparato, e da uno stelo in lega di titanio con testa integrale, inserito nel fusto del primo metacarpo. La testa in titanio si articola con l'elemento in UHMWPe formando una sostituzione protesica vincolata "snap-fit" per l'articolazione basale del pollice. L'impianto è disponibile in tre misure, ciascuna delle quali può essere utilizzata per la mano destra o sinistra. Inoltre, per ogni tipo di impianto è disponibile una serie di calibratori di prova, che possono essere d'ausilio per la preparazione dell'osso.

Materiali

- Testa/stelo metacarpale in lega di titanio 6AL-4V ELI ASTM F 136
- Elemento trapezoidale in polietilene ad altissimo peso molecolare (UHMWPe) ASTM F-648
- Filo marcatore radiografico in cromo-cobalto ASTM F75.

INDICAZIONI

La protesi trapezio-metacarpale Avanta CMC è indicata per la sostituzione totale dell'articolazione in pazienti con sviluppo scheletrico completo, che acquisano dolore o instabilità dell'articolazione trapezio-metacarpale in seguito a trauma, patologie infiammatorie o degenerative oppure revisione di procedure precedenti, in alternativa all'artrodesi o alla chirurgia ricostruttiva.

CONTROINDICAZIONI

- Ossa, muscolatura, tendini o tessuti molli adiacenti affetati da patologie, infezioni o precedenti impianti, che non sono in grado di fornire supporto o fissaggio adeguato per la protesi.
- Infezioni in atto o sospette nell'area interessata o circostante l'articolazione del pollice.
- Immaturità scheletrica.

AVVERTENZE (Si veda anche la sezione relativa alle informazioni per la Consulenza al Paziente)

- Questo presidio è destinato esclusivamente all'uso cementato.
- I carichi particolarmente pesanti, l'eccessiva mobilità e l'instabilità articolare possono accelerare l'usura e provocare eventuali danni alla protesi per distacco, frattura o lussazione. Si raccomanda di informare i pazienti sulla maggiore probabilità che si verifichi tale evenienza, se vengono esercitate eccessive sollecitazioni.

PRECAUZIONI

- L'impianto viene fornito sterile in confezione integra. Non utilizzarlo se l'impianto stesso o la confezione sembrano danneggiati, se è superata la data di scadenza o in caso di dubbi per qualsiasi motivo sulla sterilità delle confezione. Non risterilizzare.
- Una preparazione meticolosa del sito d'impianto e la scelta delle misure adeguate dell'impianto aumentano le probabilità di esito positivo dell'intervento.
- L'impianto deve essere prelevato dalla confezione sterile solo dopo aver preparato e correttamente misurato il sito dell'impianto.
- Manipolare gli impianti con strumenti smussati per evitare che subiscano graffi, tagli o incisioni.

EVENTI AVVERSI

- Gli eventi avversi pubblicati per un campione rappresentativo di 50 pazienti comprendono il distacco, la neurite radiale transitoria, la lesione dell'estrusione di cemento ai nervi digitali palmari e la tendinite di de Quervain1.

Evento	Numero di eventi (n=50)
Distacco	5 (10%)
Neurite radiale transitoria	2 (4%)
Lesione dell'estrusione di cemento	1 (2%)
Tendinite di de Quervain	6 (12%)

- I potenziali eventi avversi resi noti in relazione ad altre protesi per articolazioni falangee comprendono il distacco, la frattura, la lussazione o infezione dell'impianto. Non sono stati resi noti ulteriori effetti avversi rilevanti durante tutto il periodo di commercializzazione di questo presidio.
- In seguito all'inserimento di questo impianto possono verificarsi lesioni ai nervi circostanti, ai vasi sanguigni, ai tendini o ai tessuti molli.
- Sono stati resi casi di ipersensibilità ai metalli dopo la sostituzione dell'articolazione.

RISULTATI CLINICI

Sono stati resi noti i risultati di ventinove pazienti a cui è stato impiantato questo presidio2. La sostituzione è stata effettuata a causa di artrite, insuccesso di una tentata artrodesi, precedente insuccesso dell'artroplastica totale o in Silastic, oppure anchilosi articolare fibrosa post-paralitica. Ventidue pazienti avevano raggiunto una buona articolarità indolore al momento della pubblicazione (fino a 7 anni di follow-up). Sette pazienti non sono riusciti a raggiungere l'articolarità normale (ROM) a causa di un notevole squilibrio muscolare o della contrattura e dello scarnire del tessuto molle. Non sono stati riferiti casi di frattura o infezione dell'impianto, ma in tre casi si è verificato il distacco in corrispondenza dell'interfaccia osseo-cemento.

In una successive pubblicazione estesa, comprendente ulteriori 21 casi della tetipiece1, la maggior parte dei 50 pazienti ha mostrato un'articolarità completa entro quattro settimane dalla rimozione delle suture e ha continuato a mostrare buoni risultati a lungo termine. Una completa articolarità asintomatica è stata raggiunta da 26 pazienti osteoartritici con lussazione articolare. In cinque casi si è verificato il distacco clinicamente o radiograficamente. Non sono stati osservati casi di frattura dell'impianto, usura superficiale, frammentazione o infezione.

PROCEDURE CHIRURGICHE

È disponibile una procedura chirurgica destinata all'uso del presente dispositivo per impianto. È responsabilità del chirurgo acquisire familiarità con tale procedura prima di utilizzare questi prodotti. Il chirurgo è altresì tenuto a conoscere la documentazione sull'argomento e a consultarsi con colleghi esperti in merito alla procedura prima di eseguire l'intervento.

INFORMAZIONI PER LA CONSULENZA AI PAZIENTE (Si vedano anche le Avvertenze)

Oltre alle informazioni specifiche, riportate nella sezione Avvertenze e Eventi avversi, si raccomanda di comunicare ai pazienti anche quanto segue:

- I componenti sostitutivi dell'articolazione hanno una durata limitata che, purtroppo, risulta difficile da stimare. Questi componenti sono realizzati con materiali estranei, che vengono inseriti nel corpo per ripristinare una potenziale mobilità o ridurre il dolore. Tuttavia, considerando i numerosi fattori biologici, meccanici e fisicochimici legati a questi dispositivi, non si può partire dal presupposto che siano in grado di sostenere il livello di attività e i carichi di un osso normalmente sano per un periodo di tempo illimitato. La percentuale di casi di distacco riferita in uno studio clinico relativo a questo dispositivo è stata del 10% in un periodo di 10 anni di follow-up. (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985; 195:161-7).
- L'eventuale insorgenza di eventi avversi potrebbe richiedere un secondo intervento, la revisione o la fusione dell'articolazione coinvolta.

STERILIZZAZIONE

- Il presente impianto è stato sterilizzato con ossido di etilene o raggi gamma.
- L'impianto risulta sterile nella confezione integra. Non utilizzarlo se l'impianto stesso o la confezione sembrano danneggiati, se è trascorsa la data di scadenza o se si dubita della sterilità per qualsiasi motivo. Non risterilizzare.
- Sono disponibili calibratori di prova per evitare l'apertura della confezione sterile prima d'impiantare la protesi. Prelevare l'impianto dalla confezione sterile solo dopo aver preparato e correttamente misurato il sito dell'impianto.

GARANZIA LIMITATA

Avanta Orthopaedics Corporation garantisce che il presente prodotto risponde alle specifiche del produttore e non presenta difetti di lavorazione al momento della consegna. La presente garanzia esclude specificamente i difetti risultanti da uso improprio, abuso o manipolazione scorretta del prodotto dopo il ricevimento da parte dell'acquirente. Avanta Orthopaedics non risponde per l'esito della procedura chirurgica.

RAPPRESENTANTE PER L'UE:

Medical Products International Europe, BV
Schutweg 13a
5145 NP Waalwijk, Paesi Bassi
31 (0) 416 563754

[1] Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. In: Clin Orthop (maggio 1985);195;161-7

[2] Braun RM. Total joint replacement at the base of the thumb - relazione preliminare. In: J Hand Surg (Am)(maggio 1982

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19-0353 Rev. C

DO NOT REMOVE THIS ROUTE SLIP!!!!

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FA

K-93-1588

4/16/93

PJW

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
SUTTER CORPORATION ATTN: LOUISE M FOCHT 9425 CHESAPEAKE DRIVE SAN DIEGO, CA 92123	03/29/93	03/31/93	06/29/93
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K931588
SHORT NAME: SUTTER	PHONE NO: 619-569-8148 ESTABLISHMENT NO: 2028601		

TO:	
ODE/DMC	CONT. CONF.: ? STATUS : R REV PANEL : OR PAN/PROD CODE(S): OR/ / /

SUBJECT:
SUTTER PROXIMAL INTERPHALANGEAL JOINT

DECISION:	RQST INFO DATE: / /	INFO DUE DATE: / /
DECISION DATE: / /	DATE: / /	DATE: / /
MAR 10 1994	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date 3-15 94

From Mark Wright , Clerk-Typist, (CDRH, ODE, DMC) HFZ-401

Subject Premarket Notification Number(s) K931581A1

To Division Director

The attached information has been received by the 510(K) Document Mail Center (DMC), on the above referenced 510(K) file(s). Since a final decision has been rendered, the record is officially closed.

Please review the documents(s) and return to DMC directed to my attention, with one of the statements checked below. Feel free to note any additional comments below. If there are any questions, please contact me on 594-3027.

✓ Information does not change status of 510(K); no other action required by DMC; please file. The Division should prepare a confirmation letter - example attached.

____ Additional information requires a new 510(K); please process.

____ Requests CLIA Categorization

Comments:

This information should be returned by 3-29-94.

Reviewed by: Mark N Milhern

Panel: OR

Date: 3/15/94

Attachment

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Re: Device Name
Dated:
Received:

Dear _____:

We have reviewed the information dated _____, regarding the 510(k) notification (K_____) previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

If you have any questions regarding the contents of this letter, please contact _____ at (301) 427-____.

Sincerely yours,

Division Director
Division of _____
Office of Device Evaluation
Center for Devices and
Radiological Health

Facsimile Cover Sheet

To: Mark N. Melkerson
Company: DGRD/Orthopedic Branch
Phone: 301-594-2036
Fax: 301-594-2358

From: Louise M. Focht
Company: Sutter Corporation
Phone: 619-569-8148
Fax: 619-279-8249

Date: 03/08/94
Pages including this cover page: 4

Comments:

File K931588

Please let me know if there are additional questions or any information submitted is unclear. The original copy of the letter will be delivered Thursday March 10.

Thanks,

Louise Focht

3

SUTTER CORPORATION
SMALL JOINT ORTHOPAEDICS

9425 CHESAPEAKE DRIVE
SAN DIEGO, CA 92123
TEL. (800) 854-2216
FAX (619) 279-8249

March 8, 1994

510 (k) Number: K 91588

Food and Drug Administration
510 (k) Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Attn.: Mark N. Melkerson DGRD/Orthopedic Branch

This document has been sent by FAX March 8, 1994 and a follow-up copy has been sent to be delivered March 10, 1994.

Dear Mr. Melkerson:

Thank you for your FAX and reference to the draft guidance for the preparation of premarket notification applications for orthopedic devices. The following information is provided in response to your questions regarding Sterilization of the Proximal Interphalangeal Joint Implant, and the information follows the outline of the draft guidance for orthopedic devices.

STERILITY INFORMATION, IMPLANT

Radiation Sterilization Method

1. Gamma Sterilization
2. Cobalt 60
3. Minimum dose 25 kGy, Maximum dose (b)(4)
4. Sterility Assurance Level 10E-6
5. Sterilization Validation according to AAMI Method 1. Routine audit is performed using AAMI Method 3B.
6. There is no claim in the labeling that the device is pyrogen-free.

For implants provided sterile the labeling is being changed to not recommend resterilization. The statement is being changed from the following:

Sterilization:

These implants are provided sterile in an undamaged package.
Warning: If either the implant or the package appears damaged, or if sterility is questioned for any reason the implant should not be used.

These devices may be removed from their package and resterilized by steam autoclaving at 270F(132C) for 15-20 minutes (fast cycle) or at 252F(121C) for 35-40 minutes (standard cycle). Ethylene oxide gas sterilization may be used but is not recommended because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer.

Labeling for implants is being changed to the following:

4

Sterilization:

These implants are provided sterile in an undamaged package.

Warning: If either the implant or the package appears damaged, or if sterility is questioned for any reason the implant should not be used. Resterilization of this product is not recommended.

STERILITY INFORMATION FOR NON-STERILE DEVICES THAT MUST BE STERILIZED PRIOR TO USE

STERILITY INFORMATION, SIZER (The sizer is used as a trial)

ETHYLENE OXIDE GAS STERILIZATION METHOD. (labeling is being changed to not recommend ethylene oxide gas sterilization, see below)

1.	Temperature	54°C ±1°C
2.	Humidity	60% ±10%
3.	Gas concentrations	6-7 psig of 12/88 Ethylene Oxide/dichlorodifuoromethane.
4.	Exposure time	4 hours
5.	Aeration cycle	18 hours

STEAM STERILIZATION METHOD

1.	Cycle	Standard Gravity
2.	Temperature	250°F (121°C)
3.	Exposure time	35-40 min.

1.	Cycle	Prevacuum
2.	Temperature	270°F (132°C)
3.	Exposure time	15-20 min.

Labeling for trials is being changed from:

Sterilization:

Instruments and sizers may be sterilized using either steam or ethylene oxide gas. Ethylene oxide gas is not recommended for silicone elastomer because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer.

Labeling for trials is being changed to:

Sterilization:

Instruments and sizers may be sterilized using steam. Ethylene oxide gas is not recommended for silicone elastomer because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer. The product may be resterilized using an autoclave by one of the following methods: Standard

gravity sterilization at 250° F (121° C) for 35-40 min, or prevacuum sterilization at 270° F (132° C) for 15-20 min.

Since the submission of this 510 (k) I have been obtaining the guidances via the Flash FAX. I have found them to be very helpful in the preparation of our 510 (k) applications.

Please let me know if I may clarify any of the information provided.

Sincerely,

Louise M Focht

Louise M. Focht
Director of Regulatory Affairs
619-569-8148x 2213

4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2005

Mr. Mike Simpson
President
Small Bone Innovations
505 Park Avenue, 14th Floor
New York, NY 10022

Re: k812691 – Silicone Implants
k870200 – Sutter Finger Joint Prosthesis
k931588 – Sutter Proximal Interphalangeal Joint
k943853 – Distal Radius Fracture Fixation Plate System
k943873 – Orthomet Anatomcially Guided Carpal Tunnel Release System
k964359 – Avanta Orthopaedics Tendon Spacer
k965204 – Avanta Orthopaedics Trapezium Implant
k974911 – External Fixator
k981715 – Distal Radius Fracture Fixation Plate System
k981716 – External Fixator
k982268 – Ulnar Head Implant
k982288 – Radial Head Implant
k990596 – Distal Radius Fracture Fixation Plate System
k002644 – Avanta Radial Head Implant
k003033 – SCAPHIX Staple
k010786 – Ulnar Head Implant
k010847 – K'fix pin cap
k011819 – Radial Head Implant
k013629 – Finger Joint Prosthesis
k021859 – Wrist Implant
k023604 – Radial Head Implant
k030881 – Avanta Carpal Fusion Plating System

Dear Mr. Simpson:

We have reviewed your letter, dated January 31, 2005, stating that the rights to the above referenced premarket notifications (510(k)) have been transferred. Transfer of 510(k) rights alone does not require submission of new 510(k)s under 21 CFR 807.81(a)(3). Consequently, we cannot change the name of the original 510(k) submitters in our database. We suggest that information showing the transfer of the 510(k)s and their current ownership should be maintained in the company's files for review by an FDA investigator. You may contact the Center for Devices and Radiological Health's Office of Compliance at (240) 276-0100 if you have any questions on what information we expect to be maintained in your files.

If you have any other questions regarding this letter, please contact the 510(k) Staff at (301) 594-1190.

Sincerely yours,

Heather S. Rosecrans
Director, Premarket Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: Don Guthner
Vice President
Musculoskeletal Clinical Regulatory Advisers, LLC
505 Park Avenue, 14th Floor
New York, NY 10022

H.Doug Plunkett
Avanta Orthopaedics, Inc.
9369 Carroll Park Drive, Suite A
San Diego, CA 92121

Avanta Ortopaedics
9369A Carroll Park Drive
San Diego, CA 92121

Sutter Corporation
9425 Chesapeake Drive
San Diego, CA 92123

Orthomet, Inc.
6301 Cecilia Circle
Minneapolis, MN 55439

Wright Medical Technology
5677 Airline Road
Arlington, TN 38002

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Official Business
Penalty for Private Use $300

K

Return to Sender

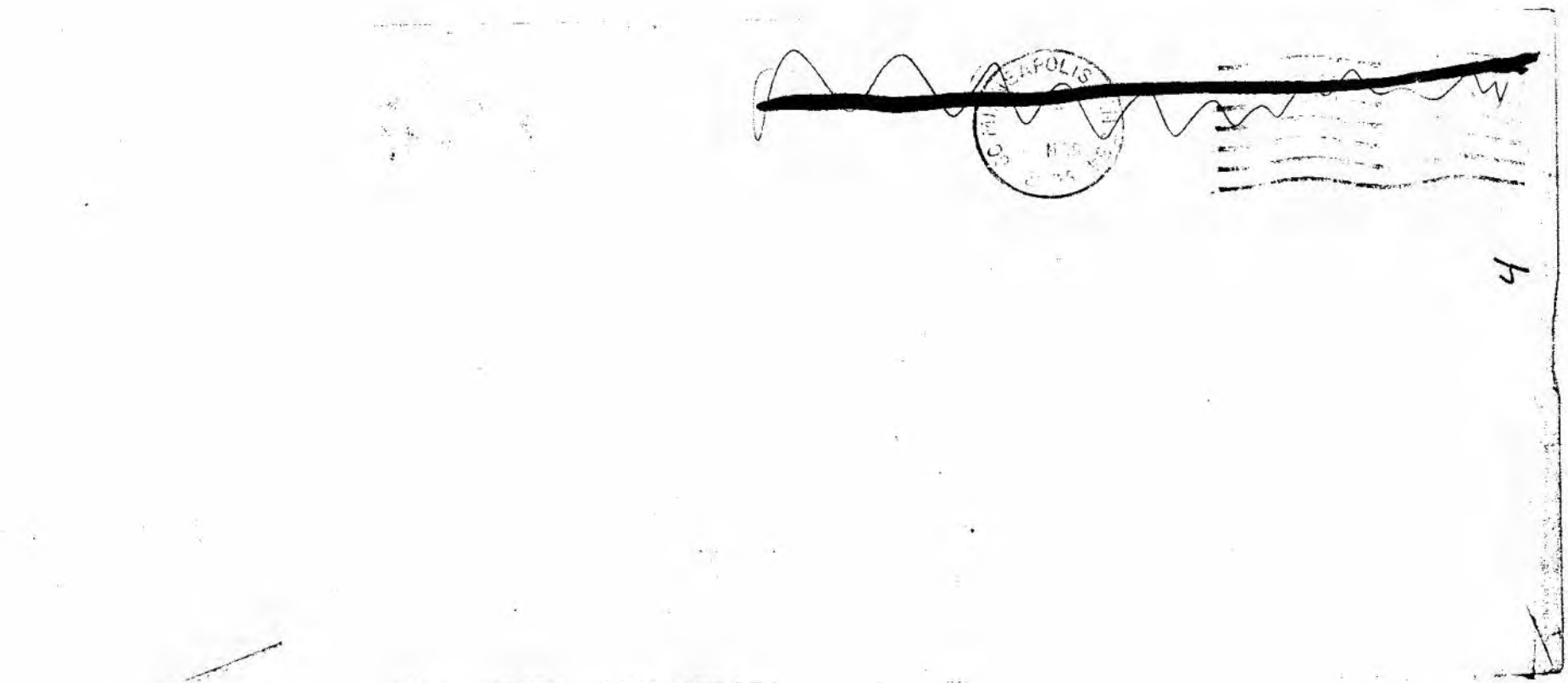
Orthomet, Inc.
6301 Cecilia Circle
Minneapolis, MN 55439

55439+2715

55439+2715 06

102/137

3



DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

MAR 10 1994

Ms. Louise M. Focht
Director Quality Assurance
Sutter Corporation
9425 Chesapeake Drive
San Diego, California 92123

Re: K931588
Sutter Proximal Interphalangeal Joint
Regulatory Class: II
Dated: March 29, 1993
Received: March 31, 1993

Dear Ms. Focht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the

labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Mark N Melkerson

Subject 510(k) NOTIFICATION K931588

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

X (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

_____ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☒

This 510(k) contains: (check appropriate box(es))

☑ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

✓ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

KYJ class II

Additional Product Code(s) w/Panel (optional):

_____

REVIEW: Daniel J. McGeary (BRANCH CHIEF) ORB (BRANCH CODE) 3/10/94 (DATE)

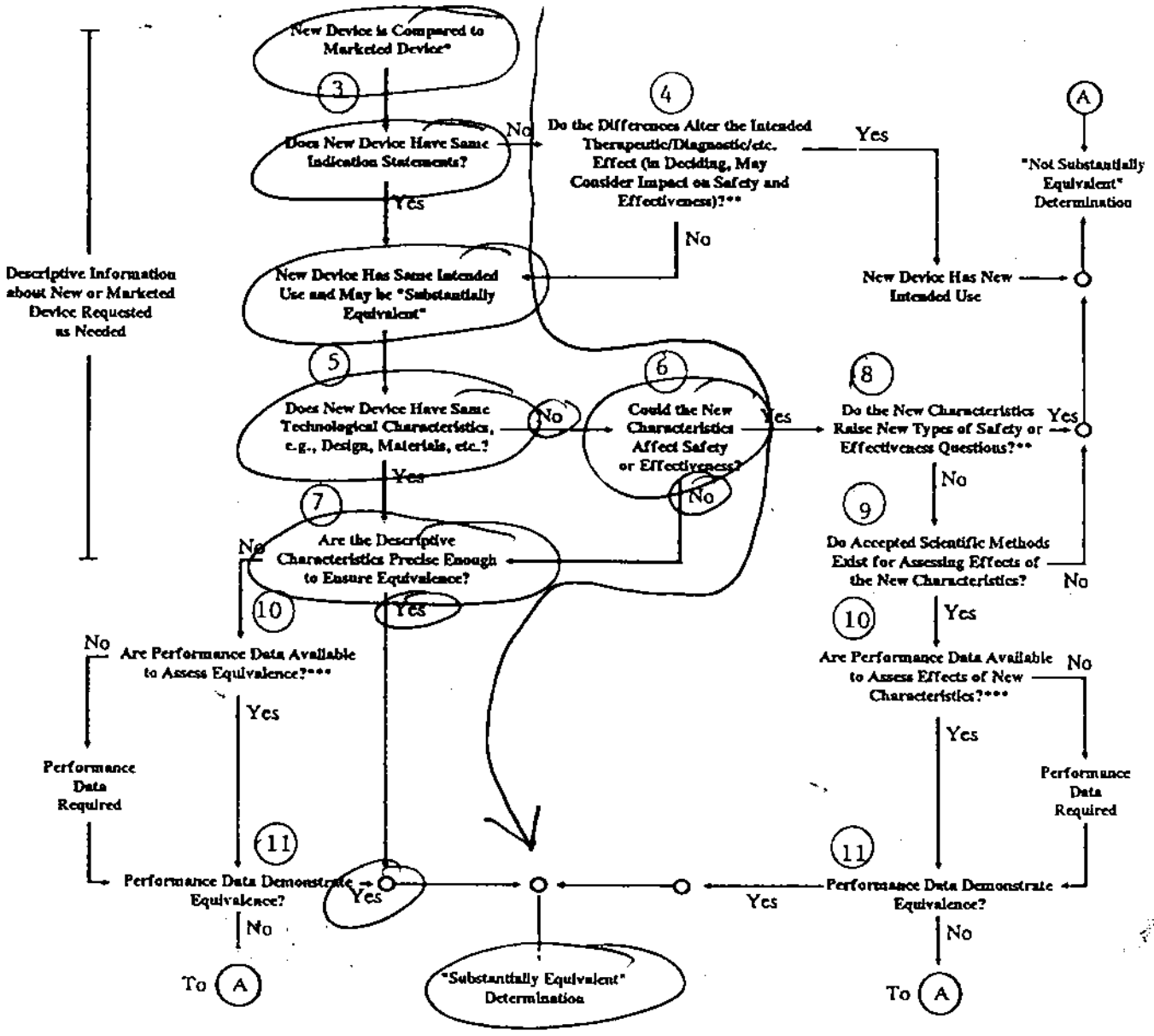
FINAL REVIEW: for (DIVISION DIRECTOR) 3/10/94 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

3

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

K 931588 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: MXM DIVISION/BRANCH: DGRD/ORDB

TRADE NAME: SUTTER PIP JT. COMMON NAME: CONSTRAINED FINGER, POLYMER

PRODUCT TO WHICH COMPARED: K802342, K870200, PREAMENDMENTS
(510(k) NUMBER IF KNOWN) SWANSON, SILASTIC FINGER

	YES	NO	
1. IS PRODUCT A DEVICE?	X		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	X		- IF NO STOP
3. SAME INDICATION STATEMENT?	X		- IF YES GO TO 5
(4.) DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?		X	- IF YES GO TO 7
(6.) COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	X		- IF NO GO TO 10 - IF YES STOP - SE
(8.) NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10. PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DATA
(11.) DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

MEMO RECORD
FROM: M.N. MELKERSON, Engineer
TO: File
DATE: ~~3/7/94~~ 3/10/94 MNM
Center/Office: CDRH/ODE
Division/Branch: DGRD/ORDB
Document Number: K931588
Common Name: Proximal InterPhalangeal (PIP) Joint Prosthesis, Finger & Toe
Trade Name: Sutter, Proximal Interphalangeal Joint Prosthesis
Classifications: 1) 21 CFR 888.3230, Finger Jt. Polymer Constrained Prosthesis
Class: II
Product Codes: KYJ: Finger
Products To Which Compared:

Preamendments Dow Corning Wright (Wright Medical), Swanson Silastic Jt. Spacers for metacarpal phalangeal (MCP), proximal interphalangeal (PIP), and distal interphalangeal (DIP) joints of fingers

K802342 and K870200, Sutter, Medical grade silicone (PEHT 400 series) Jt. Spacers for MCP and PIP joints of fingers

Contact Person: Louise M. Focht, Director of Quality Assurance (619) 569-8148, ext. 2213

Summary:

This 510(k) original dated 3/29/93, received on 3/31/93 and assigned on 3/4/94 was reviewed for a SE or NSE recommendation.

Recommendation:

I recommend that this 510(k) be found SE.

Basis of Recommendation:

INTENDED USE: Intended for total joint arthroplasty of the PIP joint of fingers for clinical indications of Rheumatoid arthritis (RA), Osteoarthritis (OA), Ankylosed joints or those with limited range of motion which have not responded to conservative treatment, Nonfunctional joint due to inadequate body alignment and joint space which cannot be restored by soft tissue reconstruction alone, and Destroyed articular surfaces.

DEVICE DESCRIPTION:

A constrained, flexible hinge design, joint space made out of a medical grade silicone elastomer (PEHT 400 series) with or without medical grade polyester mesh or fibers for reinforcement, sutures for temporarily securing the implant, and polyester mesh or velour

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surfaces to provide stabilization through tissue ingrowth. These design features are identical to the predicate Sutter MCP. The PIP implants will be offered in 6 sizes (i.e., 10, 20, 30, 40, 50, and 60).

Is the device life-supporting or life sustaining? no
Is the device implanted (short-term or long-term)? long-term
Does the device design use software? no
Is the device sterile? Yes
Is the device for single use? Yes
Is the device for home use or prescription use? Restricted to use by physicians.
Does the device contain drug or biological product as a component? - no
Is this device a kit? no

MATERIALS:

Medical grade silicone elastomer ((b)(4)), 12 years of use in other Sutter products (i.e., (b)(4)), Material properties and testing were supplied in Appendix E.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION"

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS STARTING ON PAGE 1 - NOTE: QUESTIONS WHICH ARE NOT APPLICABLE ARE FOLLOWED BY "N/A".

1. IF THE ANSWER TO QUESTION 1 IS NO, EXPLAIN WHY THE PRODUCT IS NOT A DEVICE. - Product is a device.

2. IF THE ANSWER TO QUESTION 2 IS NO, EXPLAIN WHY THE DEVICE IS NOT SUBJECT TO 510(K). - Is subject to 510(k).

3. IF THE ANSWER TO QUESTION 3 IS NO, EXPLAIN HOW THE NEW INDICATION DIFFERS FROM THE PREDICATE DEVICE'S INDICATION. - Same intended use and clinical indications.

4. IF THE ANSWER TO QUESTION 4 IS YES OR NO, EXPLAIN WHY THERE IS/IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE. - N/A

5. IF THE ANSWER TO QUESTION 5 IS NO, DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS. - Hinge design of Sutter MCP and PIP are identical while overall dimensions and stem of PIP has been modified to accommodate differences in the anatomy of the phalanges.

6. IF THE ANSWER TO QUESTION 6 IS YES OR NO, EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT SAFETY OR EFFECTIVENESS. - No, the modifications to the dimensions and

stem are slight (i.e., less of taper, thus greater cross-sectional areas) and should not adverse effect the mechanical properties of the device. The modifications did not change ratios of dimensions.

7. IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH. - Yes, the sponsor supplied drawings with dimensions allowing for the comparison to predicates dimensions and geometry.

8. IF THE ANSWER TO QUESTION 8 IS YES OR NO, EXPLAIN THE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW. - N/A

9. IF THE ANSWER TO QUESTION 9 IS NO, EXPLAIN WHY THE EXISTING SCIENTIFIC METHODS CAN NOT BE USED. - N/A

10. IF THE ANSWER TO QUESTION 10 IS NO, EXPLAIN WHAT PERFORMANCE DATA IS NEEDED. - N/A

11. IF THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT. - N/A

The following additional information also provides the basis for my recommendation:

LABELING: Provided Adequate labeling.

STERILIZATION:

Device is supplied sterile. Radiation Type: gamma, Radiation source: Cobalt 60, Minimum and maximum: [redacted] Sterility validation method: AAMI Method I routine audit is performed using AAMI Method 3B, Statement whether pyrogen-free and method used to make that determination: There is no claim of being pyrogen-free.

RESPONSE: The sponsor supplied the omitted information.

Device may be resterilized as described in labeling. Identified the cycle parameters (Did not specify cycle type: gravity or vacuum ????): 270° F (132° C) for 15 - 20 minutes (fast cycle) or at 252° F (121° C) for 35-40 minutes (standard cycle), SAL: ???, Sterility Validation Method ????, Statement whether pyrogen-free and method to make that determination

RESPONSE: Sponsor removed all recommendations for resterilization either by steam or ETO.

States may be ETO sterilized but does not recommend due to aeration

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time necessary to dissipate the absorbed sterilant. Sponsor should supply the following: Temperature (in ° C and F), humidity, gas concentration; exposure time, and aeration cycle.

RESPONSE: Sponsor removed all recommendations for resterilization either by steam or ETO.

TEST METHODS & RESULTS:

Material properties and testing were supplied in Appendix E. The sponsor provided the following material testing which was supplied in previous Sutter 510(k)s (K802342 and K870200) found to be SE:

Hemolysis test: Same response as negative control, test included a positive control

Physcio Chemical Results provide pass/fail criteria for allowable heavy metals, buffering capacity, nonvolatile residues, and residues on ignition

MEM Elution Same response as negative control, test included a positive control

Inhibition of Cell Growth Less of a response than negative control, a positive control was used

Limulus Inhibition test Same results as negative control, a positive control was used

USP Toxicity Class (b)(4)

Systemic Injection No toxicity noted systemically: non-toxic

Type B, Intracutaneous:: Saline, EtOH, Oil, and PEG

No toxicity noted intracutaneously

Implantation test USP XX 7 Day implant study, No significant response noted some fibrosis and inflammation but no giant cells and necrosis. Similar response to UHMWPE reference standard

Gross and Macroscopic

Flex testing PEHT series 400 (2.5Mrads):

#Cycles Flexed Millions	Quantity	Tear Strength lbs/in
(b)(4)		

Dow Corning Wright (b)(4) lbs/in - literature

Abrasion testing, Abrasion wheel method:

Abrasion rate: ((b)(4) inch/hour)

PEHT series (b)(4)

Dow HP silastic >>> (b)(4)

4

Shear testing: (psi)

PEHT-400	465
Dow HP	420

REVIEW OF OTHER 510(K)S FOR SE: Preamendment Swanson Silastic finger spacers, K870200 and K802342

SUMMARY:

My recommendation is based on the following information. The device is made of same materials and has undergone the same testing as Sutter MCP joint prosthesis, K870200. Hinge design of Sutter MCP and PIP are identical while overall dimensions and stem of PIP has been modified to accommodate differences in the anatomy of the phalanges. The clinical indications are identical to the Sutter MCP prosthesis with the exception of being intended for the PIP joint. The clinical indications are identical to the preamendments Swanson finger implants except the Sutter PIP is not intended DIP joint replacement, only PIP and MCP joint replacement.

CONTACT HISTORY:

3/7/94, I faxed Louise Focht a copy of the ORDB guidance for 510(k) submissions and requested that omitted sterilization information be submitted. I also requested that the omitted re-sterilization information be submitted for the suggested steam or ETO re-sterilization methods.

3/8/94, I spoke with Louise Focht. She stated that she would fax in the response and follow it with a hard copy by overnight mail.

M.N. Melkerson MXM
Disc: Mark025, File: MK931588.

10

SUTTER CORPORATION
SMALL JOINT ORTHOPAEDICS

9425 CHESAPEAKE DRIVE
SAN DIEGO, CA 92123
TEL (800) 854-2216
FAX (619) 279-8249

March 8, 1994

510 (k) Number: 931588

Food and Drug Administration
150 (k) Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Attn.: Mark N. Melkerson DGRD/Orthopedic Branch

This document has been sent by FAX March 8, 1994 and a follow-up copy has been sent to be delivered March 10, 1994.

Dear Mr. Melkerson:

Thank you for your FAX and reference to the draft guidance for the preparation of premarket notification applications for orthopedic devices. The following information is provided in response to your questions regarding Sterilization of the Proximal Interphalangeal Joint Implant, and the information follows the outline of the draft guidance for orthopedic devices.

STERILITY INFORMATION, IMPLANT

Radiation Sterilization Method

1. Gamma Sterilization
2. Cobalt 60
3. Minimum dose 25 kGy, Maximum dose [redacted]
4. Sterility Assurance Level 10E-6
5. Sterilization Validation according to AAMI Method 1. Routine audit is performed using AAMI Method 3B.
6. There is no claim in the labeling that the device is pyrogen-free.

For implants provided sterile the labeling is being changed to not recommend resterilization. The statement is being changed from the following:

Sterilization:

These implants are provided sterile in an undamaged package.
Warning: If either the implant or the package appears damaged, or if sterility is questioned for any reason the implant should not be used.

These devices may be removed from their package and resterilized by steam autoclaving at 270F(132C) for 15-20 minutes (fast cycle) or at 252F(121C) for 35-40 minutes (standard cycle). Ethylene oxide gas sterilization may be used but is not recommended because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer.

Labeling for implants is being changed to the following:

Sterilization:

These implants are provided sterile in an undamaged package.

Warning: If either the implant or the package appears damaged, or if sterility is questioned for any reason the implant should not be used. Resterilization of this product is not recommended.

STERILITY INFORMATION FOR NON-STERILE DEVICES THAT MUST BE STERILIZED PRIOR TO USE

STERILITY INFORMATION, SIZER (The sizer is used as a trial)

ETHYLENE OXIDE GAS STERILIZATION METHOD. (labeling is being changed to not recommend ethylene oxide gas sterilization, see below)

1.	Temperature	54°C ±1°C
2.	Humidity	60% ±10%
3.	Gas concentrations	6 7 psig of 12/88 Ethylene Oxide/dichlorodifuoromethane.
4.	Exposure time	4 hours
5.	Aeration cycle	18 hours

STEAM STERILIZATION METHOD

1.	Cycle	Standard Gravity
2.	Temperature	250°F (121°C)
3.	Exposure time	35-40 min.

1.	Cycle	Prevacuum
2.	Temperature	270°F (132°C)
3.	Exposure time	15-20 min.

Labeling for trials is being changed from:

Sterilization:

Instruments and sizers may be sterilized using either steam or ethylene oxide gas. Ethylene oxide gas is not recommended for silicone elastomer because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer.

Labeling for trials is being changed to:

Sterilization:

Instruments and sizers may be sterilized using steam. Ethylene oxide gas is not recommended for silicone elastomer because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer. The product may be resterilized using an autoclave by one of the following methods: Standard

12

gravity sterilization at 250° F (121° C) for 35-40 min, or prevacuum sterilization at 270° F (132° C) for 15-20 min.

Since the submission of this 510 (k) I have been obtaining the guidances via the Flash FAX. I have found them to be very helpful in the preparation of our 510 (k) applications.

Please let me know if I may clarify any of the information provided.

Sincerely,

Louise M. Focht

Louise M. Focht
Director of Regulatory Affairs
619-569-8148x 2213

13

ORTHOPEDIC 510(k) SUBMISSION CHECKLIST

K 931588

Sponsor: Sutter Corp.

Based on the draft Orthopedic 510(k) Guidance Document, the information checked in the "NO" column is missing and must be addressed before the review can begin.

	Additional Information Required
MANUFACTURER IDENTIFICATION	☐
DEVICE IDENTIFICATION	☐
PROPOSED REGULATORY CLASS.	☐
INTENDED USE	☐
DEVICE DESCRIPTION	☐
MATERIALS	☐
LABELING	☐
TESTING OR OTHER ADDITIONAL INFORMATION	☐
CLINICAL DATA	☐
STERILITY INFORMATION	☐
PACKAGING DESCRIPTION	☐
SUBSTANTIAL EQUIVALENCE INFORMATION	☐
510(k) SUMMARY OR STATEMENT	☐

These are the basic elements that must be addressed before ODE will begin a comprehensive review of the 510(k). All applicable topics contained in the 510(k) guidance must be addressed in sufficient detail to enable ODE to determine the equivalence of the device.

Recommendation:

- ☒ proceed with a comprehensive review of the document
- ☐ issue a modified K-OR-3.A1 letter

Reviewed by: M. Courtney

Date: 8/24/93

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

APRIL 16, 1993

SUTTER CORPORATION
ATTN: LOUISE M. FOCHT
9425 CHESAPEAKE DRIVE
SAN DIEGO, CA 92123

510(k) Number: K931588
Received: 03-31-93
Product: SUTTER PROXIMAL INTERPHALANGEAL JOINT

We have received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date, you may want to check with FDA to determine the status of your submission.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages manufacturers to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law

requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 227-8006.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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SUTTER CORPORATION
BIOMOTION SPECIALISTS™

March 29, 1993

510(k) Notification
Proximal Interphalangeal Joint

K931588

Food and Drug Administration
510(k) Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Sutter Corporation hereby submits a Premarket Notification Submission pursuant to Section 510(k) of the Federal Food, Drug and Cosmetics Act and in accordance with regulations established in 21CFR807. This submission is to notify the Agency of our intent to market a new device as an extension of our orthopedic implant product line. We intend to continue production and distribution of our other devices.

1. DEVICE NAME:

a. Proprietary Name - Sutter Proximal Interphalangeal Joint
b. Classification Name - Prosthesis, Finger and Toe
c. Panel Classifying Device - Orthopedic (87)

2. ESTABLISHMENT REGISTRATION NUMBER:

Owner Operator Number	9002987
Registration Number:	2028601

3. CLASSIFICATION UNDER SECTION 513: Class II

4. PERFORMANCE STANDARDS: N/A

5. REPRESENTATIVE LABELING:

Proposed labeling and draft of surgical techniques are included in Appendix A and Appendix B respectively. The product is terminally sterilized by gamma radiation at 25 KGy.

6. SIMILARITIES TO DEVICES IN DISTRIBUTION:

The finger implant is substantially equivalent to several silicone implants in commercial distribution both before and after May 28, 1976. These include the Sutter PIP, Sutter MCP, and Dow Corning Wright Swanson design implants which are used both in the Proximal Interphalangeal and Metacarpal Phalangeal joints and distal interphalangeal joints. Literature is in Appendix C.

Sutter PIP finger joint implant currently on the market consists of silicone rubber molded over an inner layer of reinforcing mesh and polyester anchoring sutures. The stems are covered with polyester mesh to permit infiltration of bone and fibrous tissue. Over 15 years of clinical experience with this design has demonstrated long term functional stability. The surgical technique for the Sutter PIP prosthesis follows the same protocol as for other flexible hinge silicone implants.

The Sutter implant is substantially equivalent in materials, design principle and intended clinical function to Dow Corning Wright implants. The Silastic Finger Joint Implant manufactured by Dow Corning Wright is used in the metacarpophalangeal (MP), proximal interphalangeal (PIP) and distal interphalangeal (DIP) joints. Both the Sutter and the Dow product are fabricated of medical grade silicone and are used clinically to maintain normal joint space and provide an acceptable range of motion . The Dow design utilizes a single design implant for use in three different joints of the hand. The new Sutter PIP design is similar in principal to the existing Sutter Metacarpal Phalangeal joint which has been on the market for five years.

9425 CHESAPEAKE DRIVE | SAN DIEGO, CA 92123 | (619) 569-8148 | (800) 854-2216 | FAX: (619) 279-8249

The hinge design of the two products is the same with slight modifications in the implant stem shape to accommodate differences in the anatomy of the phalanges. Drawing is included in Appendix D.

The new Sutter PIP prosthesis is constructed of silicone, the material was originally approved for use in 1981 under the Material Identification of PEHT 400 series. The material has twelve years of proven clinical performance. Material properties and independent laboratory testing of the material is included in Appendix E.

Material testing performed includes:

Hemolysis test
Physico Chemical
MEM Elution
Inhibition of Cell Growth
Limulus Inhibition test
USP Toxicity Class VI-121 deg C
    Systemic Injection
    Type B, Intracutaneous::Saline
    Type B, Intracutaneous::EtOH
    Type B, Intracutaneous::Oil
    Type B, Intracutaneous::PEG
Implantation test USP XX
    Gross and Macroscopic
Flex testing
Abrasion testing
Shear testing

7. SAFETY AND EFFECTIVENESS SUMMARY:

Materials used in the Sutter finger implant are the same materials and manufacturing processed currently used in many Sutter implants including the Sutter MCP finger joint implant. The implants are made of Bulk Silicone Elastomer. GMP controls are in place and adhered to for current manufacturing of all Sutter Products.

We believe the proximal interphalangeal joint implant to be safe and effective. No new technologies are employed in the design or manufacture of the device. We believe that the device is substantially equivalent to other Sutter implants as well as the referenced competitors' product already in commercial distribution. We request clearance to introduce the device for distribution in ninety days.

Sincerely,

Louise M Focht

Louise M. Focht
Director Quality Assurance
Sutter Corporation
619-569-8148 x 2213

Enclosures:

Appendix A	Proposed Labeling
Appendix B	Surgical Technique
Appendix C	Equivalent Product Literature
Appendix D	Drawing
Appendix E	Material properties, testing, previously approved under 510k submission

SUTTER CORPORATION
BIOMOTION SPECIALISTS™

March 29, 1993

510(k) Notification
Proximal Interphalangeal Joint

Food and Drug Administration
510(k) Document Mail Center (HFZ-401)
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619-569-8148 x 2213

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SUTTER CORPORATION
BIOMOTION SPECIALISTS™

March 29, 1993

510(k) Notification
Proximal Interphalangeal Joint

Food and Drug Administration
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1390 Piccard Drive
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9425 CHESAPEAKE DRIVE | SAN DIEGO, CA 92123 | (619) 569-8148 | (800) 854-2216 | FAX: (619) 279-8249

3/10/94 MNM

MEMO RECORD
FROM: M.N. MELKERSON, Engineer
TO: File
DATE: 3/10/94
Center/Office: CDRH/ODE
Division/Branch: DGRD/ORDB
Document Number: K931588
Common Name: Proximal InterPhalangeal (PIP) Joint Prosthesis, Finger & Toe
Trade Name: Sutter, Proximal Interphalangeal Joint Prosthesis
Classifications: 1) 21 CFR 888.3230, Finger Jt. Polymer Constrained Prosthesis

Class: II
Product Codes: KYJ: Finger
Products To Which Compared:

Preamendments Dow Corning Wright (Wright Medical), Swanson Silastic Jt. Spacers for metacarpal phalangeal (MCP), proximal interphalangeal (PIP), and distal interphalangeal (DIP) joints of fingers

K802342 and K870200, Sutter, Medical grade silicone (PEHT 400 series) Jt. Spacers for MCP and PIP joints of fingers

Contact Person: Louise M. Focht, Director of Quality Assurance (619) 569-8148, ext. 2213

Summary:

This 510(k) original dated 3/29/93, received on 3/31/93 and assigned on 3/4/94 was reviewed for a SE or NSE recommendation.

Recommendation:

I recommend that this 510(k) be found SE.

Basis of Recommendation:

INTENDED USE: Intended for total joint arthroplasty of the PIP joint of fingers for clinical indications of Rheumatoid arthritis (RA), Osteoarthritis (OA), Ankylosed joints or those with limited range of motion which have not responded to conservative treatment, Nonfunctional joint due to inadequate body alignment and joint space which cannot be restored by soft tissue reconstruction alone, and Destroyed articular surfaces.

DEVICE DESCRIPTION:

A constrained, flexible hinge design, joint space made out of a medical grade silicone elastomer (PEHT 400 series) with or without medical grade polyester mesh or fibers for reinforcement, sutures for temporarily securing the implant, and polyester mesh or velour

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surfaces to provide stabilization through tissue ingrowth. These design features are identical to the predicate Sutter MCP. The PIP implants will be offered in 6 sizes (i.e., 10, 20, 30, 40, 50, and 60).

Is the device life-supporting or life sustaining? no
Is the device implanted (short-term or long-term)? long-term
Does the device design use software? no
Is the device sterile? Yes
Is the device for single use? Yes
Is the device for home use or prescription use? Restricted to use by physicians.
Does the device contain drug or biological product as a component? - no
Is this device a kit? no

MATERIALS:

Medical grade silicone elastomer (PEHT 400 series), 12 years of use in other Sutter products (i.e., MCP jt.), Material properties and testing were supplied in Appendix E.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION"

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS STARTING ON PAGE 1 - NOTE: QUESTIONS WHICH ARE NOT APPLICABLE ARE FOLLOWED BY "N/A".

1. IF THE ANSWER TO QUESTION 1 IS NO, EXPLAIN WHY THE PRODUCT IS NOT A DEVICE. - Product is a device.

2. IF THE ANSWER TO QUESTION 2 IS NO, EXPLAIN WHY THE DEVICE IS NOT SUBJECT TO 510(K). - Is subject to 510(k).

3. IF THE ANSWER TO QUESTION 3 IS NO, EXPLAIN HOW THE NEW INDICATION DIFFERS FROM THE PREDICATE DEVICE'S INDICATION. - Same intended use and clinical indications.

4. IF THE ANSWER TO QUESTION 4 IS YES OR NO, EXPLAIN WHY THERE IS/IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE. - N/A

5. IF THE ANSWER TO QUESTION 5 IS NO, DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS. - Hinge design of Sutter MCP and PIP are identical while overall dimensions and stem of PIP has been modified to accommodate differences in the anatomy of the phalanges.

6. IF THE ANSWER TO QUESTION 6 IS YES OR NO, EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT SAFETY OR EFFECTIVENESS. - No, the modifications to the dimensions and

stem are slight (i.e., less of taper, thus greater cross-sectional areas) and should not adverse effect the mechanical properties of the device. The modifications did not change ratios of dimensions.

7. IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH. - Yes, the sponsor supplied drawings with dimensions allowing for the comparison to predicates dimensions and geometry.

8. IF THE ANSWER TO QUESTION 8 IS YES OR NO, EXPLAIN THE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW. - N/A

9. IF THE ANSWER TO QUESTION 9 IS NO, EXPLAIN WHY THE EXISTING SCIENTIFIC METHODS CAN NOT BE USED. - N/A

10. IF THE ANSWER TO QUESTION 10 IS NO, EXPLAIN WHAT PERFORMANCE DATA IS NEEDED. - N/A

11. IF THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT. - N/A

The following additional information also provides the basis for my recommendation:

LABELING: Provided Adequate labeling.

STERILIZATION:

Device is supplied sterile. Radiation Type: gamma, Radiation source: Cobalt 60, Minimum and maximum: 25kGy - 50kGy, SAL: 10^{-6}, Sterility validation method: AAMI Method I routine audit is performed using AAMI Method 3B, Statement whether pyrogen-free and method used to make that determination: There is no claim of being pyrogen-free.

RESPONSE: The sponsor supplied the omitted information.

Device may be resterilized as described in labeling. Identified the cycle parameters (Did not specify cycle type: gravity or vacuum ????): 270° F (132° C) for 15 - 20 minutes (fast cycle) or at 252° F (121° C) for 35-40 minutes (standard cycle), SAL: ???, Sterility Validation Method ????, Statement whether pyrogen-free and method to make that determination

RESPONSE: Sponsor removed all recommendations for resterilization either by steam or ETO.

States may be ETO sterilized but does not recommend due to aeration

time necessary to dissipate the absorbed sterilant. Sponsor should supply the following: Temperature (in ° C and F), humidity, gas concentration; exposure time, and aeration cycle.

RESPONSE: Sponsor removed all recommendations for resterilization either by steam or ETO.

TEST METHODS & RESULTS:

Material properties and testing were supplied in Appendix E. The sponsor provided the following material testing which was supplied in previous Sutter 510(k)s (K802342 and K870200) found to be SE:

Hemolysis test: Same response as negative control, test included a positive control

Physcio Chemical Results provide pass/fail criteria for allowable heavy metals, buffering capacity, nonvolatile residues, and residues on ignition

MEM Elution Same response as negative control, test included a positive control

Inhibition of Cell Growth Less of a response than negative control, a positive control was used

Limulus Inhibition test Same results as negative control, a positive control was used

USP Toxicity Class VI-121°C

Systemic Injection No toxicity noted systemically: non-toxic

Type B, Intracutaneous:: Saline, EtOH, Oil, and PEG

No toxicity noted intracutaneously

Implantation test USP XX 7 Day implant study, No significant response noted some fibrosis and inflammation but no giant cells and necrosis. Similar response to UHMWPE reference standard

Gross and Macroscopic

Flex testing PEHT series 400 (2.5Mrads):

#Cycles Flexed Millions	Quantity	Tear Strength lbs/in
[redacted]		

Dow Corning Wright 190 lbs/in - literature

Abrasion testing, Abrasion wheel method:

Abrasion rate: [redacted] inch/hour)

PEHT series [redacted]

Dow HP silastic >>> [redacted]

Shear testing: (b)(4)

PEHT- (b)(4)
Dow HP (b)(4)

REVIEW OF OTHER 510(K)S FOR SE: Preamendment Swanson Silastic finger spacers, K870200 and K802342

SUMMARY:

My recommendation is based on the following information. The device is made of same materials and has undergone the same testing as Sutter MCP joint prosthesis, K870200. Hinge design of Sutter MCP and PIP are identical while overall dimensions and stem of PIP has been modified to accommodate differences in the anatomy of the phalanges. The clinical indications are identical to the Sutter MCP prosthesis with the exception of being intended for the PIP joint. The clinical indications are identical to the preamendments Swanson finger implants except the Sutter PIP is not intended DIP joint replacement, only PIP and MCP joint replacement.

CONTACT HISTORY:

3/7/94, I faxed Louise Focht a copy of the ORDB guidance for 510(k) submissions and requested that omitted sterilization information be submitted. I also requested that the omitted re-sterilization information be submitted for the suggested steam or ETO re-sterilization methods.

3/8/94, I spoke with Louise Focht. She stated that she would fax in the response and follow it with a hard copy by overnight mail.

M.N. Melkerson MXM
Disc: Mark025, File: MK931588.

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The hinge design of the two products is the same with slight modifications in the implant stem shape to accommodate differences in the anatomy of the phalanges. Drawing is included in Appendix D.

The new Sutter PIP prosthesis is constructed of silicone, the material was originally approved for use in 1981 under the Material Identification of PEHT 400 series. The material has twelve years of proven clinical performance. Material properties and independent laboratory testing of the material is included in Appendix E.

Material testing performed includes:

- Hemolysis test
- Physico Chemical
- MEM Elution
- Inhibition of Cell Growth
- Limulus Inhibition test
- USP Toxicity Class VI-121 deg C
  - Systemic Injection
  - Type B, Intracutaneous::Saline
  - Type B, Intracutaneous::EtOH
  - Type B, Intracutaneous::Oil
  - Type B, Intracutaneous::PEG
- Implantation test USP XX
  - Gross and Macroscopic
- Flex testing
- Abrasion testing
- Shear testing

7. SAFETY AND EFFECTIVENESS SUMMARY:

Materials used in the Sutter finger implant are the same materials and manufacturing processed currently used in many Sutter implants including the Sutter MCP finger joint implant. The implants are made of Bulk Silicone Elastomer. GMP controls are in place and adhered to for current manufacturing of all Sutter Products.

We believe the proximal interphalangeal joint implant to be safe and effective. No new technologies are employed in the design or manufacture of the device. We believe that the device is substantially equivalent to other Sutter implants as well as the referenced competitors' product already in commercial distribution. We request clearance to introduce the device for distribution in ninety days.

Sincerely,

Louise M. Focht

Louise M. Focht
Director Quality Assurance
Sutter Corporation
619-569-8148 x 2213

Enclosures:

Appendix A	Proposed Labeling
Appendix B	Surgical Technique
Appendix C	Equivalent Product Literature
Appendix D	Drawing
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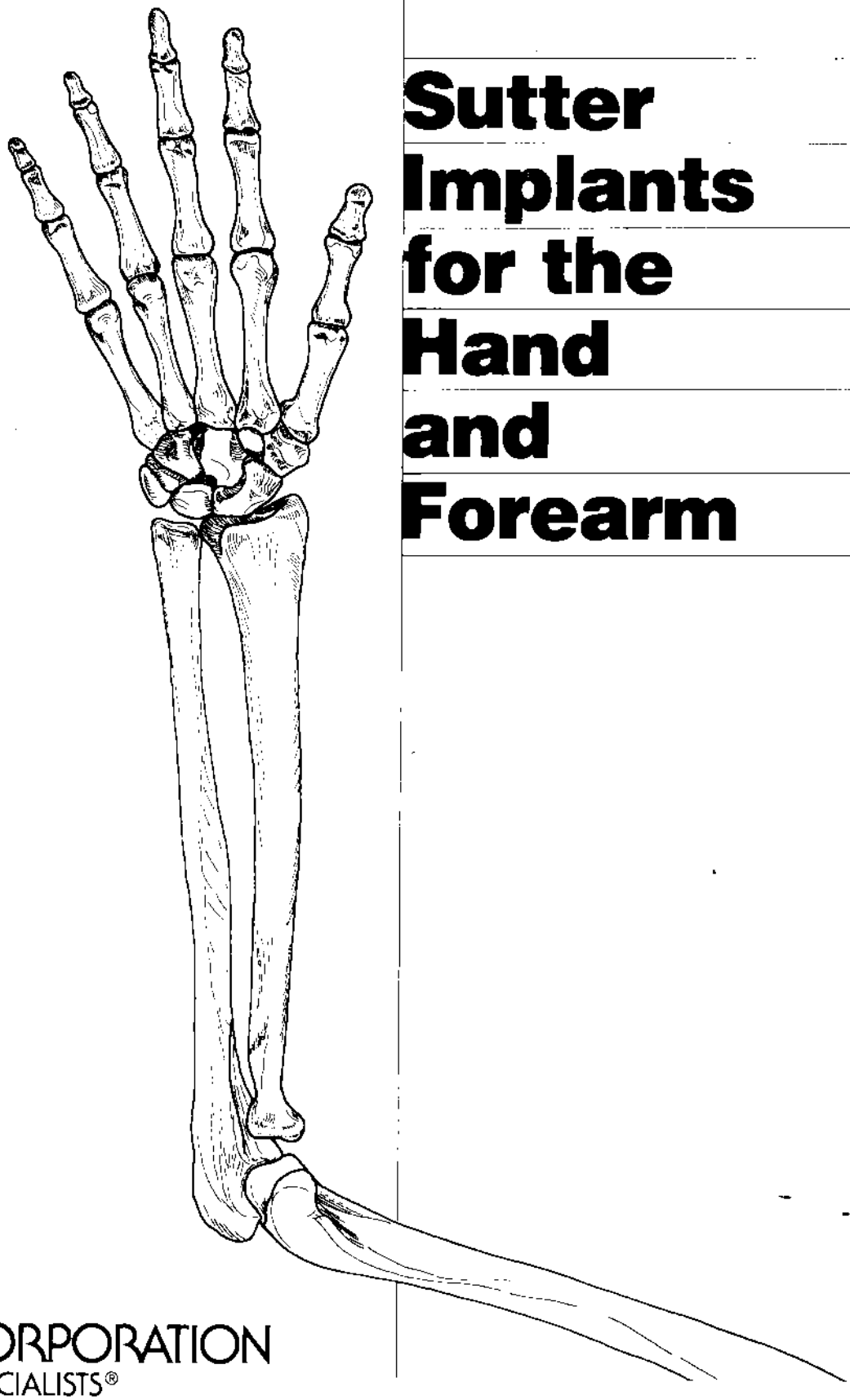
Appendix A
Proposed Labeling

Appendix C
Equivalent product literature



Sutter Implants for the Hand and Forearm

SUTTER CORPORATION
BIOMOTION SPECIALISTS®

Proximal Radius Implant

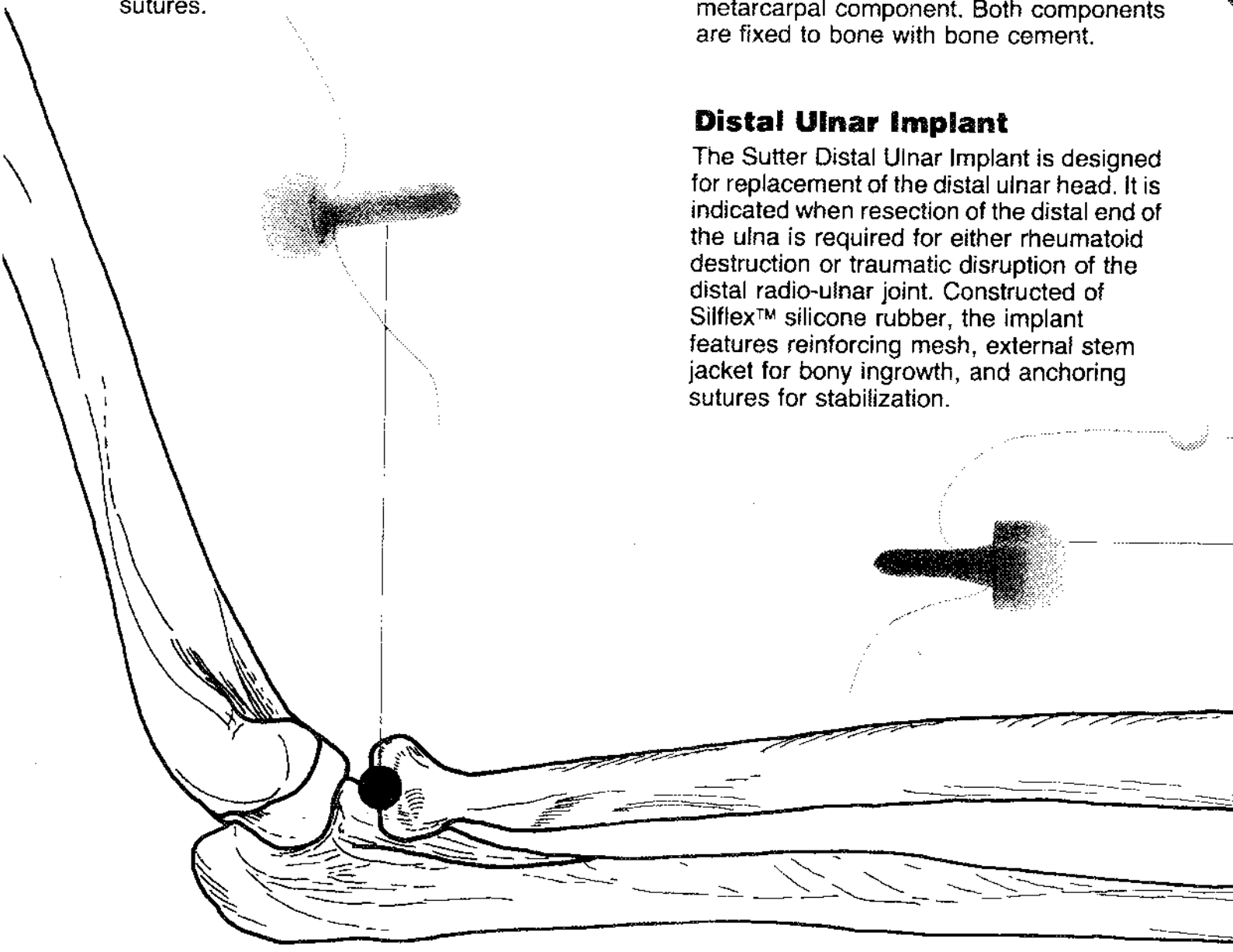
The Sutter Proximal Radius Implant replaces the proximal radial head when radial head resection is indicated in the presence of rheumatoid degeneration, traumatic arthritis, or radial head fracture. The implant has a smooth Silflex™ silicone articular head and a stem with a polyester ingrowth surface for stability. Immediate stabilization is possible with the anchoring sutures.

Carpometacarpal Implant

The Sutter Carpometarcarpal Implant is indicated for patients with disabled CMC joints secondary to degenerative arthritis, post-traumatic arthrosis or instability of the CMC joint. The design is a captured ball-in-socket prosthesis with total range of motion. It is composed of the UHMWPE cup which is inserted into the prepared trapezium, and a titanium alloy (Ti-6A1-4V) metarcarpal component. Both components are fixed to bone with bone cement.

Distal Ulnar Implant

The Sutter Distal Ulnar Implant is designed for replacement of the distal ulnar head. It is indicated when resection of the distal end of the ulna is required for either rheumatoid destruction or traumatic disruption of the distal radio-ulnar joint. Constructed of Silflex™ silicone rubber, the implant features reinforcing mesh, external stem jacket for bony ingrowth, and anchoring sutures for stabilization.



SUTTER CORPORATION
BIOMOTION SPECIALISTS®

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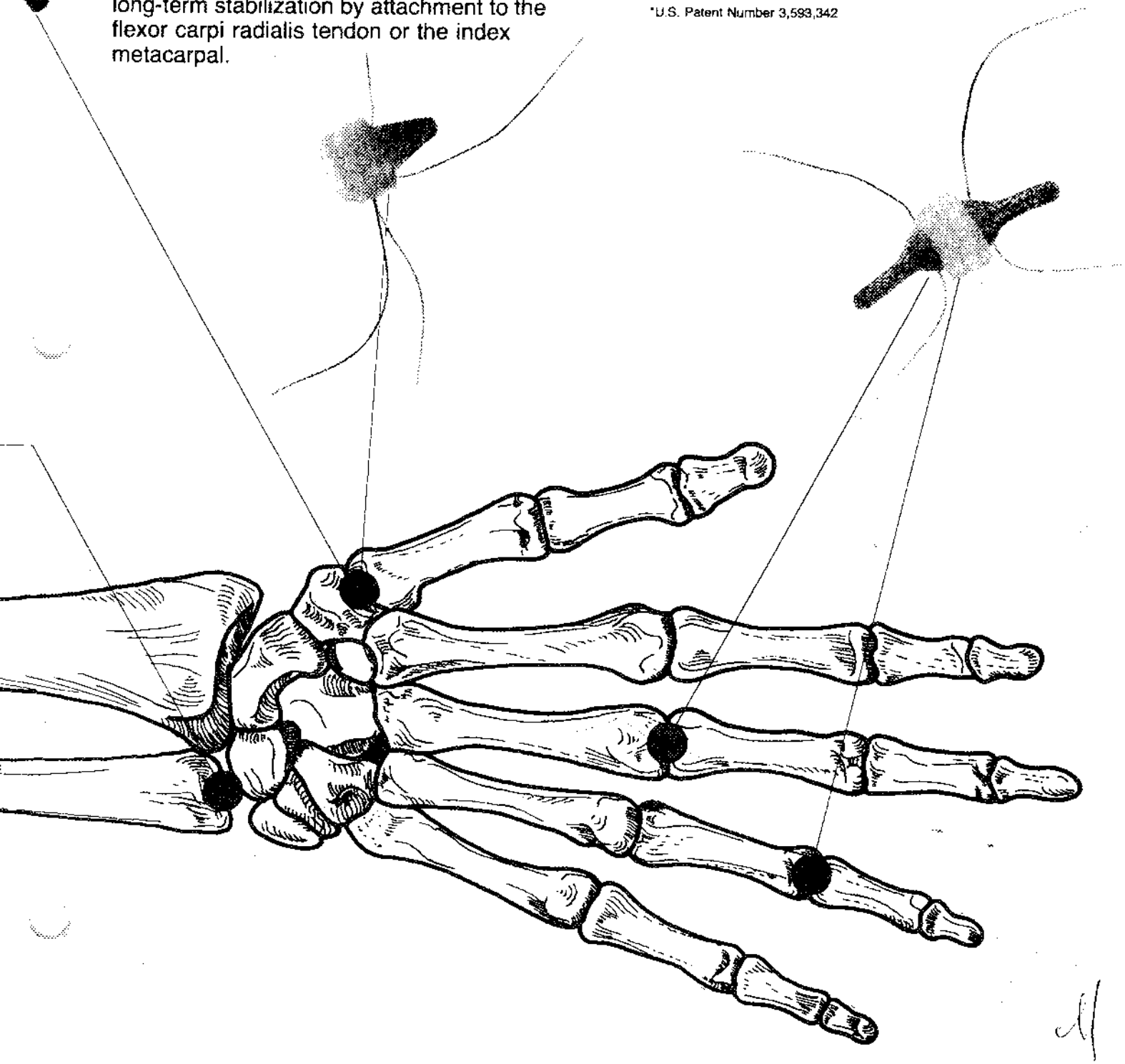
Trapezium Implant

The Sutter Trapezium Implant is for replacement of the trapezium in cases of carpometarcarpal arthritis or failed previous resection arthroplasty of the trapezium. The prosthesis, available in two stem sizes, is constructed of Silflex™ silicone rubber, polyester mesh, and braided polyester cords. The polyester mesh jacket on the stem provides long-term fixation through bony ingrowth into the mesh. The braided polyester cords facilitate immediate and long-term stabilization by attachment to the flexor carpi radialis tendon or the index metacarpal.

Finger Joint Implant*

The Sutter Finger Joint Implant is a total joint replacement for the metacarpo-phalangeal and proximal interphalangeal joints. The prosthesis consists of Silflex™ silicone rubber molded over an inner layer of reinforcing mesh and polyester anchoring sutures. The stems are covered with polyester mesh to permit infiltration of bone and fibrous tissue. Over 15 years of clinical experience with this design has demonstrated long term functional stability.

*U.S. Patent Number 3,593,342



[redacted]

Finger Joint Implant

Catalog Number	Size
MPIP-00	00
MPIP-10	10
MPIP-20	20
MPIP-30	30
MPIP-40	40

Sizer

Catalog Number	Size
MPIP-005	00
MPIP-105	10
MPIP-205	20
MPIP-305	30
MPIP-405	40

Finger Joint Broach

Catalog Number	Size
FJBR-00	00
FJBR-10	10
FJBR-20	20
FJBR-30	30
FJBR-40	40

[redacted]

Standard Stem Trapezium Implant

Catalog Number	Size
TR-10	10
TR-20	20
TR-30	30

Sizer

Catalog Number	Size
TR-105	10
TR-205	20
TR-305	30

[redacted]

Short Stem Trapezium Implant

Catalog Number	Size
STR-10	10
STR-20	20
STR-30	30

Sizer

Catalog Number	Size
STR-105	10
STR-205	20
STR-305	30

Trapezium Burr

Catalog Number
TB-1

[redacted]

Proximal Radius Implant

Catalog Number	Size
RH-10	10
RH-20	20
RH-30	30

Sizer

Catalog Number	Size
RH-105	10
RH-205	20
RH-305	30

[redacted]

Distal Ulnar Implant

Catalog Number	Size
UH-10	10
UH-20	20
UH-30	30
UH-40	40

Sizer

Catalog Number	Size
UH-105	10
UH-205	20
UH-305	30
UH-405	40

[redacted]

Carpometacarpal Implant

Catalog Number	Size
TMC-10	Small
TMC-20	Medium
TMC-30	Large
TMC-15	Replacement Head
TMC-25	Replacement Head

- All Sutter implants, except for the Carpometacarpal Implants, are shipped presterilized by gamma radiation.
- Sizers are not for implantation.

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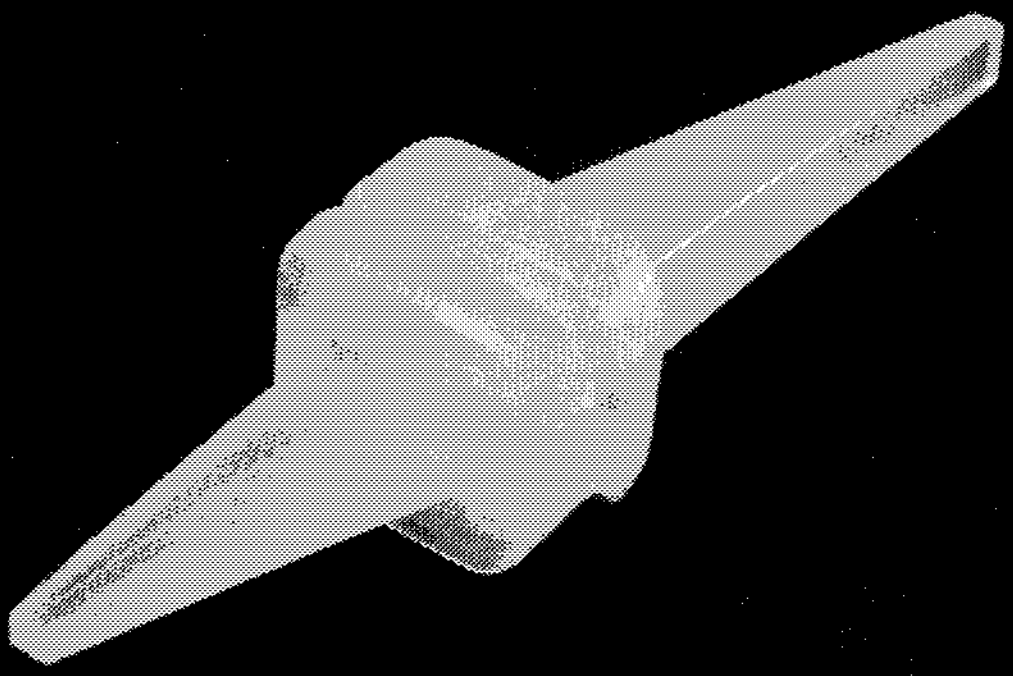
Now.
A full range of motion.
No volar impingement.
Same surgical technique.



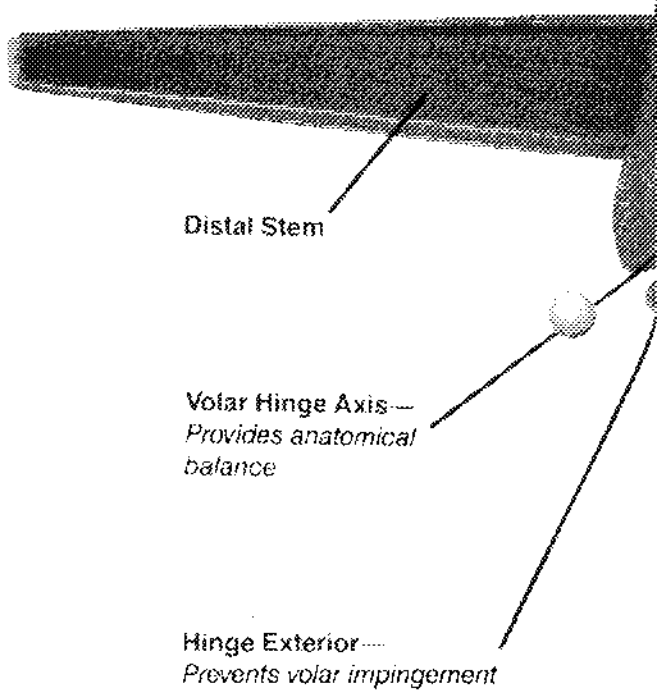
Introducing the Sutter MCP™
Finger Joint Prosthesis.

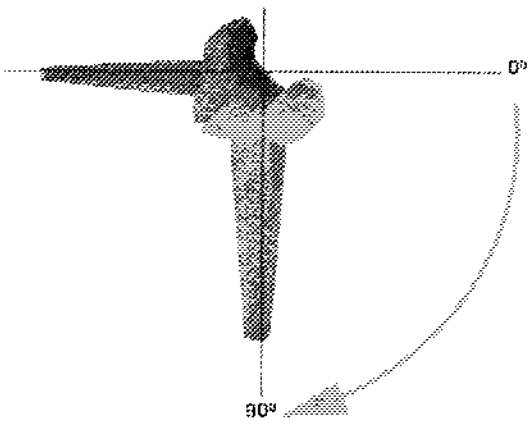
SUTTER CORPORATION

Biomechanically engine

The same surgical technique as other silicone MCP implants

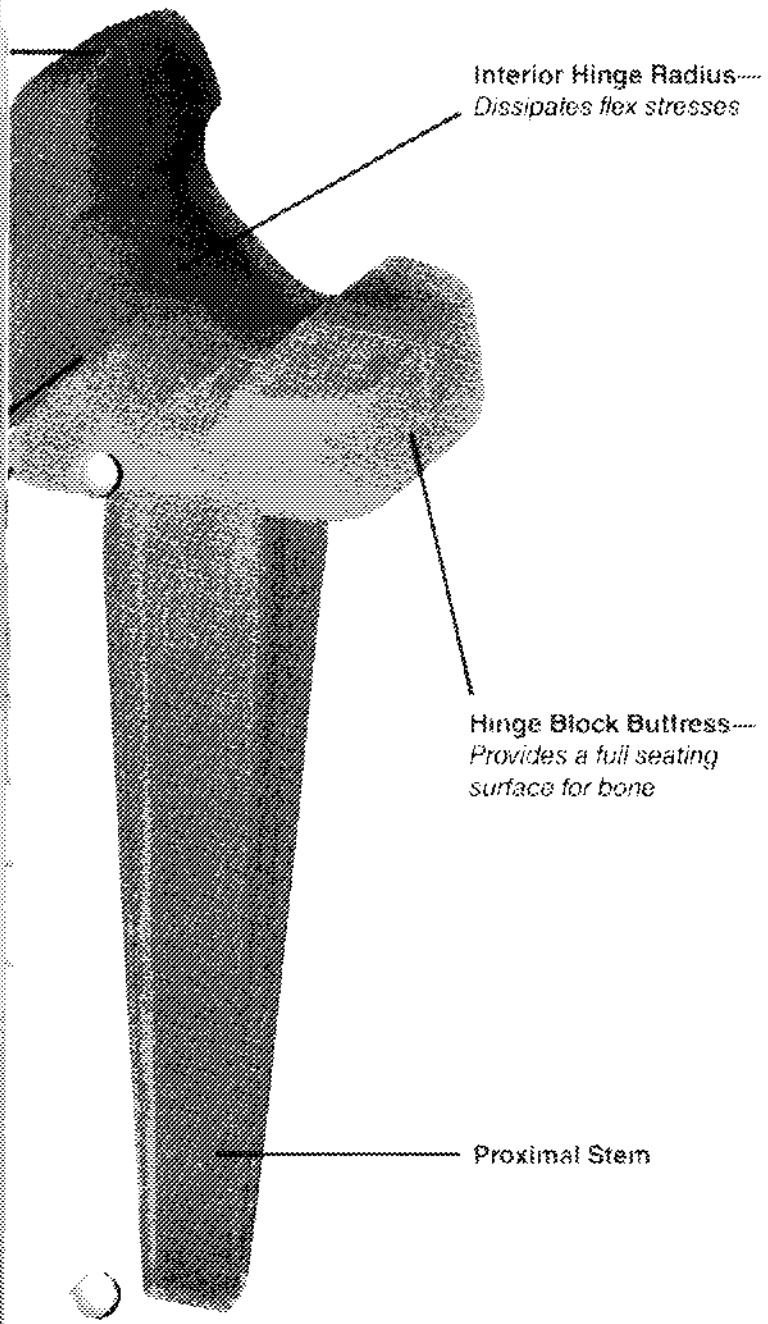
The surgical technique for the Sutter MCP® Finger Joint Prosthesis follows the same protocol for other flexible hinge silicone implants currently in use. The technique requires neither sutures for fixation nor grommets for protection of the prosthesis.





Closely Duplicates Normal
Elliptical Joint Motion

ered for superior results.



The offset hinge axis provides a full range of motion

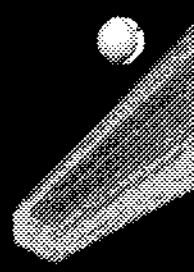
With the hinge axis in the volar position, the Sutter MCP Prosthesis maintains an anatomical balance between the flexor and extensor tendons thereby reducing extensor lag and providing well over 90° of flexion, without volar impingement. This offset of the hinge axis also creates an elliptical arc of motion similar to that of the anatomical MCP joint.

The Complete Sutter

Complete instrumentation and seven implant sizes

The Sutter MCP Implant System includes a complete set of 14 broaches, 7 implant sizers, a double-ended MCP rasp, MCP awl, and a custom sterilization tray. The System also includes implants ranging in size from the "00" to size "60." (See Ordering Information on back panel for complete list of sizes and dimensions.)

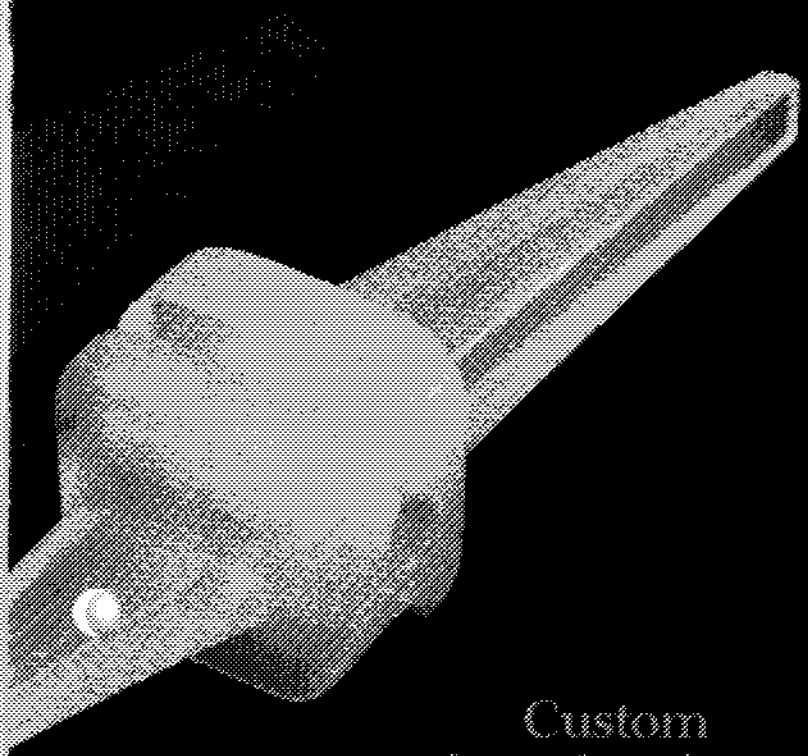
The MCP System also includes the surgical technique reference in print and video versions. The video is available in ½" VHS format.



Color-coded sizers for quick visual reference

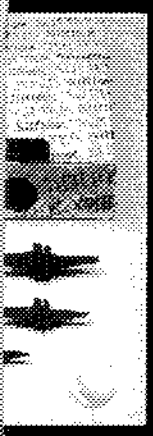
Sizers in the Sutter MCP Implant System are color-coded to coordinate with a large color marker which appears on each implant package. This color-coding system provides added convenience to the ease of set up and surgical procedure.

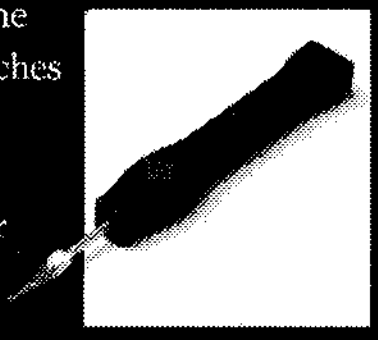
MCP Implant System



Custom broaches for better results

A full set of 14 custom MCP broaches is available. Each implant is supported by two broaches, a metacarpal broach and a phalangeal broach, for more efficient bone preparation. Broaches feature two-way cutting teeth for quicker and easier broaching of the intramedullary canal and light-weight, formed handles for superior procedural management. All broaches are color-coded to match sizers for fast and accurate identification.





Flexural durability through a superior material

With over five years of proven clinical performance, the Sutter Silflex™ silicone hinge has demonstrated unmatched flexural durability in rigorous laboratory tests. Through machine testing, the prosthesis has been flexed from 0° to 90° and back to 0° at a rate of 315 cycles per minute, producing over 450,000 cycles per day. Today, the Sutter MCP Implant has been flexed over 50,000,000 cycles with no wear or tear propagation observed.

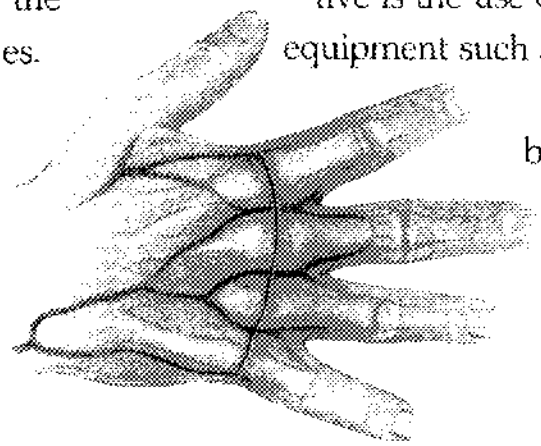
A simple technique

► Superior post-surgical results—durability and performance

The new Sutter MCP™ joint prosthesis, constructed of Silflex™ silicone, offers post-surgical results unavailable in any other finger joint implant. Its biomechanically engineered hinge block delivers a full range of motion and superior durability without the addition of grommets.

► Step One

A skin incision is made over the necks of the metacarpal bones. This incision can be a single transverse incision, or two longitudinal incisions, one between the second and third metacarpals and the other between the fourth and fifth metacarpals.

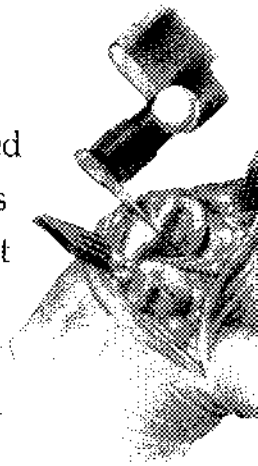


► Step Two

A blunt dissection is performed to expose extensor tendons and to preserve superficial veins and nerves.

► Step Three

The metacarpal head is resected and the intramedullary canal is prepared to receive the implant stem. This procedure may be performed by a variety of techniques with the most common being the use of a hand-held broach or awl. An alternative is the use of power equipment such as a small burr or oscillating broach head.

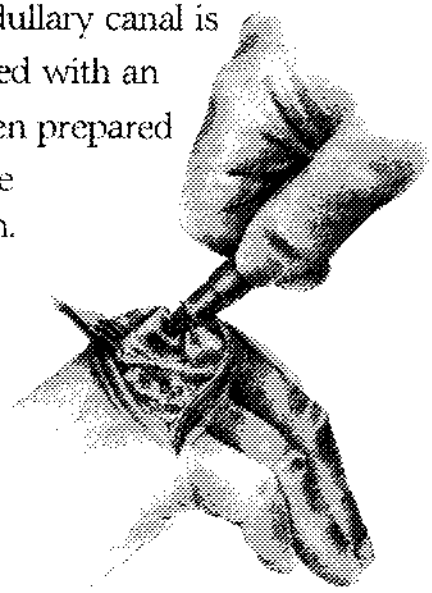


HB

for long-term results

► Step Four

The intramedullary canal of the proximal phalanx is then prepared in the same manner as the metacarpal. Since resection of the proximal phalanx is not commonly done, preparation of the intramedullary canal is usually started with an awl, and then prepared to receive the implant stem.

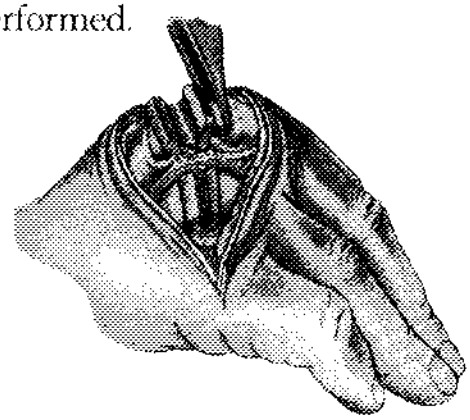


► Step Five

Implant size is determined by trial use of color-coded implant sizers. Once the proper size is determined, a range of motion is performed.

► Step Six

After size is determined and the intramedullary canals have been prepared, the implant is inserted into the metacarpal and then the proximal phalanx. A final range of motion is then performed.



► Step Seven

If necessary, ligament and tendon reconstruction and alignment are done at this time. Then the capsule is repaired and the wound is closed in the usual manner.

Ordering Information

The Sutter MCP™ Finger Joint Prosthesis System

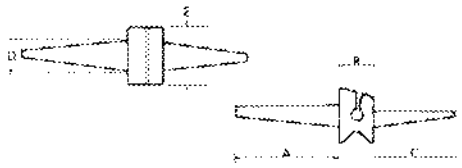
INDICATIONS

- Degenerative or inflammatory joint disease of the metacarpophalangeal joints.
- Dislocation or subluxation of the metacarpophalangeal joints.
- Painful metacarpophalangeal joints with limitation of motion.
- Ulnar drift not correctable by soft tissue procedure alone.

CONTRAINDICATIONS

- Psychologically unstable patient.
- Medically compromised patient.
- Infection.
- Inadequate bone stock.
- Irreparable flexor and extensor apparatus.

TYPICAL DIMENSIONS



SIZE	A	B	C	D	E
00	.618/15.7	.236/15.7	.483/5.2	.176/4.5	.352/8.9
10	.691/17.6	.240/6.10	.514/13.1	.197/5.0	.396/10.2
20	.768/19.5	.260/6.6	.603/15.3	.219/5.6	.440/11.3
30	.890/22.6	.280/7.1	.700/17.8	.246/6.2	.484/12.4
40	1.03/26.2	.308/7.8	.811/20.6	.276/7.0	.552/14.2
50	1.16/29.5	.340/8.6	.903/22.9	.310/7.9	.618/15.9
60	1.284/32.6	.364/8	1.000/25.4	.326/8.3	.648/16.5

SIZE – INCHES/MILLIMETERS

TO ORDER

Sizer

CATALOG NUMBER	SIZE
MCP-000	00
MCP-105	10
MCP-205	20
MCP-305	30
MCP-405	40
MCP-505	50
MCP-605	60

Implant

CATALOG NUMBER	SIZE
MCP-00	00
MCP-10	10
MCP-20	20
MCP-30	30
MCP-40	40
MCP-50	50
MCP-60	60

Broaches

CATALOG NUMBER	SIZE
MBR-M00 Broach	00 Metacarpal
MBR-P00 Broach	00 Phalangeal
MBR-M10 Broach	10 Metacarpal
MBR-P10 Broach	10 Phalangeal
MBR-M20 Broach	20 Metacarpal
MBR-P20 Broach	20 Phalangeal
MBR-M30 Broach	30 Metacarpal
MBR-P30 Broach	30 Phalangeal
MBR-M40 Broach	40 Metacarpal
MBR-P40 Broach	40 Phalangeal
MBR-M50 Broach	50 Metacarpal
MBR-P50 Broach	50 Phalangeal
MBR-M60 Broach	60 Metacarpal
MBR-P60 Broach	60 Phalangeal

Broaches, cont.

CATALOG NUMBER	
MBR-S Instrument/Sizer Set	
14 Broaches	
1 Awl	
1 Double-Ended Rasp	
7 Sizers	
1 Custom Sterilization Tray	

MISCELLANEOUS

Double-ended MCP Rasp	RSP-001
MCP Awl	SAL-002
Custom Sterilization Tray	CST-003

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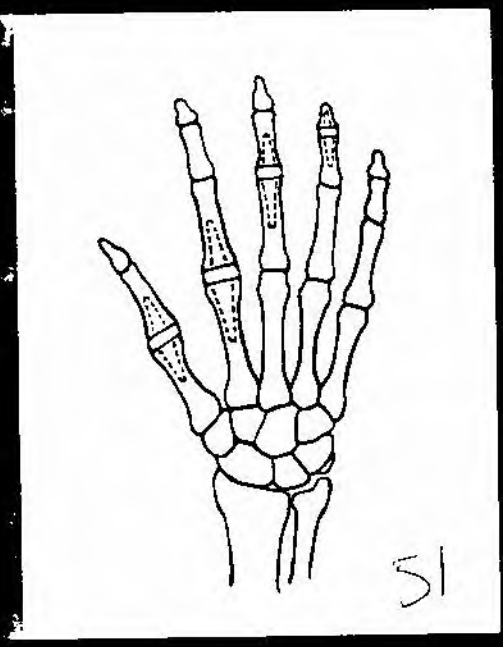


SILASTIC® BRAND Finger Joint Implant H.P.

(Swanson* Design)

DOW CORNING

WRIGHT

Description

A flexible, intramedullary-stemmed, one-piece implant developed to help restore function to hands disabled by rheumatoid, degenerative or traumatic arthritis.

Designed for metacarpophalangeal (MP), proximal interphalangeal (PIP) and distal interphalangeal (DIP) joint implant arthroplasty, this medical-grade high performance silicone elastomer implant serves to preserve normal joint space relationship during formation of the supportive capsule. Flexible, hinge-like construction helps maintain proper internal joint alignment with good lateral stability and minimal flexion-extension restriction.

The SILASTIC® Finger Joint Implant H.P. (designed and developed by Alfred B. Swanson, M.D.) is available in 11 sizes to adequately meet various operative requirements. A sizing set supplied non-sterile and not suitable for implantation is available for proper size determination during surgery.

High Performance Silicone Elastomer

The letters H.P. in the product name indicate the implant is fabricated from medical-grade high performance silicone elastomer. This elastomer shows greater resistance to tear propagation than conventional silicone rubber.[46]

Implant Design

The mid-section has been designed to flex easily while at the same time maintaining vertical stability. This load distributing flexible hinge in the mid-section of the implant acts as both a spacer and a flexible hinge mechanism. The absence of stress concentration during repeated flex loading contributes to the tolerance of the implant by the host and to the durability of the implant.

Specific Advantages

- Minimal irritation to bone and surrounding soft tissue.
- Pliable medical-grade silicone elastomer (softer than bone) unlikely to cause necrosis or bone resorption.
- Fabricated from medical-grade, high performance silicone elastomer.
- Design characteristics include: Intramedullary-stemmed, flexible one-piece hinge-like construction of homogeneous material with stiffness/flexibility balance of implant material, and proper compression-tension force distribution in midsection.
- No intramedullary permanent fixation required.
- Extensive testing has demonstrated high flexural durability (over 600 million flexion repetitions to 90° without evidence of material fatigue or fracture).
- Anatomical sizing (length, height, width) available in eleven sizes to meet various operative requirements.
- Visible on X-ray evaluation.
- Product sterilized; if resterilization is indicated refer to section "To Clean and Resterilize."

Clinical Advantages

1. Improves range of motion (especially extension)
2. Makes results more predictable, reproducible, and durable
3. Maintains joint space and alignment
4. Orients and supports joint encapsulation
5. Intramedullary stem gliding: less stress to bone and less stress to implant; allows joint to find its own center of axis of rotation
6. Early post-operative motion
7. Facilitates post-operative rehabilitation

Concept of Fixation by Encapsulation

The following explanation is furnished by Dr. Alfred B. Swanson for information purposes only. Each surgeon must, of course, evaluate the appropriateness of this explanation based on his own medical knowledge and experience.

Joint Resection + Implant + Capsule = New Joint

Regular joint resection arthroplasty works well in the hand if the joint space and alignment can be maintained.[7,13,28,29] This frequently requires excessive postoperative fixation with pins and external support. The fixation, if overused, will compromise the expected range of motion. In a considerable number of these cases, the joint space gradually narrows and stiffness and subluxation may result. Excellent results do occur however, and are related to the development of a supportive fibrous joint capsule organized during the time when a guarded range of motion is allowed. In finger joint arthroplasty, the proper amount of flexion-extension, appropriate lateral movement and reduction of dorsopalmar subluxation are difficult to obtain, but necessary for a good result. Therefore, one of the most important functions of a successful implant is to maintain proper joint alignment internally while allowing early motion as this new, functionally adapted, fibrous capsule matures.[9,33] By continuing to support the important fibrous capsule and acting to keep the joint surfaces apart, the implant further serves its useful purpose in the post-operative course. This important phenomenon has been named the "Encapsulation Process."

The intramedullary stems of the implant help to maintain alignment and prevent joint displacement. Orientation of the proper capsule is extremely important in the early stages of healing. The immediate post-operative positioning and control of joint movement during the six to eight week rehabilitation period are as important as the surgery itself and these are achieved by dynamic bracing and physiotherapy.

Because the implant becomes so well stabilized by the capsuloligamentous system, it is felt that no other fixation of the implant is required; in fact, it is contraindicated. Dr. Swanson's early experiences with permanent fixation of flexible implants with cross pins, cement, or Dacron cover on the intramedullary stems of the implants and some nonabsorbable suture fixations have led to early breakage of the implants.[30,37] In fact, lateral stability decreased in time because of bone absorption at the fixation site. Most of these implants have been removed, and it has been found that Dacron in a synovium-lined cavity can cause severe inflammatory reaction, which in turn enlarges the joint capsule and results in instability. An implant should cause no inflammatory reaction if it is to be long tolerated.

Stability of a reconstructed joint cannot be dependent on any implant if it is to be tolerated on a long-term basis. Long-standing host-implant reciprocal tolerance requires achievement of joint stability from the extrinsic capsular ligamentous and musculotendinous systems. The flexible implant concept respects this biological requirement. What appears to be a reasonable biomechanical model for an implant may not be tolerated physiologically because of failure of consideration of these facts.

The smooth flexible implant is completely included in the encapsulation process (Fig. 1). A slight amount of movement of the stems increases the life of the implant because forces that develop around the implant on motion are not concentrated in any particular area but rather spread over a broader section, and because the flexible hinge implants can find the best position with respect to the axis of rotation of the joint. This distribution of forces on the implant is also reflected at its interface with the bone or cartilage. The bone is less likely to react at the juncture with the implant if the forces are within the strain tolerance of the bone. Furthermore, the intramedullary stem of the implant has a supportive action on

the cut end of the amputated bone; it prevents excessive resorption and remodeling phenomena that frequently occur after amputation, as noted in a 15-year study of the finger joint arthroplasty. The low modulus implant is softer than bone and has force-dampening characteristics that further protect the bone or cartilage and soft tissues.

Salvageability of an arthroplasty procedure must be one of the important considerations; this implies preservation of bone and soft tissues so that a secondary procedure can be performed. This requirement was of particular importance in the flexible implant arthroplasty procedure we designed. The capsuloligamentous structures around any flexible implant can be reconstructed to improve the stability, alignment, and durability of the arthroplasty, and revision procedures to further reinforce, release or realign the capsule and ligaments when necessary are easily performed. Because the implants are not firmly attached to bone, replacement of an implant for either infection, fracture, or subluxation is a relatively simple procedure. Furthermore, if a fracture of an implant develops or removal becomes necessary, a functioning resection arthroplasty remains. In case of fracture, the implant continues to function by maintaining the joint space and the integrity of the capsular space. In case of implant removal, the implant has fulfilled much of its mission as a spacer to support the development of the capsule-ligament system. The bone stock removal is minimal, and bone absorption practically never occurs, so that an arthrodesis procedure with a bone graft can easily be accomplished.

The results of metacarpophalangeal and proximal interphalangeal joint flexible implant arthroplasty have shown that this method can provide a pain-free, durable, mobile, stable, and salvageable arthroplasty. This method has received an overwhelming acceptance as the method of choice in most countries throughout the world.[1-6, 8, 9, 11, 13, 18, 20-24, 26, 27, 47-49] The correction of the deformity is predictable if the operative and postoperative techniques are followed. The range of motion obtained has varied in clinics, depending in part upon their aggressiveness in the rehabilitation program. The average range of motion in our clinic for 1506 metacarpophalangeal joints was found to be from 4° of lack of extension to 67° of flexion. It is of interest to note that the range of motion on long-term evaluations has not changed significantly. The average range of motion in 493 operated proximal interphalangeal joints has been from 8° of lack of extension to 64° of flexion. Most of these cases were reconstructed for osteoarthritis or posttraumatic arthritis. This procedure also requires aggressive and detailed postoperative therapy. It should be emphasized that other surgical procedures necessary to balance the hand are equally important in flexible implant arthroplasties as in any arthroplasty.

General Indications

Any joint implant reconstruction requires consideration of the following general indications:

- Good condition of the patient.
- Good neurovascular status.
- Adequate skin coverage.
- Possibility of a functional musculotendinous system.
- Adequate bone stock to receive the implant.
- Availability of postoperative therapy.
- Cooperative patient.

Contraindications

- Physiologically or psychologically inadequate patient.
- Inadequate skin, bone and/or neurovascular status.
- Irreparable tendon system.

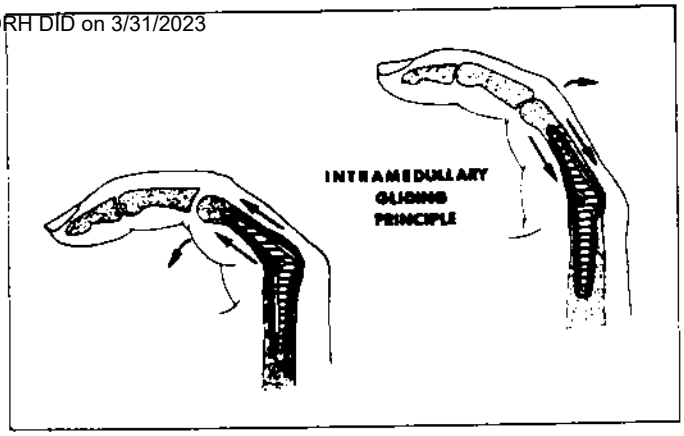


Fig. 1: *The stems of the Silastic® implant are included in the encapsulation process and the implant glides within the intramedullary canals a distance of 1 or 2 mm. on flexion/extension movements. This gliding allows a greater range of motion to occur and permits the implant to find the best position with respect to the axis of rotation of the joint. The gliding flexible implant is subjected to less stress and in turn causes less stress on the surrounding bone.*

Metacarpophalangeal Joint Implant Arthroplasty

Indications

Rheumatoid or Post Traumatic Disabilities with:

1. Fixed or stiff MP joints.
2. X-ray evidence of joint destruction or subluxation.
3. Ulnar drift, not correctable by surgery of soft tissues alone.
4. Contracted intrinsic and extrinsic musculature and ligament system.
5. Associated stiff interphalangeal joints.

Note: Severe and disabling flexor synovitis should preferably be treated before implant arthroplasty. After a reasonable rehabilitation period, the arthroplasties can be performed. Excessive manual labor and awkward weight bearing on hand(s) such as occasionally occurs in some crutch walkers should be avoided after surgery.

If crutches are absolutely necessary, platform crutches should be used. Lower extremity reconstructive surgery should be carried out first if feasible.

Surgical Technique

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only as a technique used by Dr. Alfred B. Swanson. Each surgeon must, of course, evaluate the appropriateness of the procedure based on his own medical training and experience.

Reconstruction of complex hands, those that have severe involvement of both MP and PIP joints or wrist joints, require special consideration. It is impossible in this data sheet to cover this topic in detail. Further study of this problem is strongly recommended in the appropriate references listed, including the recently published test book on flexible implant resection arthroplasty.[10,12,31,32,34,35,37,38,40-45]

Incision and Exposure

A long transverse skin incision is made on the dorsum of the hand over the necks of the metacarpals. The dissection is carried down through subcutaneous tissue to expose the extensor tendons. The dorsal veins which lie between the metacarpal heads are carefully released by blunt longitudinal dissection and are retracted laterally. The extensor hood is exposed to the base of the proximal phalanx. Its radial portion is

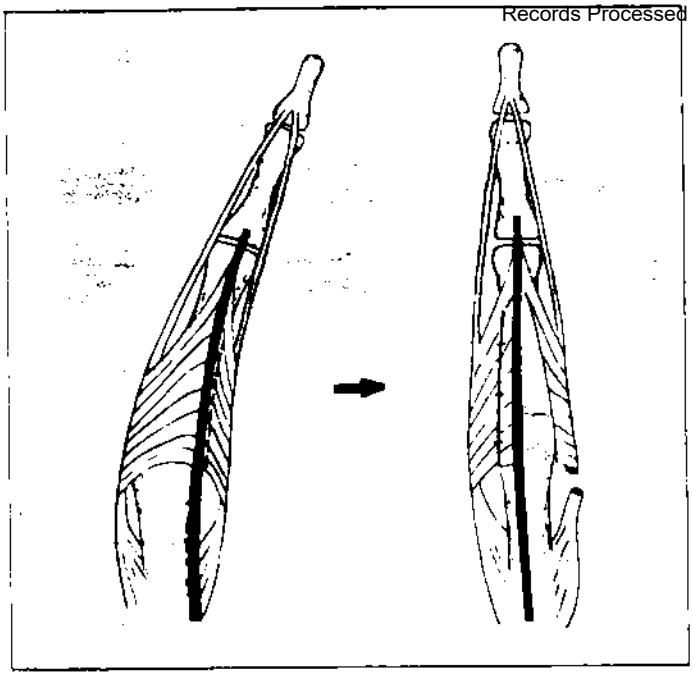


Fig. 2: *The dislocated extensor tendon is released by incision on its ulnar border. The ulnar intrinsics are released if tight. The sagittal fibers of the dorsal hood are reefed on the radial side to maintain the correction.*

usually stretched out and the extensor tendon dislocated ulnarward. A longitudinal incision is made in the extensor hood fibers parallel to the extensor tendon on its ulnar aspect (Fig. 2). In the little finger, the approach is made between the extensor communis and proprius tendons. The hood fibers and capsule are carefully dissected from the underlying synovium and retracted to the radial side. The joint is exposed and the head of the metacarpal identified.

Resection of Metacarpal Head

The neck of the metacarpal is exposed sub-periosteally and transected with an air drill, motor saw or bone cutting forceps leaving part of the metaphyseal flare (Fig. 3). Care should be taken to avoid splintering the bone. The head of the metacarpal is grasped and the collateral ligaments and capsule attachments are incised and preserved. The head of the metacarpal along with the hypertrophied synovial material is thereby removed en masse. Further involved synovia of the joint cavity and surrounding tissues is removed. A pituitary rongeur has been found to be useful for this purpose.

Soft Tissue Release

A comprehensive soft tissue release procedure must be done at this stage so that the base of the proximal phalanx can be displaced dorsally above the metacarpal. This may require incision of the palmar plate and collateral ligament attachments from the proximal phalanx. This release should be symmetrical and complete. Identify the ulnar intrinsic tendon at its point of insertion into the extensor mechanism. If it is tight, pull it up into the wound with a blunt hook and section at the myotendinous junction.

In some patients who have demonstrated evidences of a flexor synovitis, the flexor sheath can be incised longitudinally in its dorsal aspect. The long flexor tendons can be identified and pulled up gently into the wound with a blunt hook. The degree of involvement of the flexor tendons can be evaluated. In some cases a partial synovectomy and tendon sheath release or injection of corticosteroids is done through this incision.

The tendon of the abductor digiti minimi is exposed on the ulnar aspect of the fifth metacarpophalangeal joint, pulled into the wound with a blunt hook and sectioned. Care should be taken to avoid the ulnar digital nerve in the dissection. It is thought that this tendon eventually reattaches but in a lengthened position. The tendon of the flexor digiti minimi is preserved because of its importance to obtain flexion at the metacarpophalangeal joint of the little finger.

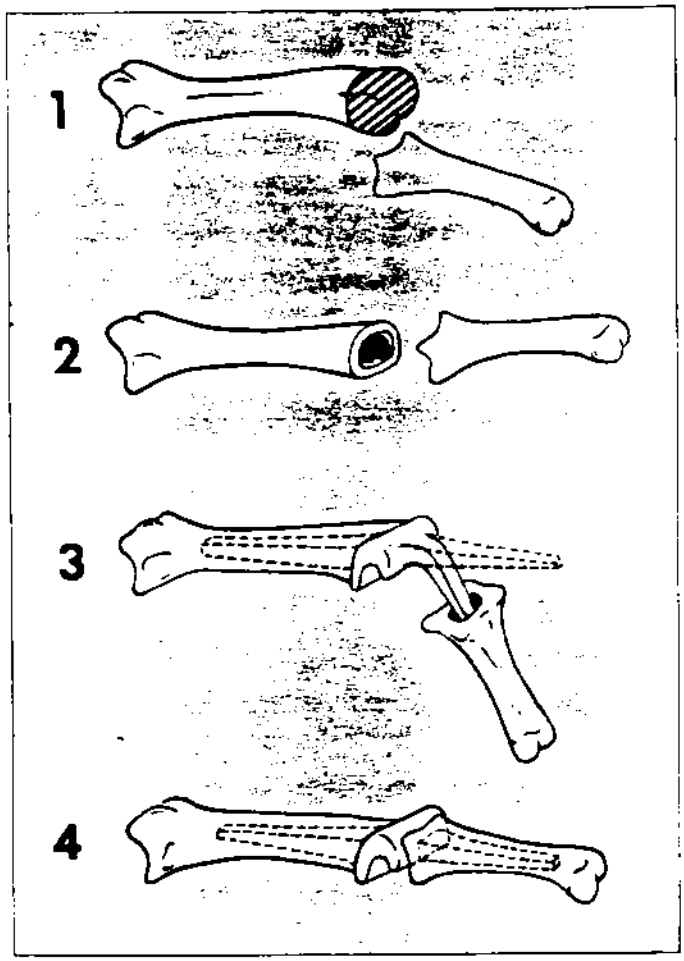


Fig. 3: *Resection of metacarpal head and insertion of implant stems into intramedullary canal. Use the largest implant that can be properly seated. The appropriate joint space should be obtained by bone removal and if necessary soft tissue release. Bone should be removed from the metacarpal head and also the base of the proximal phalanx particularly if it is eroded. A comprehensive soft tissue release should be done depending on the severity of the contracture.*

Preparation of Proximal Phalanx and Intramedullary Canals

Bony resection of the base of the proximal phalanx is not usually performed except for marginal osteophytes which might interfere with the implant. Occasionally in patients with osteoporosis and longstanding dislocation, deformities of the base of the proximal phalanx will be severe. In these cases, a shaping of the base of the phalanx may be necessary. The intramedullary canal of the metacarpal is prepared with a curet, broach or air drill with a special bur*. These burs have a smooth leader point which helps keep them in the canal and prevents inadvertent perforation through the cortex. The occasional constriction in the intramedullary canal of the proximal third of the proximal phalanx can easily be enlarged with the bur. Care should be taken to avoid too much reaming of the canal, especially in patients with thin bones. Test implants are used to select the proper size. The implant stems should fit well down into the canal so that the transverse midsection of the implant abuts against the bone

* Dow Corning-Wright

end. The largest implant possible should be used. Implants of sizes 4 through 9 are generally used. A rectangular hole is then made in the joint surface of the proximal phalanx with an osteotome, knife, broach or air drill. The intramedullary canal is reamed in the same fashion as the metacarpal to receive the distal stem of the implant selected for the metacarpal. This procedure is repeated for all digits. The intramedullary canal of the ring metacarpal is frequently quite small and requires careful preparation. Any sharp points or rough surfaces on the bone ends should be completely smoothed.

Implant Insertion

The wound is thoroughly irrigated with saline to remove debris. Blunt instruments should be used with a "no-touch technique" when inserting silicone finger joint implants. First the implant is firmly inserted into the intramedullary canal of the metacarpal and then by slight traction on the finger, the joint is distracted and the implant is flexed so that the distal stem can easily be inserted into the proximal phalanx. With the joint in extension, there should be no impingement of the implant. If there is, soft tissue release or bone resection has not been adequate.

Note

The implant should be handled with blunt instruments to avoid traumatizing its surface or contamination with foreign bodies. Reshaping of the implant should be avoided because modification might create mechanical weakness. Shortening of the end of the stem is permissible.

Extensor Hood Reefing

The radial portion of the sagittal fibers of each extensor hood mechanism is reefed in an overlapping fashion so that the extensor tendon is brought slightly to the radial side of the center of the joint. Three to five 4-0 Dacron sutures with a buried-knot technique are used. In certain cases of severe or long standing flexion deformity, the extensor tendons may become stretched and an extensor tendon lag may persist if not corrected. In these cases, the extensor tendon should be reefed not only transversely as described, but also longitudinally. Exceptionally, an extensor tendon tenodesis can be accomplished by suturing it to the dorsal base of the proximal phalanx through small drill holes.

Rheumatoid patients often present an inadequate first dorsal interosseous muscle or have a tendency for pronation deformity of the index finger and occasionally the middle finger; a reconstruction of the radial collateral ligament is then indicated. A distally based flap made of the collateral ligament and related structures is prepared by releasing the radial collateral ligament from the neck of the metacarpal and suturing it to the dorsoradial aspect of the neck of the metacarpal through small drill holes using 3-0 Dacron sutures. The radial capsule that has been preserved, may also be included in this repair (Fig. 4). The sutures are placed before the implant is inserted and are tied as the finger is held in supination and abduction. Note that the first dorsal interosseous muscle fibers which attach to the ligament become dorsally relocated with this repair. When the radial collateral ligament is inadequate, a palmar plate flap may be used to reconstruct this ligament (Fig. 5). This procedure has seemed to be important in correction of pronation deformities and provides some improved lateral stability for pinch. It seems to decrease flexion of the index metacarpophalangeal joint by 10 to 20 degrees by tightening the capsule, but this loss is outweighed by increased stability and a better correction of the pronation deformity.

Meticulous evaluation and correction of the balance of the capsuloligamentous and musculotendinous structures will be rewarded by improved results.

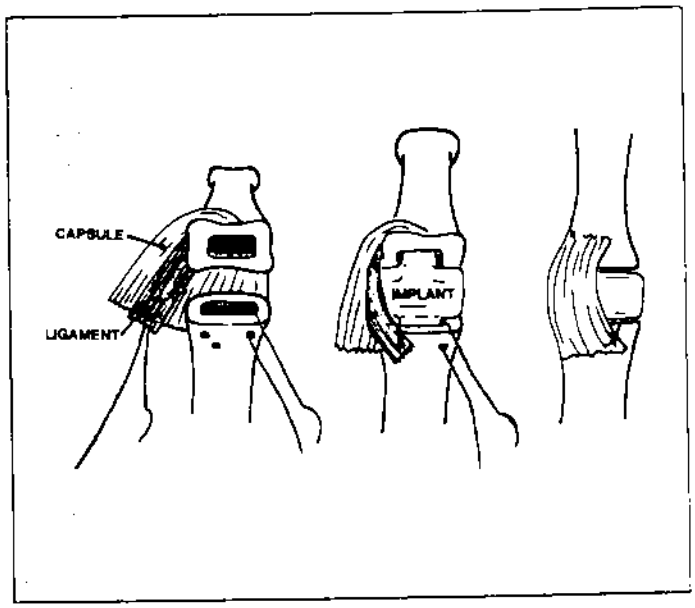


Fig. 4: *Radial collateral ligament reconstruction.* **A:** *The radial collateral ligament and joint capsule are incised from their attachment to the neck of the metacarpal. Two small drill holes (1 mm) are made on the radio-dorsal aspect and one small drill hole is made on the dorsal ulnar aspect of the neck of the metacarpal.*

B&C: *3-0 Dacron sutures are passed in the drill holes. After the implant is inserted, the radiocollateral ligament and capsule are firmly sutured to the bone.*

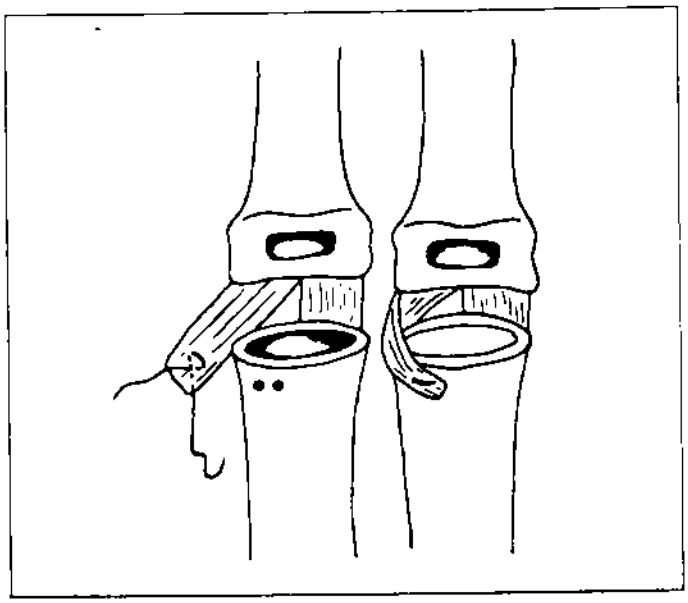


Fig. 5: *Collateral ligament reconstruction at the MP joint when the radial collateral ligament is inadequate: The palmar plate and its attachments are incised longitudinally through the middle. The sesamoid bone, if present, is resected. A distally based flap is made from the radial half of the palmar plate and collateral ligament, which are separated from the underlying intrinsic muscles and flexor tendons. This flap, 1.5 to 2 cm. in length, is attached to the radial aspect of the neck of the metacarpal through a hole in the dorsoradial cortex of the neck of the bone with nonabsorbable suture material.*

Closure and Dressing

The skin incision is closed with interrupted 5-0 nylon sutures; two small drains made from strips of silicone elastomer sheeting are inserted into the wound under the skin. A non-adherent dressing such as rayon is applied over the wound along with a Furacin or alternate gauze overlay. A voluminous hand conforming dressing is applied, gauze is placed between the fingers but not down into the clefts which might cause vascular constriction. A roll of Dacron batting is placed across the palm and is layered across the dorsal and palmar aspect of the forearm, wrist, hand and fingers. Sheet wadding or Webril is then applied. A narrow plaster splint is applied to the palmar aspect and the entire dressing is wrapped in a conforming bandage such as Kling.

Post-Operative Care and Bracing

The ideal motion would provide adequate flexion of the ulnar digits, allowing the surface of their pulps to touch the palm at the distal palmar crease for adequate grasp of smaller objects. Full flexion of the index and middle fingers is less critical for grasping as these digits are mainly used for pinch activities. A degree of spreading of the fingers into abduction, especially of the index finger, is important. Full extension at these joints is also important to perform normal hand activities and to maintain the balance of the distal joints. Chronic flexion deformity of the metacarpophalangeal joints can further aggravate hyperextension tendencies at the proximal interphalangeal joints. Pronation deformity of the index finger and occasionally the middle finger can be a problem in the rheumatoid hand and can, to some degree, be corrected in the postoperative program.

Immediate and continuous elevation of the hand and the forearm during the post-operative course is very important. The wound is usually checked on the second day and the stains removed. Swelling is generally minimal so use of the dynamic brace* can begin on the third to fifth post-operative day. A light dressing is applied to the hand and forearm and the dynamic brace is fitted and adjusted enabling the patient to start finger movements in a protected arc. A ¼" felt pad is placed between the forearm and the brace.

Fig. 6: *An adjustable dynamic brace is placed over a slightly padded dressing after the third to fifth day. The patient is encouraged to flex joints within his limits of pain and fatigue.*

The rubber band slings are placed on the proximal phalanges to guide the alignment of the digits into the desired position (Fig. 6). The pull of the slings in the radial direction will usually require adjustment to prevent recurrent ulnar drift. The tension of the rubber bands should be tight enough to support the digits and yet loose enough to allow 70 degrees of active flexion; this is especially true of the little finger, which may have weak flexion power. The brace may require adjustment once or twice a day in the early postoperative course. Joint motion is measured with a goniometer and recorded.

The thumb outrigger is usually applied in all cases because of the tendency for the patient to bring the thumb over the fingers on flexion. This movement should be avoided because the pressure applied by the thumb to the index finger would be in the ulnar direction, thus aggravating the tendency toward ulnar drift deformity.

If there is a tendency toward medial rotation (pronation) of the metacarpophalangeal joint of the index or middle fingers, additional outrigger bars are applied to provide a supinatory force to the joint.

The extension portion of the brace is worn continuously day and night for the first 3 weeks, alternating with specific flexion exercises. The exercises are started 3 days after surgery. Exceptionally, if there is severe flexor weakness of the little finger with adequate extension, the extensor slings can be removed during the exercise periods.

During the second and third weeks, the extension portion of the brace is also worn continuously day and night. If there is severe flexor weakness and good extension, the extensor sling can be removed 1 to 2 hours a day to achieve greater active flexion of the metacarpophalangeal joints. The joints have a tendency to tighten up in the second week post-operatively. The patient is encouraged to flex his joints within his limits of pain and fatigue.

Patients who have normal proximal interphalangeal joints frequently will not gain the full expected motion at the metacarpophalangeal joint after arthroplasty because they tend to flex the proximal interphalangeal joint during their exercise program and thus relatively immobilize their metacarpophalangeal joints. To gain active motion of the metacarpophalangeal joints in these patients, we occasionally will tape small, padded aluminum splints on the dorsum of the proximal interphalangeal joints for the first three or four weeks after surgery which encourages the patient to localize all flexion force at the metacarpophalangeal joint.

At 3 weeks any residual flexor weakness should be energetically treated. The flexion cuff may be worn 1 to 2 hours twice a day to flex the metacarpophalangeal joints passively in some cases of flexor weakness. As this cuff is used, the figure eight elbow strap should be applied to prevent distal migration of the brace (Fig. 7). Other traction devices have also been designed to improve flexion in presence of adequate extension.

Fig. 7: *The flexion cuff may be used intermittently to assist flexion movements. Proper use of bracing is essential to insure an adequate range of motion.*

*Pope Brace Co., Greenwood, South Carolina

The extension portion of the brace is usually worn at night only, starting on the fourth postoperative week for another 3 weeks. In a few cases where there is a persistent extensor lag or a tendency for flexion contracture or deviation of the digits, continued part-time support by the use of the brace must be prescribed for several more weeks or even months. The patient should follow a continued exercise and stretching program for 3 months postoperatively to maintain the movement obtained in the earlier phase. After this time the final range of motion will have been established.

This most important rehabilitation program has been thoroughly described in previous publications and should be faithfully followed to obtain the ideal result[42](Fig. 8).

Fig. 8A: *Preoperative radiogram showing severe and typical deformities in a rheumatoid hand.*

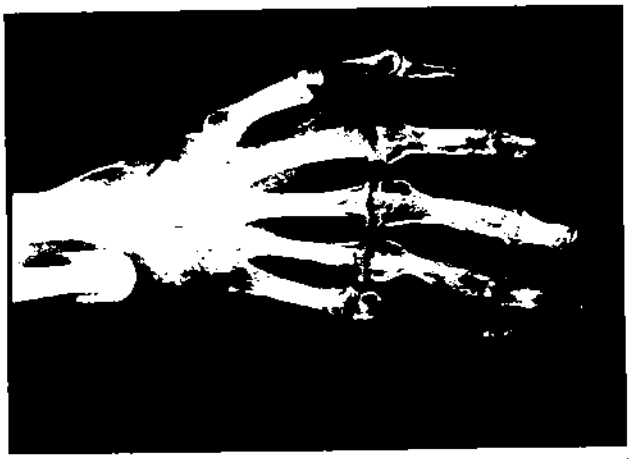


Fig. 8B: *Radiogram 4 years after implant arthroplasty of all MP joints and of the distal radioulnar joint. Note the excellent correction of deformities and acceptance of the implants.*

The Proximal Interphalangeal Joint

Indications

Rheumatoid, degenerative or post-traumatic disabilities with:

1. Destroyed or subluxated joints.
2. Stiffened joints in which a soft tissue release alone would be adequate.

Surgical Technique

Technique for a stiff PIP joint without collapse deformity (Fig. 9).

Fig. 9 A-F: Technique for Implant Arthroplasty in a Stiff Nondeformed Arthritic Joint: A: *The longitudinal "S" shaped incision is made over the dorsum of the PIP joint.* **B:** *The extensor mechanism is incised longitudinally and proximally from the base of the middle phalanx. Care is taken to maintain tendon insertion on the base of the middle phalanx.* **C:** *The split extensor tendon is retracted laterally and the head of the proximal phalanx is exposed. Using an air drill the head of the proximal phalanx is sectioned through the neck and removed. If the joint is tightly contracted, the bone may have to be removed piecemeal before the tendon can be safely retracted.* **D:** *To prepare the intramedullary canal a special bur with a smooth tip extension is used to avoid perforation through the cortex of the phalanx.* **E:** *A blue colored sizing unit is used to determine correct implant size. Sizes 0 through 4 are usually used for PIP arthroplasty. Implant in place with the finger in extension. Proper bone removal and soft tissue release must be done so that on extension there is enough space without impingement on the midsection of the implant.* **F:** *Using an inverted knot technique the extensor mechanism is reapproximated with 3-0 Dacron sutures. Arthroplasty for boutonniere and swan-neck deformities usually requires an individualized tendon reconstruction.*

Incision

A gentle "S" or preferrably "C" shaped incision is made over the dorsum of the joint so that the skin suture line does not lie directly over the tendon repair. In the little and index fingers, the incision is placed away from the presenting surface. The dorsal veins are respected. If associated flexor tendon surgery is also indicated, a mid-lateral incision or palmar incision is used. This allows accessibility to both the joint and the tendon.

Exposure

The extensor mechanism is exposed by sharp and blunt dissection avoiding injury to its surface. The central tendon is identified and incised longitudinally in a proximal fashion from its insertion at the base of the middle phalanx through the distal two-thirds of the proximal phalanx. In flexible deformities of the PIP joint, the extensor mechanism can be gently dislocated palmarward as the joint is flexed. The collateral ligaments are left intact when possible. If they are incised for joint exposure, they should be reattached. The insertion of each half of the central tendon into the middle phalanx should not be disturbed. However, in hypertrophic osteoarthritic joints, it may be necessary to section this attachment of the central tendon to excise bony spurs. The tendon is later reattached to the bone with a suture passed through small drill holes (1mm) made in the base of the middle phalanx. If the joint is contracted, the extensor mechanism cannot be readily dislocated and therefore the head of the proximal phalanx may be excised first by cutting it transversely at the neck with an air drill and then removing it piecemeal or it can be removed with the burring tool of the air drill.

Joint Release

Adequate release of the joint is essential for good results. If the joint is severely contracted, it may be released by removing bone from the proximal and middle phalanges. If this is inadequate, the palmar plate and collateral ligaments may be incised at their proximal insertion. However, the collateral ligaments should be reattached in a lengthened position passing the sutures through small drill holes (1mm) made in the dorsal aspect of the neck of the proximal phalanx (Fig. 10).

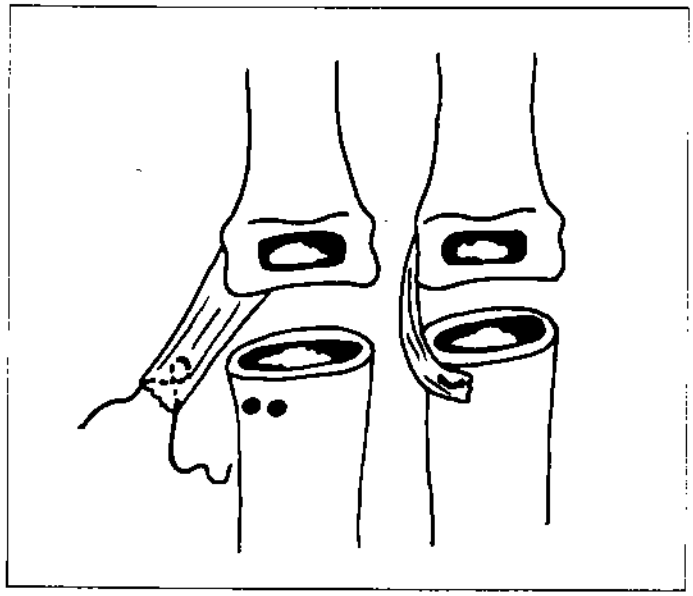


Fig. 10: *Technique for reattachment of the collateral ligament of the proximal interphalangeal joint to the neck of the proximal phalanx passing 4-0 Dacron sutures through two one millimeter drill holes made in the dorsal aspect of the neck of the proximal phalanx.*

A radial collateral ligament can be reconstructed in certain cases requiring correction of ulnar deviation or cases of increased radial instability as in the index finger. A distally based flap made of the radial collateral and accessory collateral ligaments is prepared. The flap is attached through a small drill hole to the radial aspect of the neck of the proximal phalanx, using nonabsorbable sutures. This procedure seems to limit flexion of the proximal interphalangeal joint slightly but can be important in the cases mentioned earlier.

Bone Preparation

After resecting the head of the proximal phalanx at the metaphyseal flare with a rongeur or on a side cutting bur, the intramedullary canal is prepared to receive the implant stem. It's first penetrated with a thin broach, then reamed into a rectangular shape to accept the implant stem with an air drill and smooth leader point bur. The intramedullary canal of the middle phalanx is prepared in a similar fashion. The base of the middle phalanx is usually not resected except in cases of severe joint contracture as mentioned above; osteophytes are trimmed if present.

Implant Section and Insertion

Using the sizing set, the largest acceptable implant is selected (sizes 0 through 4 and most often size 1). The midsection of the implant should seat well against the adjacent surfaces of the phalanges. With the joint in extension, there must be no impingement of the implant midsection by the bone ends; if this fit is not ideal there should be additional bone resection and/or soft tissue release. The bone ends should be smoothened to avoid sharp edges that could cut into the implant.

Prior to the insertion of the selected implant, the required sutures are placed in the drill holes made in the proximal phalanx for reconstruction of the collateral ligament system and, in the base of the middle phalanx for reconstruction of the central tendon.

Following wound irrigation with saline, the implant is inserted in a similar fashion as that described for the metacarpophalangeal joint.

Sizing Set

A reuseable sizing set containing one of each size implant is available to assist proper size determination during surgery. Numerically marked and blue in color for easy identification, the sizing set is supplied non-sterile and is not suitable for implantation. For use, follow instructions under section, "To Clean and Resterilize."

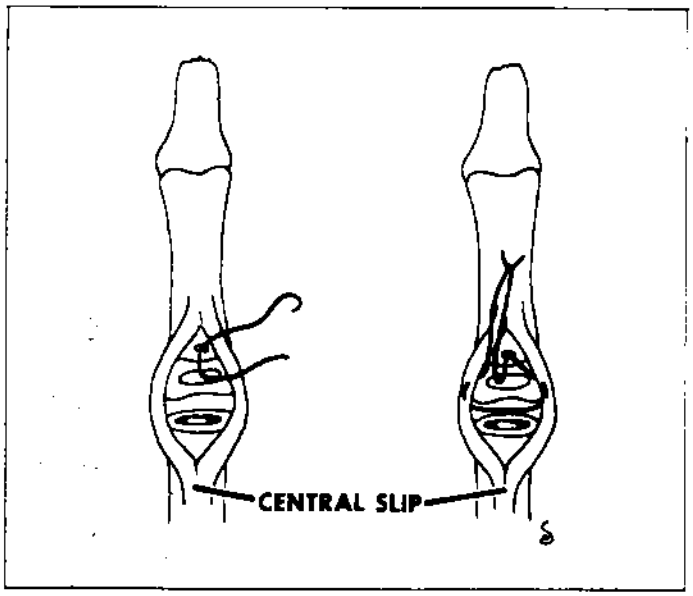


Fig. 11: *Technique for repair and reattachment of the central slip to the middle phalanx passing a 3-0 Dacron suture through a one millimeter drill hole made in the dorsal aspect of the middle phalanx.*

Closure

If sectioned, the collateral ligament is firmly reattached to the proximal phalanx using 4-0 Dacron sutures previously passed through small drill holes in the bone. The radial collateral ligament reconstruction, if used, is similarly secured to the proximal phalanx. The tension of the repair must be sufficient to obtain good lateral stability and alignment and to allow passive motion of the joint from full extension to 90 degrees of flexion.

The halves of the incised central tendon are drawn together and sutured to the base of the middle phalanx with a 3-0 Dacron suture previously passed through a drill hole in the bone (Fig. 11). The suture to the bone of the central tendon is especially important if the central tendon has been elongated, ruptured or divided. Wherever possible, tendons or ligaments must be sutured to bone to obtain a firm fixation.

At the end of the procedure, full passive range of motion should be present and slight traction on the joint should show an adequate joint space. The most common causes of failure of extension, are, inadequate bone removal and soft tissue release, failure to obtain proper tension of the central slip and scar formation.

The skin is reapproximated with 5-0 Nylon and small silicone rubber strips are used as drains. The hand dressing is applied similarly as that described for the metacarpophalangeal joint arthroplasty.

Extensor Mechanism in Collapse Deformities

Special consideration must be given to the extensor mechanism in collapse deformities of the digits. Adjustment of the unbalanced tension of the central and lateral tendons is essential to the correction of these deformities in resection implant arthroplasty of the proximal interphalangeal joints. Simply stated, in swan-neck deformity the central tendon is relatively tight as compared to the tension of the lateral tendons, and in the boutonniere deformity the central tendon is relatively loose as compared to the tension of the lateral tendons. Readjustment of the tension of these structures is important to avoid recurrence of these collapse deformities.

Swan-Neck Deformity

In swan-neck deformity, flexor synovitis is treated first and the hyperextension of the proximal interphalangeal joint is corrected through readjustment of the joint system. At least 10 degrees of flexion contracture of the proximal interphalangeal joint should be obtained and associated deformities of the contiguous joints should be corrected. In mild flexible deformity in weak hands, dermadesis of the proximal interphalangeal joint is indicated. In severe cases of swan-neck deformity, a fusion of the joint is preferred.

The technique for implant arthroplasty in a swan-neck deformity differs slightly from that for a nondeformed stiff proximal interphalangeal joint. The central tendon is separated from the dorsally displaced lateral tendons, which are allowed to relocate palmarward. The central tendon is step-cut transversely and dissected proximally, thereby lengthening it (Fig. 12). After insertion of the implant, the cut ends of the central tendon are reapproximated with interrupted sutures, with the knots buried. Occasionally, if the distal joint is severely flexed, it is fixed in a position of extension by an intramedullary Kirschner wire to increase the flex-

ion force on the proximal interphalangeal joint during the early postoperative period.

A modification of the Littler procedure for the treatment of the swan-neck deformity can also be used in some moderately involved cases.

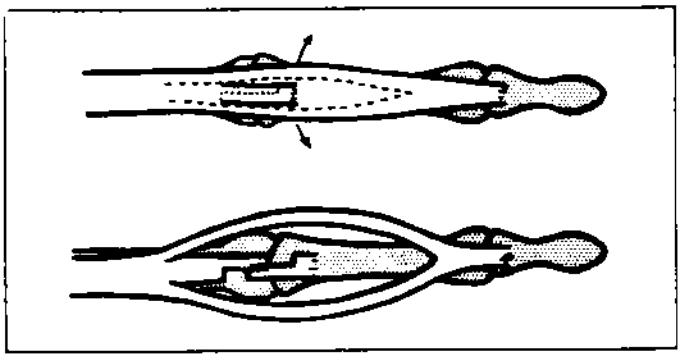


Fig. 12: *Technique for a stiff swan-neck deformity. The central tendon is separated from the dorsally displaced lateral tendons, which are allowed to relocate palmarward. The central tendon is step-cut transversely and dissected proximally, thereby lengthening it. After insertion of the implant, the cut ends of the central tendon are reapproximated with interrupted sutures, with the knots buried.*

Boutonniere Deformity

In a boutonniere deformity caused by rheumatoid arthritis, the central tendon has usually been relatively lengthened and the lateral tendons are usually displaced palmarward and the connecting fibers stretched out. Implant arthroplasty must be accompanied by reconstruction of the extensor mechanism. Two methods of reconstruction have been used. In one method the attachment of the central tendon to the base of the middle phalanx is repaired by suturing the stretched-out central tendon to the bone by means of a one millimeter drill hole in the base of the middle phalanx (Fig. 13A). The lateral tendons are released and relocated dorsally by suturing their connecting fibers or overlapping the fibers if they are redundant. In the alternative technique (Matev technique), a lateral tendon, usually the one on the radial side, is used to reconstruct the central tendon, attaching it to the insertion of the central tendon. The other lateral tendon may be reattached in a lengthened position distally (Fig. 13-B). Release of the lateral tendons may be required to correct hyperextension deformities of the distal joint if passive flexion cannot be accomplished after reconstruction. This release is usually done proximal to the insertion of the fibers of Landsmeer's ligament by sectioning the lateral tendons over the middle phalanx.

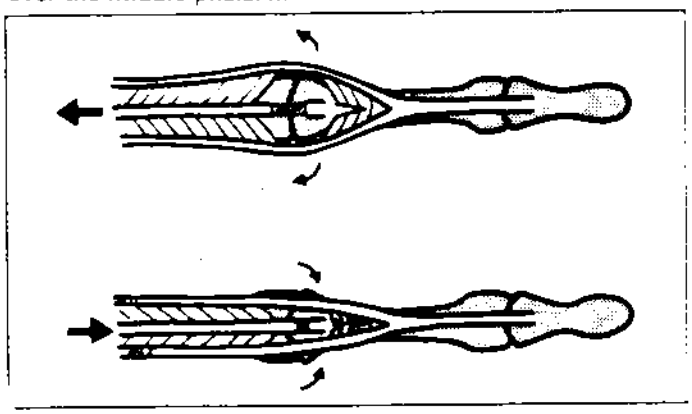


Fig. 13A: *The preferred method for repair of the extensor mechanism in boutonniere deformity. The lengthened central tendon is advanced and the lateral tendons are released and relocated dorsally by suturing their connecting fibers.*

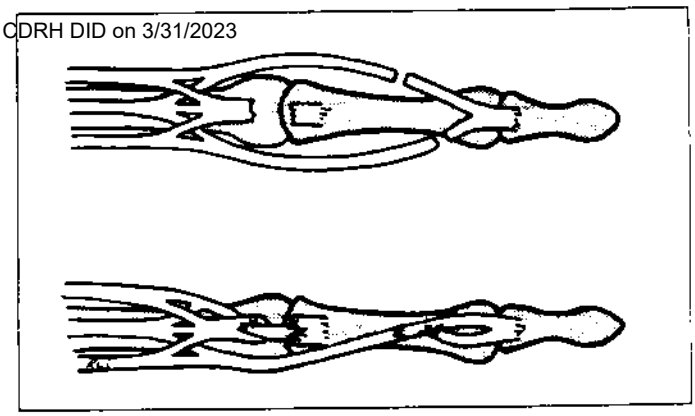


Fig. 13B: *Matev's method of repair of the extensor mechanism in a boutonniere deformity. A lateral tendon, usually on the radial side, is used to reconstruct the central tendon. The other lateral tendon is reattached in a relatively lengthened position distally.*

Post-Operative Care

The type of postoperative care depends on the situation presented.

Stiff Proximal Interphalangeal Joint

Active flexion/extension movements are started 3 to 5 days after surgery. The ideal range of motion would be full extension to 70 degrees of flexion. A small taped on padded aluminum splint to hold the digit in extension is worn mainly at night for 3 to 6 weeks after surgery depending on the degree of extensor lag present. The splint may also be applied slightly to the ulnar or radial side of the dorsum of the digit to correct any associated angulatory deformity. The exercises are performed with a variety of devices always taking care to support the metacarpophalangeal joint in extension. If necessary, after 3 weeks, passive flexion devices such as a flexor cuff or rubber band traction from a special wrist strap to finger nail hooks can be useful.

Swan-Neck Deformity

It is important in any of these tendon reconstructions for swan-neck deformities to obtain a permanent flexion contracture of the PIP joint of at least 10 degrees. For approximately 10 days the proximal interphalangeal joint is held in 10 to 20 degrees of flexion with a small, taped-on aluminum splint. Active movements are then begun and encouraged, and flexion exercises are performed while the proximal phalanx is supported. The flexor splint is still worn on a part time basis. After 2 weeks, gentle passive flexion exercises of the proximal interphalangeal joint are started if necessary. Hyperextension of the reconstructed joints must be avoided in the first three to six weeks so that a slight flexion contracture will develop and correction of the hyperextension deformity will be maintained.

Boutonniere Deformity

The proximal interphalangeal joint is maintained in extension for 3 to 6 weeks with a dorsal taped on padded aluminum splint. The distal joint should be allowed to flex freely. Active flexion/extension exercises are started from 10 to 14 days after surgery in alternation with the use of the extension splint at night; night splinting should be continued until the joint is stable and this may require 10 weeks.

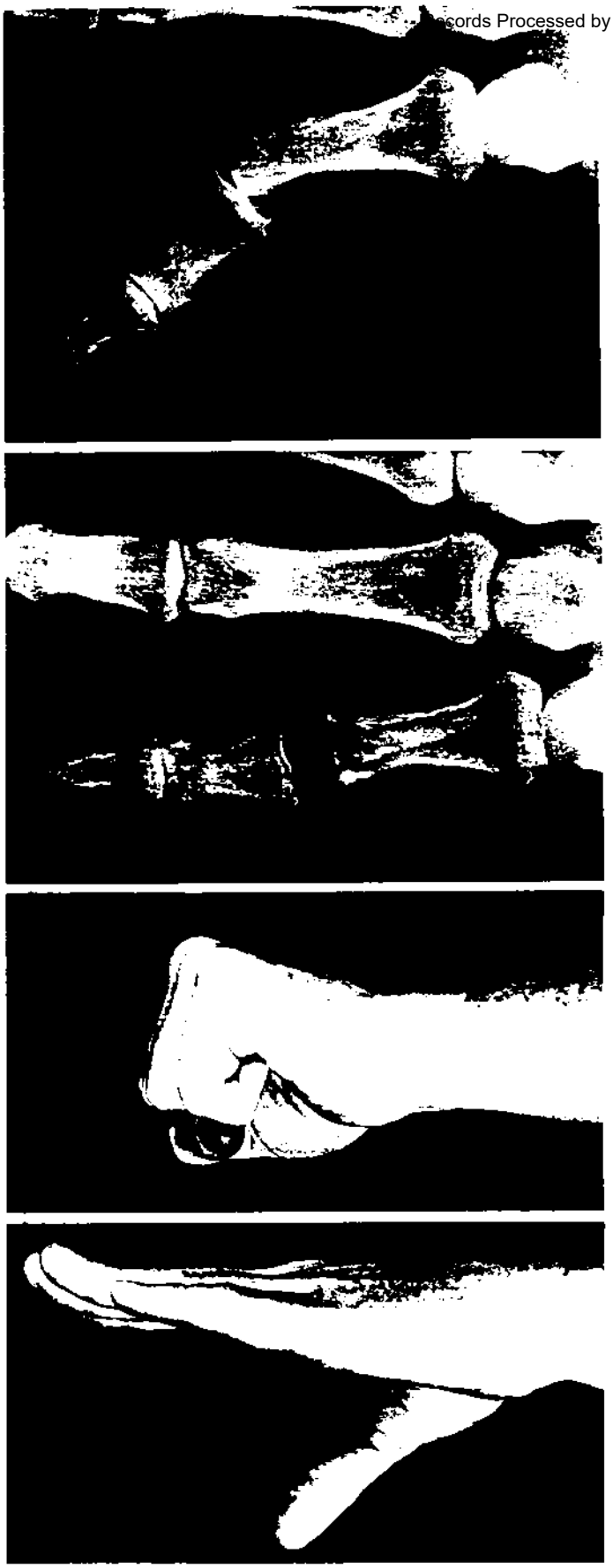


Fig. 14A: *Long-standing dislocation of proximal interphalangeal joint of little finger in young athletic man.* B: *Roentgenogram showing excellent position and tolerance of implant 3 years after surgery.* C and D: *Patient recovered full use of hand with excellent flexion and extension.*

The Distal Interphalangeal Joint

Indications

Degenerative or posttraumatic disabilities when preservation of joint motion is desired and, the following conditions are present:

1. Destroyed and painful joints
2. Stiffened joints in which soft tissue release alone would be inadequate
3. There should be adequate bone, ligamentous integrity, a potential tendon system and adequate skin and neurovascular system.

Surgical Technique

A "Y" shaped incision is made over the distal phalanx approximately 3mm from the base of the nail (Fig. 15-A). The skin flaps are carefully dissected as to avoid injury to the underlying extensor tendon and the dorsal nerves and vessels. The extensor tendon is incised transversely one centimeter proximal to the distal interphalangeal joint and carefully elevated from the bone; its distal insertion on the distal phalanx is preserved (Fig. 15-B). The dorsal capsule is incised transversely and the joint surfaces are exposed by sharply flexing the distal phalanx. In some cases, the dorsal half of the collateral ligaments are incised to facilitate the exposure: however, these ligaments are always retained to preserve lateral stability. With a side cutting or a rounded bur of the air drill, enough bone is removed from the base of the distal phalanx and the head of the middle phalanx to obtain a sufficient joint space to accomodate the midsection of the implant without bony impingement as the joint is fully extended. Lateral and palmar osteophytes or bony irregularities are carefully smoothed with a rounded bur. The intramedullary canals are penetrated first with a thin broach; their preparation in a rectangular shape to accept the implant stems is carefully completed with the special leader point bur of the air drill. The correct size implant, usually sizes 0, 1 or 2, is then selected. The cut bone ends must be smoothened.

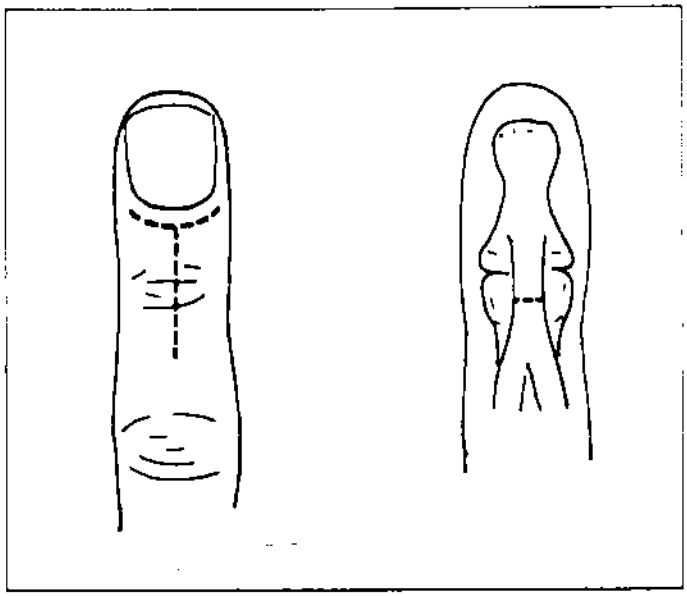


Fig. 15: *Technique for implant arthroplasty of the distal interphalangeal joint:*
Fig. 15A: *A "Y" shaped incision is made 3 mm. from the base of the nail and the skin flaps are elevated preserving the underlying tendon and the dorsal nerves and veins.*
Fig. 15B: *the extensor tendon is incised transversely one centimer proximal to the distal interphalangeal joint and carefully elevated from the bone.*

Following irrigation of the wound with saline, the proximal implant stem is inserted in the intramedullary canal of the middle phalanx with a no touch technique and atraumatic instruments. As the joint is flexed, and slightly distracted, the distal stem is fitted in the distal phalanx. Perfect position of the implant is assured by gently pushing it in position with a rounded instrument as the joint is in full extension. The extensor tendon is then repaired with a Bunnel type "figure of 8" suture using 4-0 Dacron sutures inverting the knots. A few additional 5-0 Dexon sutures are placed to complete the reapproximation of the tendon ends. This tendon is easily damaged and must be handled with care throughout the procedure. The skin is meticulously reapproximated with interrupted 6-0 nylon sutures. Silicone strip drains are inserted subcutaneously. Following application of a non-adherent dressing, the distal joint is maintained in full extension with a dorsal padded aluminum splint. Occasionally a small 0.035" Kirschner wire can be carefully introduced through the distal pulp into the flexor tendon sheath to maintain full extension of the distal joint during the first 2 to 3 days of postoperative swelling: the proximal interphalangeal joint is not transgressed by this fixation.

The postoperative care is similar to that of a mallet finger. Using a dorsal half inch padded taped on aluminum splint, the distal joint and the proximal interphalangeal joint are maintained in full extension for the first 2 weeks. Following this, the distal joint only is immobilized in extension and the proximal interphalangeal joint is allowed to flex freely. After this time, use of the digit is resumed. Active extension and flexion exercises are prescribed. Rough activity is not recommended for these or the other finger joint arthroplasties.

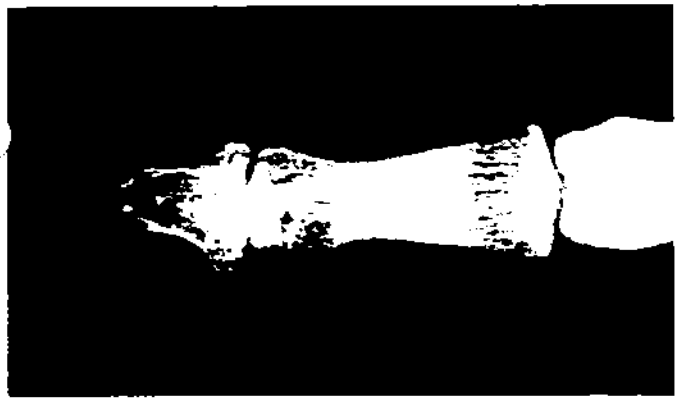


Fig. 16A: *Post traumatic painful arthritis of distal interphalangeal joint of 3rd digit of a 35 year old man who desired a surgical procedure which would provide movement as well as pain relief.*

Fig. 16B: *Post-operative silicone flexible hinged implant resection arthroplasty of distal interphalangeal joint. Patient has a stable, painfree, functional joint with range of motion of 5° to 40°. This method offers an alternative to arthrodesis in selected cases.*

To Clean and Resterilize

The SILASTIC® Finger Joint Implant H.P. (Swanson Design) has been sterilized.

However in the event that the implant is contaminated prior to use and resterilization is indicated, the following sequential steps to clean and resterilize are recommended:

1. Scrub the implant thoroughly with a clean, soft-bristled brush in a hot water-soap solution to remove possible surface contaminants. Use a non-oily mild soap such as Ivory Flakes or Ivory bar soap. Do not use synthetic detergents or oil based soaps, as these soaps may be absorbed and subsequently leach out to cause a tissue reaction.
2. Rinse thoroughly with distilled water.
3. Wrap in a lint-free cloth or place on a clean open tray, and autoclave by one of the following methods:
   a. High speed instrument sterilizer - 10 minutes at 270°F (132°C).
   b. Standard gravity sterilizer - 30 minutes at 250°F (121°C).
   c. Prevacuum high temperature sterilizer - either 10 minutes at 270°F (132°C), or 30 minutes at 250°F (121°C).

Caution

Evidence suggests that repeated sterilization may affect the physical characteristics of the implant. Accordingly, resterilization in excess of three times is contraindicated.

The foregoing statement *does not* apply to the blue sizers where ultimate physical properties are medically irrelevant.

NOTE: Gas sterilization is not recommended for silicone rubber elastomers. Should this be the only available method of sterilization, it is essential to avoid inserting these implants within 10 days of the gas sterilization: otherwise severe tissue reaction might ensue from the vivo release of ethylene oxide.

Caution

Federal (United States) law limits this device to sale by or on the order of a physician.

A Clinical Case History

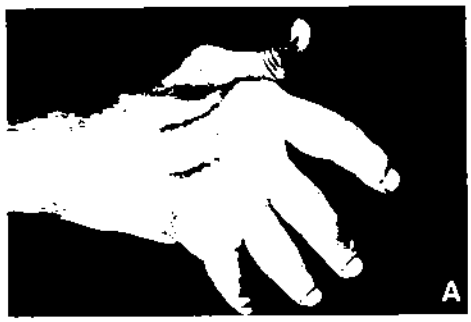
This 58 year old patient with an eight year history of Rheumatoid Arthritis had severe loss of function of the hands. He had marked ulnar drift and subluxation of the MP joints with extensor tendon subluxation and also Boutonniere deformity of the thumb. The patient had implant resection arthroplasty of the MP joints of the fingers and thumb. Postoperatively he was pain free and very pleased with his functional and cosmetic result. He was able to return to all his previous activities including playing the violin, which he had not been able to do since the onset of his disease.

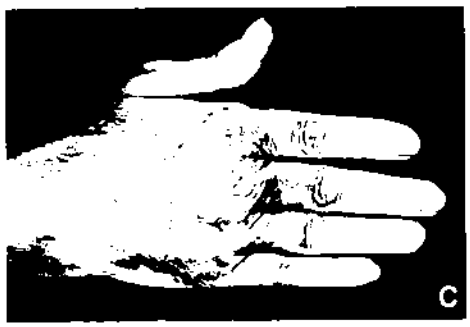
Fig: A, B: *Preoperative clinical views.*

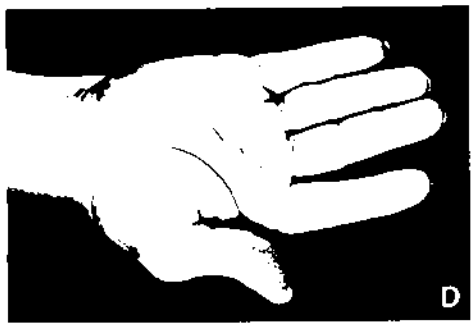
Fig: C, D, E, F; *Postoperative clinical views. Note the good correction of the deformities and the excellent range of flexion and extension of the digits.*

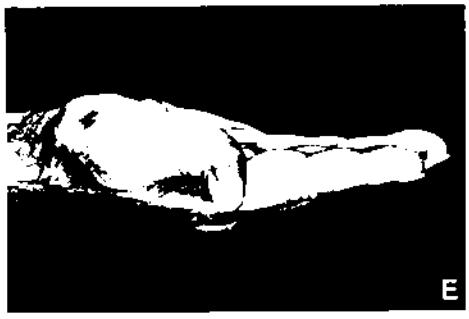
Fig: G; *Preoperative roentgenogram.*

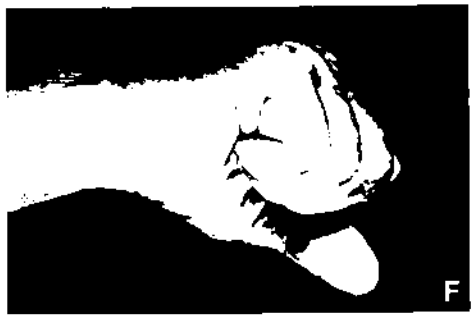
Fig: H; *Postoperative roentgenogram showing correction of the deformities and good tolerance of the implants.*











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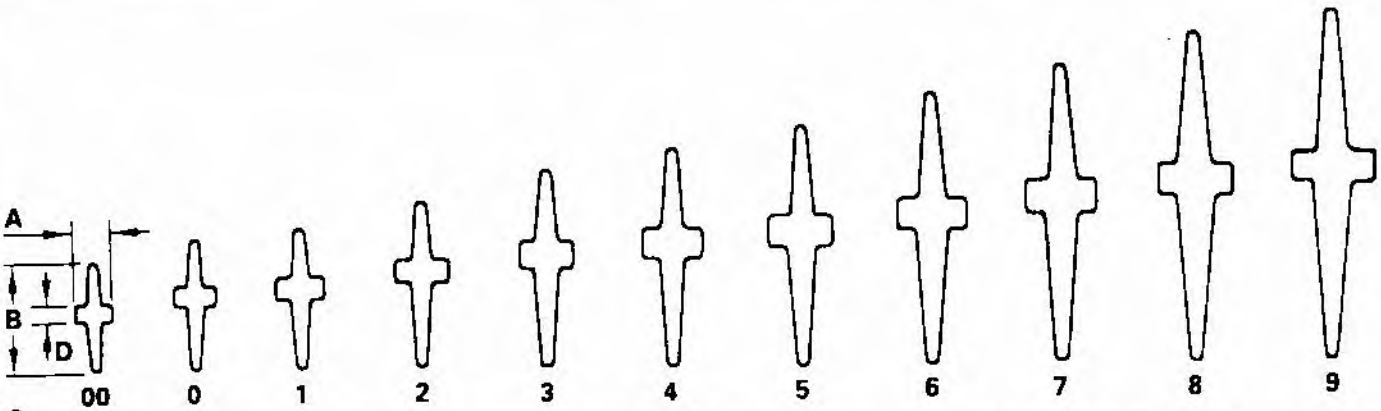
Typical Dimensions



	00	0	1	2	3	4	5	6	7	8	9
A	.31 (7.9)	.37 (9.4)	.45 (11.4)	.48 (12.2)	.51 (13.0)	.54 (13.7)	.58 (14.7)	.61 (15.5)	.64 (16.3)	.68 (17.3)	.72 (18.3)
B	1.00 (25.4)	1.16 (29.6)	1.25 (31.8)	1.45 (36.8)	1.70 (43.2)	1.94 (49.3)	2.19 (55.6)	2.44 (62.0)	2.68 (68.1)	2.93 (74.4)	3.17 (80.5)
C	.13 (3.3)	.16 (4.1)	.19 (4.8)	.22 (5.6)	.25 (6.4)	.28 (7.1)	.32 (8.1)	.33 (8.4)	.36 (9.1)	.37 (9.4)	.39 (9.9)
D	.12 (3.0)	.14 (3.6)	.18 (4.6)	.20 (5.1)	.20 (5.1)	.215 (5.46)	.22 (5.6)	.23 (5.8)	.25 (6.4)	.26 (6.6)	.27 (6.9)

Dimensions—Inches
(Millimeters)

How Supplied

The SILASTIC® Finger Joint Implant H.P. (Swanson Design) has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
1 box	One each, Size 00	1470-0020
1 box	One each, Size 0	1470-0010
1 box	One each, Size 1	1470-0001
1 box	One each, Size 2	1470-0002
1 box	One each, Size 3	1470-0003
1 box	One each, Size 4	1470-0004
1 box	One each, Size 5	1470-0005
1 box	One each, Size 6	1470-0006
1 box	One each, Size 7	1470-0007
1 box	One each, Size 8	1470-0008
1 box	One each, Size 9	1470-0009
1 sizing set	One each, Sizes 00, 0, 1, 2, 3, 4, 5, 6, 7, 8, 9. Numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	1480-0000

DOW CORNING
DOW CORNING WRIGHT

P.O. Box 100 Arlington, TN 38002 901-867-9971

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Appendix D
Drawing

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(b)(4) Schematics

of the Freedom of Information and Privacy Act

Appendix E

Material properties and testing, previously approved under 510k submission

Material testing performed includes:

- Hemolysis test
- Physico Chemical
- MEM Elution
- Inhibition of Cell Growth
- Limulus Inhibition test
- USP Toxicity Class VI-121 deg C
  - Systemic Injection
  - Type B, Intracutaneous::Saline
  - Type B, Intracutaneous::EtOH
  - Type B, Intracutaneous::Oil
  - Type B, Intracutaneous::PEG
- Implantation test USP XX
  - Gross and Macroscopic
- Flex testing
- Abrasion testing
- Shear testing

Material Properties

Property	Test Method	Range
Tensile Strength	ASTM D412	1200-1500 psi
Ultimate Elongation	ASTM D412	650-950
Tear Propagation Strength, Die B	ASTM 642	190-300
Durometer, Shore A	ASTM 2240	45-55.5

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ACCELERATED FLEX TESTING OF MDX-4-4515 AND SUTTER PEHT-40 SILICONE ELASTOMERS

By: Jim Christensen
Sutter Biomedical
August, 1981

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ABRASION TESTING OF

MDX-4-4515, DOW HP, AND SUTTER PEHT-40

SILICONE ELASTOMERS

By: Jim Christensen
Sutter Biomedical
August, 1981

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SHEAR TESTING OF

MDX-4-4515, DOW HP, AND SUTTER PEHT-40

SILICONE ELASTOMERS

By: Jim Christensen
Sutter Biomedical
August, 1981

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Withheld pursuant to exemption

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of the Freedom of Information and Privacy Act

K931588

DEPARTMENT OF HEALTH & HUMAN SERVICES

REDACTED BY MFR

Food and Drug Administration
Rockville MD 20857

2-23-99

IMPORTANT PREDISCLOSURE NOTIFICATION (PDN)
REPLY REQUIRED WITHIN FIVE DAYS OF RECEIPT

Attn: Manager, Regulatory Affairs
9425 Chesapeake Dr.
San Diego, CA 92123
619-569-8148

In reply to: F9741315

The Food and Drug Administration (FDA) has received a Freedom of Information request for a copy of your Premarket Notification (510(k)) submission(s) K931588, k943354

Enclosed is a copy of the letter of request and a copy of your 510(k) submission(s) in order to provide you with opportunity to review the records prior to their release. You may indicate whether any information should not be released because it is exempt from disclosure under the Freedom of Information Act. Please see Attachment A for the types of information that may be deleted from your records prior to disclosure. This Predisclosure Notification (PDN) is required by Executive Order 12600 (June 23, 1987) and by FDA's Public Information Regulation (21 CFR 20.61). A claim of confidentiality must be justified and is subject to the False Reports to Government Act (18 USC 1001).

The FDA Regulation provides you with **5 working days after you receive this letter in which to respond**. If we do not receive a response from you, we will release the records following review of the 510(k)(s) by this office. If **you need additional time to review the 510(k)(s), please endorse below and fax response to (301) 594-4792 Mail any written response to:**

Freedom of Information Staff, HFZ-82
Center for Devices and Radiological Health, FDA
2094 Gaither Road
Rockville, Maryland 20850

If FDA disagrees with any statement you make relating to deletions of confidential material we will notify you by separate letter. You will then have 5 days from receipt of that letter to file suit in court to prevent FDA from releasing the records.. As the FDA Regulation requires, we are also notifying the individual who submitted the request for your records that you have received this notice.

X **I HAVE RECEIVED THE PDN AS NOTED ABOVE AND I WISH TO REQUEST AN EXTENSION NOT TO EXCEED TWO WEEKS. A REDACTED COPY OF THE 510(k) SUBMISSION(s) WILL BE MAILED TO YOUR OFFICE NO LATER THAN** 3/3/99.

____ **I HAVE RECEIVED THE PDN AS NOTED ABOVE AND HAVE DETERMINED THERE IS NO TRADE SECRET OR CONFIDENTIAL COMMERCIAL INFORMATION IN THE SUBMISSION. THE 510(k) SUBMISSION MAY BE RELEASED IN ITS ENTIRETY.**

SIGNED [signature]

Sincerely

[signature]
Freedom of Information Staff
Office of Systems Management
Center for Devices and Radiological Health
Food and Drug Administration

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 10 1994

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Ms. Louise M. Focht
Director Quality Assurance
Sutter Corporation
9425 Chesapeake Drive
San Diego, California 92123
619-627-3768

Re: K931588
Sutter Proximal Interphalangeal Joint
Regulatory Class: II
Dated: March 29, 1993
Received: March 31, 1993

Dear Ms. Focht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the

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labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

3

DO NOT REMOVE THIS ROUTE SLIP!!!!

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K-93-1588

4/16/93

PJW

FROM: SUTTER CORPORATION ATTN: LOUISE M FOCHT 9425 CHESAPEAK DRIVE SAN DIEGO, CA 92123 SHORT NAME: SUTTER	LETTER DATE 03/29/93	LOGIN DATE 03/31/93	DUE DATE 06/29/93
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K931588
	PHONE NO: 619-569-8148 ESTABLISHMENT NO: 2028601		
TO: ODE/DMC	CONT. CONF.: ? STATUS : R REV PANEL : OR PAN/PROD CODE(S): OR/ / /		

SUBJECT:
SUTTER PROXIMAL INTERPHALANGEAL JOINT

DECISION: DECISION DATE: / / MAR 10 1994	RQST INFO DATE: / / DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: / / DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /

4

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Mark N Melkerson

Subject 510(k) NOTIFICATION K931588

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

X (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

_____ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☒

This 510(k) contains: (check appropriate box(es))

☒ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

✓ Confidentiality for 90 days.

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

KYJ class II

Additional Product Code(s) w/Panel (optional):

_____

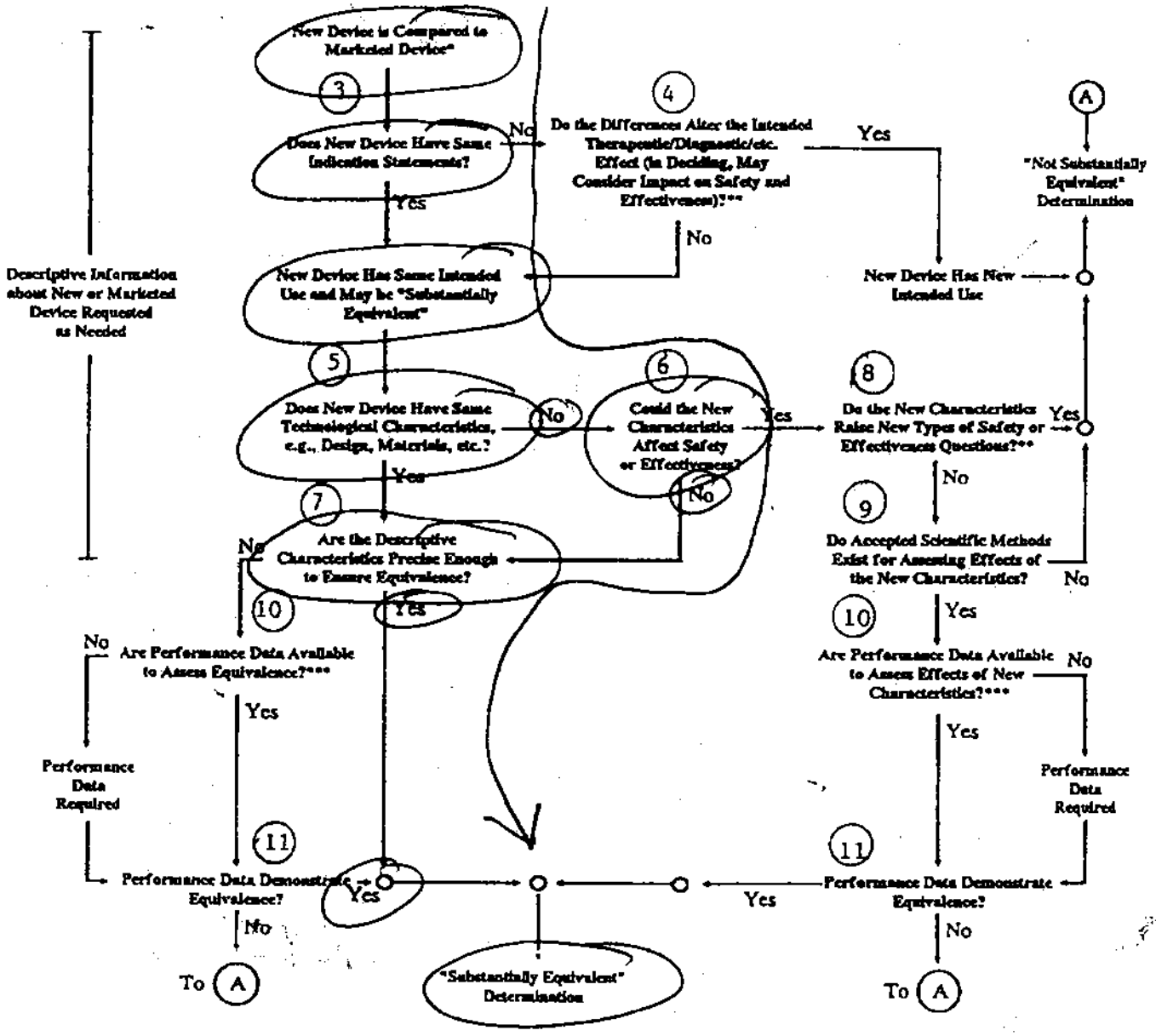
REVIEW: Daniel A. McGeary (BRANCH CHIEF) — ORTH BRANCH CODE — 3/10/94 (DATE)

FINAL REVIEW: for (DIVISION DIRECTOR) — 3/10/94 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

K 931588 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: MXM DIVISION/BRANCH: DGRD/ORDB

TRADE NAME: SUTTER PIP JT. COMMON NAME: CONSTRAINED FINGER, POLYMER

PRODUCT TO WHICH COMPARED: K802342, K870200, PROXIMENDMENTS
(510(k) NUMBER IF KNOWN) SWANSON SILASTIC FINGER

	YES	NO	
1. IS PRODUCT A DEVICE?	X		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	X		- IF NO STOP
3. SAME INDICATION STATEMENT?	X		- IF YES GO TO 5
(4.) DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?		X	- IF YES GO TO 7
(6.) COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	X		- IF NO GO TO 10 - IF YES STOP - SE
(8.) NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10. PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DATA
(11.) DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

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MEMO RECORD
FROM: M.N. MELKERSON, Engineer
TO: File

DATE: 3/10/94 MNM ~~3/7/94~~
Center/Office: CDRH/ODE
Division/Branch: DGRD/ORDB

Document Number: K931588
Common Name: Proximal InterPhalangeal (PIP) Joint Prosthesis, Finger & Toe
Trade Name: Sutter, Proximal Interphalangeal Joint Prosthesis
Classifications: 1) 21 CFR 888.3230, Finger Jt. Polymer Constrained Prosthesis

Class: II
Product Codes: KYJ: Finger
Products To Which Compared:

Preamendments Dow Corning Wright (Wright Medical), Swanson Silastic Jt. Spacers for metacarpal phalangeal (MCP), proximal interphalangeal (PIP), and distal interphalangeal (DIP) joints of fingers

K802342 and K870200, Sutter, Medical grade silicone (PEHT 400 series) Jt. Spacers for MCP and PIP joints of fingers

Contact Person: Louise M. Focht, Director of Quality Assurance (619) 569-8148, ext. 2213

Summary:

This 510(k) original dated 3/29/93, received on 3/31/93 and assigned on 3/4/94 was reviewed for a SE or NSE recommendation.

Recommendation:

I recommend that this 510(k) be found SE.

Basis of Recommendation:

INTENDED USE: Intended for total joint arthroplasty of the PIP joint of fingers for clinical indications of Rheumatoid arthritis (RA), Osteoarthritis (OA), Ankylosed joints or those with limited range of motion which have not responded to conservative treatment, Nonfunctional joint due to inadequate body alignment and joint space which cannot be restored by soft tissue reconstruction alone, and Destroyed articular surfaces.

DEVICE DESCRIPTION:

A constrained, flexible hinge design, joint space made out of a medical grade silicone elastomer (PEHT 400 series) with or without medical grade polyester mesh or fibers for reinforcement, sutures for temporarily securing the implant, and polyester mesh or velour

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surfaces to provide stabilization through tissue ingrowth. These design features are identical to the predicate Sutter MCP. The PIP implants will be offered in 6 sizes (i.e., 10, 20, 30, 40, 50, and 60).

Is the device life-supporting or life sustaining? no
Is the device implanted (short-term or long-term)? long-term
Does the device design use software? no
Is the device sterile? Yes
Is the device for single use? Yes
Is the device for home use or prescription use? Restricted to use by physicians.
Does the device contain drug or biological product as a component? - no
Is this device a kit? no

MATERIALS:

[redacted]

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION"

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS STARTING ON PAGE 1 - NOTE: QUESTIONS WHICH ARE NOT APPLICABLE ARE FOLLOWED BY "N/A".

1. IF THE ANSWER TO QUESTION 1 IS NO, EXPLAIN WHY THE PRODUCT IS NOT A DEVICE. - Product is a device.

2. IF THE ANSWER TO QUESTION 2 IS NO, EXPLAIN WHY THE DEVICE IS NOT SUBJECT TO 510(K). - Is subject to 510(k).

3. IF THE ANSWER TO QUESTION 3 IS NO, EXPLAIN HOW THE NEW INDICATION DIFFERS FROM THE PREDICATE DEVICE'S INDICATION. - Same intended use and clinical indications.

4. IF THE ANSWER TO QUESTION 4 IS YES OR NO, EXPLAIN WHY THERE IS/IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE. - N/A

5. IF THE ANSWER TO QUESTION 5 IS NO, DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS. - [redacted]

6. IF THE ANSWER TO QUESTION 6 IS YES OR NO, EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT SAFETY OR EFFECTIVENESS. - No, the modifications to the dimensions and

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stem are slight (i.e., less of taper, thus greater cross-sectional areas) and should not adverse effect the mechanical properties of the device. The modifications did not change ratios of dimensions.

7. IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH. - Yes, the sponsor supplied drawings with dimensions allowing for the comparison to predicates dimensions and geometry.

8. IF THE ANSWER TO QUESTION 8 IS YES OR NO, EXPLAIN THE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW. - N/A

9. IF THE ANSWER TO QUESTION 9 IS NO, EXPLAIN WHY THE EXISTING SCIENTIFIC METHODS CAN NOT BE USED. - N/A

10. IF THE ANSWER TO QUESTION 10 IS NO, EXPLAIN WHAT PERFORMANCE DATA IS NEEDED. - N/A

11. IF THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT. - N/A

The following additional information also provides the basis for my recommendation:

LABELING: Provided Adequate labeling.

STERILIZATION:

Device is supplied sterile. Radiation Type: gamma, Radiation source: Cobalt 60, Minimum and maximum: [redacted] Sterility validation method: AAMI Method 1 routine audit is performed using AAMI Method 3B, Statement whether pyrogen-free and method used to make that determination: There is no claim of being pyrogen-free.

RESPONSE: The sponsor supplied the omitted information.

Device may be resterilized as described in labeling. Identified the cycle parameters (Did not specify cycle type: gravity or vacuum ????): 270° F (132° C) for 15 - 20 minutes (fast cycle) or at 252° F (121° C) for 35-40 minutes (standard cycle), SAL: ???, Sterility Validation Method ????, Statement whether pyrogen-free and method to make that determination

RESPONSE: Sponsor removed all recommendations for resterilization either by steam or ETO.

[redacted]

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This page represents 2 whole page redaction(s).

SUTTER CORPORATION
SMALL JOINT ORTHOPAEDICS

9425 CHESAPEAKE DRIVE
SAN DIEGO, CA 92123
TF1 (800) 854-2216
FAX (619) 279-8249

March 8, 1994

510 (k) Number: 931588

Food and Drug Administration
150 (k) Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Attn.: Mark N. Melkerson DGRD/Orthopedic Branch

This document has been sent by FAX March 8, 1994 and a follow-up copy has been sent to be delivered March 10, 1994.

Dear Mr. Melkerson:

Thank you for your FAX and reference to the draft guidance for the preparation of premarket notification applications for orthopedic devices. The following information is provided in response to your questions regarding Sterilization of the Proximal Interphalangeal Joint Implant, and the information follows the outline of the draft guidance for orthopedic devices.

STERILITY INFORMATION, IMPLANT

Radiation Sterilization Method

1. Gamma Sterilization
2. Cobalt 60
3. Minimum dose 25 kGy, Maximum dose (b)(4)
4. Sterility Assurance Level 10E-6
5. Sterilization Validation according to AAMI Method 1. Routine audit is performed using AAMI Method 3B.
6. There is no claim in the labeling that the device is pyrogen-free.

For implants provided sterile the labeling is being changed to not recommend resterilization. The statement is being changed from the following:

Sterilization:

These implants are provided sterile in an undamaged package.
Warning: If either the implant or the package appears damaged, or if sterility is questioned for any reason the implant should not be used.

These devices may be removed from their package and resterilized by steam autoclaving at 270F(132C) for 15-20 minutes (fast cycle) or at 252F(121C) for 35-40 minutes (standard cycle). Ethylene oxide gas sterilization may be used but is not recommended because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer.

Labeling for implants is being changed to the following:

Sterilization:

These implants are provided sterile in an undamaged package.

Warning: If either the implant or the package appears damaged, or if sterility is questioned for any reason the implant should not be used. Resterilization of this product is not recommended.

STERILITY INFORMATION FOR NON-STERILE DEVICES THAT MUST BE STERILIZED PRIOR TO USE

STERILITY INFORMATION, SIZER (The sizer is used as a trial)

ETHYLENE OXIDE GAS STERILIZATION METHOD. (labeling is being changed to not recommend ethylene oxide gas sterilization, see below)

1.	Temperature	54°C ±1°C
2.	Humidity	60% ±10%
3.	Gas concentrations	6 7 psig of 12/88 Ethylene Oxide/dichlorodifuoromethane.
4.	Exposure time	4 hours
5.	Aeration cycle	18 hours

STEAM STERILIZATION METHOD

1.	Cycle	Standard Gravity
2.	Temperature	250°F (121°C)
3.	Exposure time	35-40 min.

1.	Cycle	Prevacuum
2.	Temperature	270°F (132°C)
3.	Exposure time	15-20 min.

Labeling for trials is being changed from:

Sterilization:

Instruments and sizers may be sterilized using either steam or ethylene oxide gas. Ethylene oxide gas is not recommended for silicone elastomer because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer.

Labeling for trials is being changed to:

Sterilization:

Instruments and sizers may be sterilized using steam. Ethylene oxide gas is not recommended for silicone elastomer because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer. The product may be resterilized using an autoclave by one of the following methods: Standard

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gravity sterilization at 250° F (121° C) for 35-40 min, or prevacuum sterilization at 270° F (132° C) for 15-20 min.

Since the submission of this 510 (k) I have been obtaining the guidances via the Flash FAX. I have found them to be very helpful in the preparation of our 510 (k) applications.

Please let me know if I may clarify any of the information provided.

Sincerely,

Louise M Focht

Louise M. Focht
Director of Regulatory Affairs
619-569-8148x 2213

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ORTHOPEDIC 510(k) SUBMISSION CHECKLIST

K 931588

Sponsor: Sutter Corp.

Based on the draft Orthopedic 510(k) Guidance Document, the information checked in the "NO" column is missing and must be addressed before the review can begin.

	Additional Information Required
MANUFACTURER IDENTIFICATION	☐
DEVICE IDENTIFICATION	☐
PROPOSED REGULATORY CLASS.	☐
INTENDED USE	☐
DEVICE DESCRIPTION	☐
MATERIALS	☐
LABELING	☐
TESTING OR OTHER ADDITIONAL INFORMATION	☐
CLINICAL DATA	☐
STERILITY INFORMATION	☐
PACKAGING DESCRIPTION	☐
SUBSTANTIAL EQUIVALENCE INFORMATION	☐
510(k) SUMMARY OR STATEMENT	☐

These are the basic elements that must be addressed before ODE will begin a comprehensive review of the 510(k). All applicable topics contained in the 510(k) guidance must be addressed in sufficient detail to enable ODE to determine the equivalence of the device.

Recommendation:

- ☒ proceed with a comprehensive review of the document
- ☐ issue a modified K-OR-3.A1 letter

Reviewed by: M. Courtney

Date: 8/24/93

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cf

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

APRIL 16, 1993

SUTTER CORPORATION
ATTN: LOUISE M. FOCHT
9425 CHESAPEAKE DRIVE
SAN DIEGO, CA 92123

510(k) Number: K931588
Received: 03-31-93
Product: SUTTER PROXIMAL INTERPHALANGEAL JOINT

We have received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date, you may want to check with FDA to determine the status of your submission.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages manufacturers to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law

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requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 227-8006.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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SUTTER CORPORATION
BIOMOTION SPECIALISTS™

March 29, 1993

510(k) Notification
Proximal Interphalangeal Joint

K931588

Food and Drug Administration
510(k) Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Sutter Corporation hereby submits a Premarket Notification Submission pursuant to Section 510(k) of the Federal Food, Drug and Cosmetics Act and in accordance with regulations established in 21CFR807. This submission is to notify the Agency of our intent to market a new device as an extension of our orthopedic implant product line. We intend to continue production and distribution of our other devices.

1. DEVICE NAME:

a. Proprietary Name - Sutter Proximal Interphalangeal Joint
b. Classification Name - Prosthesis, Finger and Toe
c. Panel Classifying Device - Orthopedic (87)

2. ESTABLISHMENT REGISTRATION NUMBER:

Owner Operator Number 9002987
Registration Number: 2028601

3. CLASSIFICATION UNDER SECTION 513: Class II

4. PERFORMANCE STANDARDS: N/A

5. REPRESENTATIVE LABELING:

Proposed labeling and draft of surgical techniques are included in Appendix A and Appendix B respectively. The product is terminally sterilized by gamma radiation at 25 KGy.

6. SIMILARITIES TO DEVICES IN DISTRIBUTION:

The finger implant is substantially equivalent to several silicone implants in commercial distribution both before and after May 28, 1976. These include the Sutter PIP, Sutter MCP, and Dow Corning Wright Swanson design implants which are used both in the Proximal Interphalangeal and Metacarpal Phalangeal joints and distal interphalangeal joints. Literature is in Appendix C.

Sutter PIP finger joint implant currently on the market consists of silicone rubber molded over an inner layer of reinforcing mesh and polyester anchoring sutures. The stems are covered with polyester mesh to permit infiltration of bone and fibrous tissue. Over 15 years of clinical experience with this design has demonstrated long term functional stability. The surgical technique for the Sutter PIP prosthesis follows the same protocol as for other flexible hinge silicone implants.

The Sutter implant is substantially equivalent in materials, design principle and intended clinical function to Dow Corning Wright implants. The Silastic Finger Joint Implant manufactured by Dow Corning Wright is used in the metacarpophalangeal (MP), proximal interphalangeal (PIP) and distal interphalangeal (DIP) joints. Both the Sutter and the Dow product are fabricated of medical grade silicone and are used clinically to maintain normal joint space and provide an acceptable range of motion . The Dow design utilizes a single design implant for use in three different joints of the hand. The new Sutter PIP design is similar in principal to the existing Sutter Metacarpal Phalangeal joint which has been on the market for five years.

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9425 CHESAPEAKE DRIVE | SAN DIEGO, CA 92123 | (619) 569-8148 | (800) 854-2216 | FAX: (619) 279-8249

[redacted]

Material testing performed includes:

[redacted]

7. **SAFETY AND EFFECTIVENESS SUMMARY:**

Materials used in the Sutter finger implant are the same materials and manufacturing processed currently used in many Sutter implants including the Sutter MCP finger joint implant. [redacted]. GMP controls are in place and adhered to for current manufacturing of all Sutter Products.

We believe the proximal interphalangeal joint implant to be safe and effective. No new technologies are employed in the design or manufacture of the device. We believe that the device is substantially equivalent to other Sutter implants as well as the referenced competitors' product already in commercial distribution. We request clearance to introduce the device for distribution in ninety days.

Sincerely,

Louise M Focht

Louise M. Focht
Director Quality Assurance
Sutter Corporation
619-569-8148 x 2213

Enclosures:

Appendix A	Proposed Labeling
Appendix B	Surgical Technique
Appendix C	Equivalent Product Literature
Appendix D	Drawing
Appendix E	Material properties, testing, previously approved under 510k submission

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SUTTER CORPORATION
BIOMOTION SPECIALISTS™

March 29, 1993

510(k) Notification
Proximal Interphalangeal Joint

Food and Drug Administration
510(k) Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

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1. DEVICE NAME:

a. Proprietary Name - Sutter Proximal Interphalangeal Joint
b. Classification Name - Prosthesis, Finger and Toe
c. Panel Classifying Device - Orthopedic (87)

2. ESTABLISHMENT REGISTRATION NUMBER:

Owner Operator Number 9002987
Registration Number: 2028601

3. CLASSIFICATION UNDER SECTION 513: Class II

4. PERFORMANCE STANDARDS: N/A

5. REPRESENTATIVE LABELING:

Proposed labeling and draft of surgical techniques are included in Appendix A and Appendix B respectively. The product is terminally sterilized by gamma radiation at 25 KGy.

6. SIMILARITIES TO DEVICES IN DISTRIBUTION:

The finger implant is substantially equivalent to several silicone implants in commercial distribution both before and after May 28, 1976. These include the Sutter PIP, Sutter MCP, and Dow Corning Wright Swanson design implants which are used both in the Proximal Interphalangeal and Metacarpal Phalangeal joints and distal interphalangeal joints. Literature is in Appendix C.

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The Sutter implant is substantially equivalent in materials, design principle and intended clinical function to Dow Corning Wright implants. The Silastic Finger Joint Implant manufactured by Dow Corning Wright is used in the metacarpophalangeal (MP), proximal interphalangeal (PIP) and distal interphalangeal (DIP) joints. Both the Sutter and the Dow product are fabricated of medical grade silicone and are used clinically to maintain normal joint space and provide an acceptable range of motion . The Dow design utilizes a single design implant for use in three different joints of the hand. The new Sutter PIP design is similar in principal to the existing Sutter Metacarpal Phalangeal joint which has been on the market for five years.

9425 CHESAPEAKE DRIVE | SAN DIEGO, CA 92123 | (619) 569-8148 | (800) 854-2216 | FAX: (619) 279-8249

The hinge design of the two products is the same with slight modifications in the implant stem shape to accommodate differences in the anatomy of the phalanges. Drawing is included in Appendix D.

[redacted]

7. **SAFETY AND EFFECTIVENESS SUMMARY:**

Materials used in the Sutter finger implant are the same materials and manufacturing processed currently used in many Sutter implants including the Sutter MCP finger joint implant[redacted] controls are in place and adhered to for current manufacturing of all Sutter Products.

We believe the proximal interphalangeal joint implant to be safe and effective. No new technologies are employed in the design or manufacture of the device. We believe that the device is substantially equivalent to other Sutter implants as well as the referenced competitors' product already in commercial distribution. We request clearance to introduce the device for distribution in ninety days.

Sincerely,

Louise M. Focht

Louise M. Focht
Director Quality Assurance
Sutter Corporation
619-569-8148 x 2213

Enclosures:

Appendix A	Proposed Labeling
Appendix B	Surgical Technique
Appendix C	Equivalent Product Literature
Appendix D	Drawing

[redacted]

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SUTTER CORPORATION
BIOMOTION SPECIALISTS™

March 29, 1993

510(k) Notification
Proximal Interphalangeal Joint

Food and Drug Administration
510(k) Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Sutter Corporation hereby submits a Premarket Notification Submission pursuant to Section 510(k) of the Federal Food, Drug and Cosmetics Act and in accordance with regulations established in 21CFR807. This submission is to notify the Agency of our intent to market a new device as an extension of our orthopedic implant product line. We intend to continue production and distribution of our other devices.

1. DEVICE NAME:

a. Proprietary Name - Sutter Proximal Interphalangeal Joint
b. Classification Name - Prosthesis, Finger and Toe
c. Panel Classifying Device - Orthopedic (87)

2. ESTABLISHMENT REGISTRATION NUMBER:

Owner Operator Number 9002987
Registration Number: 2028601

3. CLASSIFICATION UNDER SECTION 513: Class II

4. PERFORMANCE STANDARDS: N/A

5. REPRESENTATIVE LABELING:

Proposed labeling and draft of surgical techniques are included in Appendix A and Appendix B respectively. The product is terminally sterilized by gamma radiation at 25 KGy.

6. SIMILARITIES TO DEVICES IN DISTRIBUTION:

The finger implant is substantially equivalent to several silicone implants in commercial distribution both before and after May 28, 1976. These include the Sutter PIP, Sutter MCP, and Dow Corning Wright Swanson design implants which are used both in the Proximal Interphalangeal and Metacarpal Phalangeal joints and distal interphalangeal joints. Literature is in Appendix C.

Sutter PIP finger joint implant currently on the market consists of silicone rubber molded over an inner layer of reinforcing mesh and polyester anchoring sutures. The stems are covered with polyester mesh to permit infiltration of bone and fibrous tissue. Over 15 years of clinical experience with this design has demonstrated long term functional stability. The surgical technique for the Sutter PIP prosthesis follows the same protocol as for other flexible hinge silicone implants.

The Sutter implant is substantially equivalent in materials, design principle and intended clinical function to Dow Corning Wright implants. The Silastic Finger Joint Implant manufactured by Dow Corning Wright is used in the metacarpophalangeal (MP), proximal interphalangeal (PIP) and distal interphalangeal (DIP) joints. Both the Sutter and the Dow product are fabricated of medical grade silicone and are used clinically to maintain normal joint space and provide an acceptable range of motion . The Dow design utilizes a single design implant for use in three different joints of the hand. The new Sutter PIP design is similar in principal to the existing Sutter Metacarpal Phalangeal joint which has been on the market for five years.

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3/10/94 MNM

MEMO RECORD
FROM: M.N. MELKERSON, Engineer
TO: File

DATE: 3/10/94
Center/Office: CDRH/ODE
Division/Branch: DGRD/ORDB

Document Number: K931588
Common Name: Proximal InterPhalangeal (PIP) Joint Prosthesis, Finger & Toe
Trade Name: Sutter, Proximal Interphalangeal Joint Prosthesis
Classifications: 1) 21 CFR 888.3230, Finger Jt. Polymer Constrained Prosthesis

Class: II
Product Codes: KYJ; Finger
Products To Which Compared:

Preamendments Dow Corning Wright (Wright Medical), Swanson Silastic Jt. Spacers for metacarpal phalangeal (MCP), proximal interphalangeal (PIP), and distal interphalangeal (DIP) joints of fingers

K802342 and K870200, Sutter, Medical grade silicone (PEHT 400 series) Jt. Spacers for MCP and PIP joints of fingers

Contact Person: Louise M. Focht, Director of Quality Assurance (619) 569-8148, ext. 2213

Summary:

This 510(k) original dated 3/29/93, received on 3/31/93 and assigned on 3/4/94 was reviewed for a SE or NSE recommendation.

Recommendation:

I recommend that this 510(k) be found SE.

Basis of Recommendation:

INTENDED USE: Intended for total joint arthroplasty of the PIP joint of fingers for clinical indications of Rheumatoid arthritis (RA), Osteoarthritis (OA), Ankylosed joints or those with limited range of motion which have not responded to conservative treatment, Nonfunctional joint due to inadequate body alignment and joint space which cannot be restored by soft tissue reconstruction alone, and Destroyed articular surfaces.

DEVICE DESCRIPTION:

A constrained, flexible hinge design, joint space made out of a [redacted]

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surfaces to provide stabilization through tissue ingrowth. These design features are identical to the predicate Sutter MCP. The PIP implants will be offered in 6 sizes (i.e., 10, 20, 30, 40, 50, and 60).

Is the device life-supporting or life sustaining? no
Is the device implanted (short-term or long-term)? long-term
Does the device design use software? no
Is the device sterile? Yes
Is the device for single use? Yes
Is the device for home use or prescription use? Restricted to use by physicians.
Does the device contain drug or biological product as a component? - no
Is this device a kit? no

MATERIALS:

[redacted]

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION"

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS STARTING ON PAGE 1 - NOTE: QUESTIONS WHICH ARE NOT APPLICABLE ARE FOLLOWED BY "N/A".

1. IF THE ANSWER TO QUESTION 1 IS NO, EXPLAIN WHY THE PRODUCT IS NOT A DEVICE. - Product is a device.

2. IF THE ANSWER TO QUESTION 2 IS NO, EXPLAIN WHY THE DEVICE IS NOT SUBJECT TO 510(K). - Is subject to 510(k).

3. IF THE ANSWER TO QUESTION 3 IS NO, EXPLAIN HOW THE NEW INDICATION DIFFERS FROM THE PREDICATE DEVICE'S INDICATION. - Same intended use and clinical indications.

4. IF THE ANSWER TO QUESTION 4 IS YES OR NO, EXPLAIN WHY THERE IS/IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE. - N/A

5. IF THE ANSWER TO QUESTION 5 IS NO, DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS. - Hinge design of Sutter MCP and PIP are identical while overall dimensions and stem of PIP has been modified to accommodate differences in the anatomy of the phalanges.

6. IF THE ANSWER TO QUESTION 6 IS YES OR NO, EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT SAFETY OR EFFECTIVENESS. - No, the modifications to the dimensions and

stem are slight (i.e., less of taper, thus greater cross-sectional areas) and should not adverse effect the mechanical properties of the device. The modifications did not change ratios of dimensions.

7. IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH. - Yes, the sponsor supplied drawings with dimensions allowing for the comparison to predicates dimensions and geometry.

8. IF THE ANSWER TO QUESTION 8 IS YES OR NO, EXPLAIN THE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW. - N/A

9. IF THE ANSWER TO QUESTION 9 IS NO, EXPLAIN WHY THE EXISTING SCIENTIFIC METHODS CAN NOT BE USED. - N/A

10. IF THE ANSWER TO QUESTION 10 IS NO, EXPLAIN WHAT PERFORMANCE DATA IS NEEDED. - N/A

11. IF THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT. - N/A

The following additional information also provides the basis for my recommendation:

LABELING: Provided Adequate labeling.

STERILIZATION:

Device is supplied sterile. Radiation Type: gamma, Radiation source: [redacted] Sterility validation method: AAMI Method 1 routine audit is performed using AAMI Method 3B, Statement whether pyrogen-free and method used to make that determination: There is no claim of being pyrogen-free.

RESPONSE: The sponsor supplied the omitted information.

Device may be resterilized as described in labeling. Identified the cycle parameters (Did not specify cycle type: gravity or vacuum ????): 270° F (132° C) for 15 - 20 minutes (fast cycle) or at 252° F (121° C) for 35-40 minutes (standard cycle), SAL: ???, Sterility Validation Method ????, Statement whether pyrogen-free and method to make that determination

RESPONSE: Sponsor removed all recommendations for resterilization either by steam or ETO.

States may be ETO sterilized but does not recommend due to aeration

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This page represents 27 whole page redaction(s).

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This page represents 29 whole page redaction(s).

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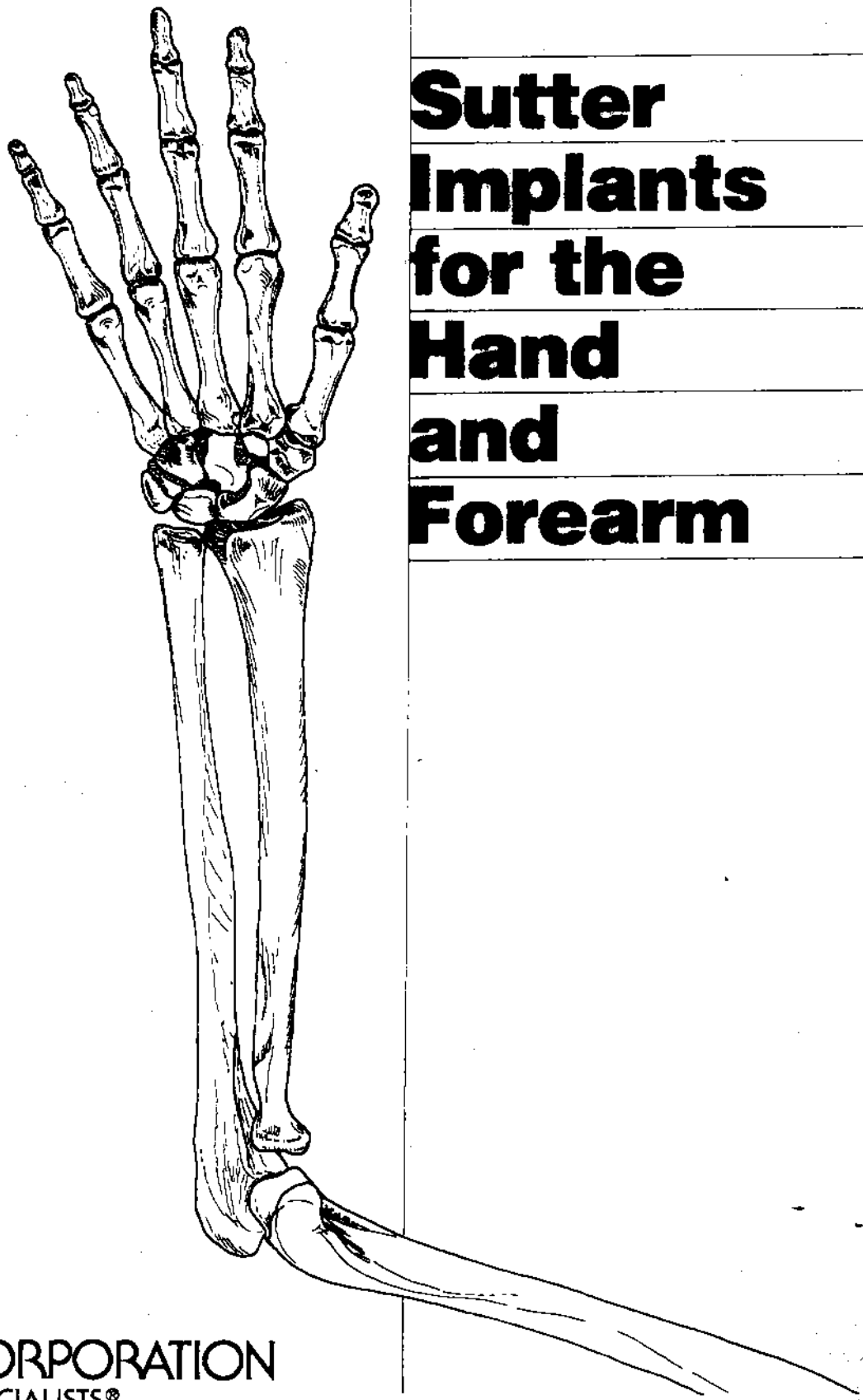
Appendix A
Proposed Labeling

Appendix C
Equivalent product literature



Sutter Implants for the Hand and Forearm

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Proximal Radius Implant

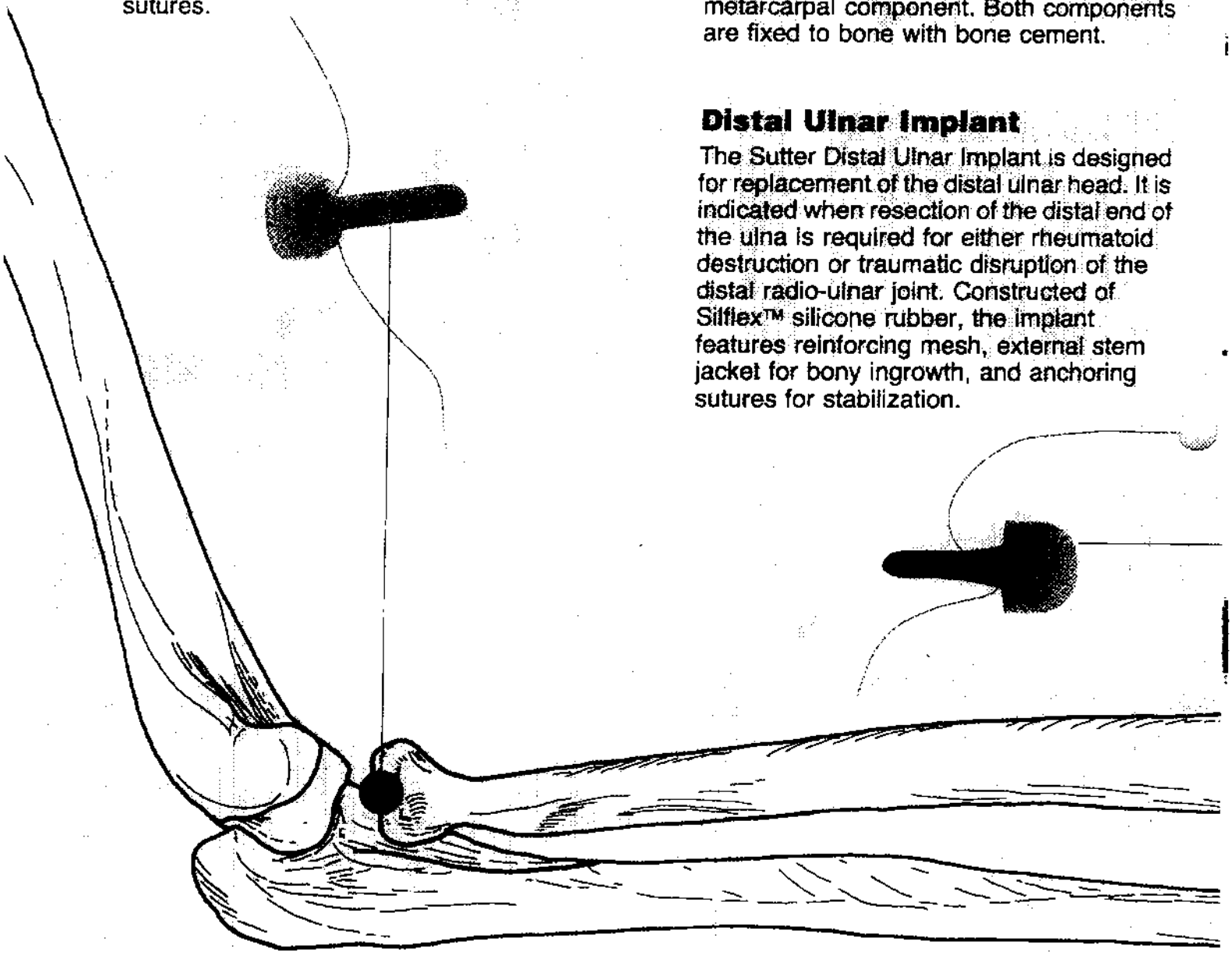
The Sutter Proximal Radius Implant replaces the proximal radial head when radial head resection is indicated in the presence of rheumatoid degeneration, traumatic arthritis, or radial head fracture. The implant has a smooth Silflex™ silicone articular head and a stem with a polyester ingrowth surface for stability. Immediate stabilization is possible with the anchoring sutures.

Carpometacarpal Implant

The Sutter Carpometarcarpal Implant is indicated for patients with disabled CMC joints secondary to degenerative arthritis, post-traumatic arthrosis or instability of the CMC joint. The design is a captured ball-in-socket prosthesis with total range of motion. It is composed of the UHMWPE cup which is inserted into the prepared trapezium, and a titanium alloy (Ti-6A1-4V) metarcarpal component. Both components are fixed to bone with bone cement.

Distal Ulnar Implant

The Sutter Distal Ulnar Implant is designed for replacement of the distal ulnar head. It is indicated when resection of the distal end of the ulna is required for either rheumatoid destruction or traumatic disruption of the distal radio-ulnar joint. Constructed of Silflex™ silicone rubber, the implant features reinforcing mesh, external stem jacket for bony ingrowth, and anchoring sutures for stabilization.



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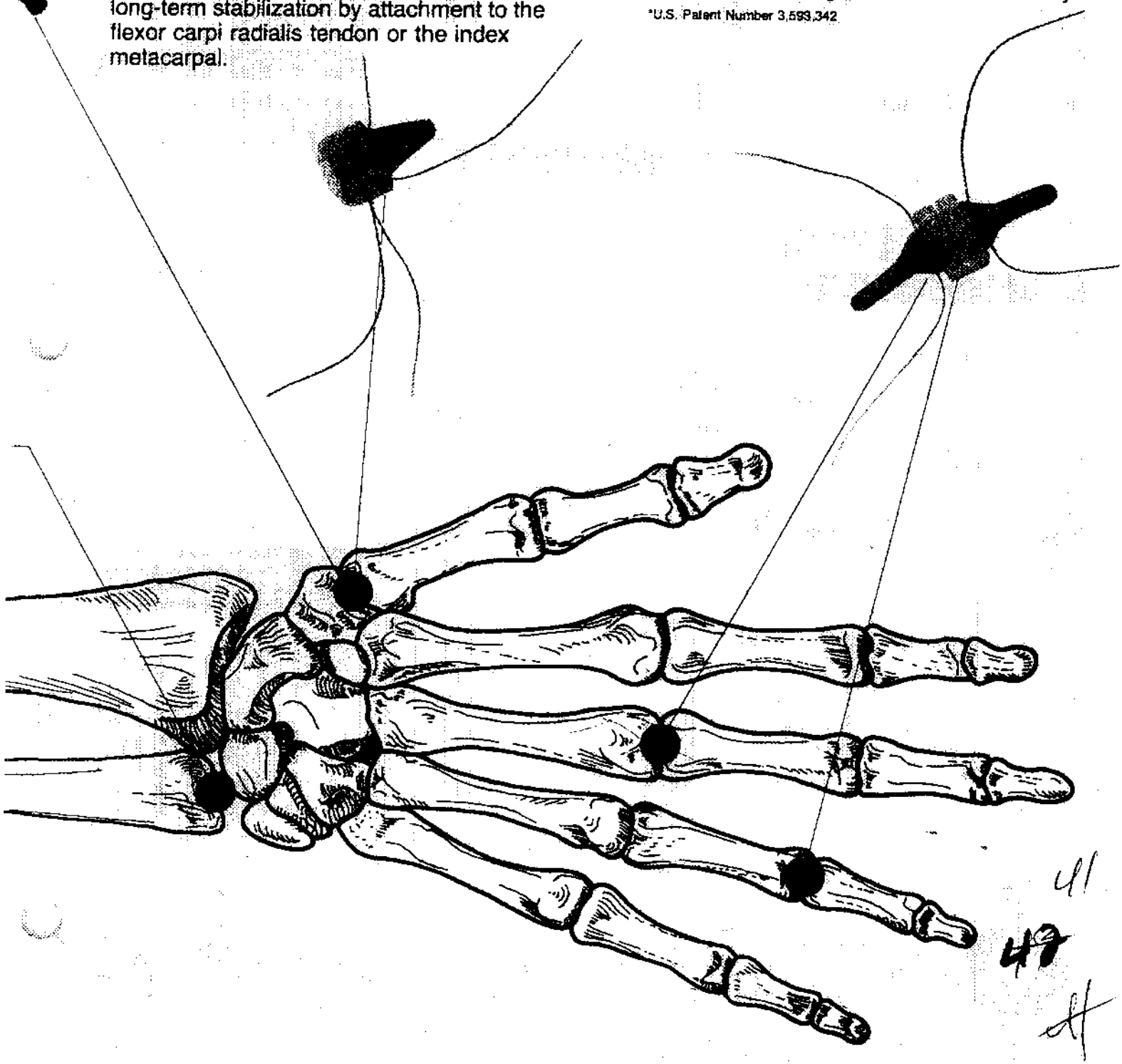
Trapezium Implant

The Sutter Trapezium Implant is for replacement of the trapezium in cases of carpometarcarpal arthritis or failed previous resection arthroplasty of the trapezium. The prosthesis, available in two stem sizes, is constructed of Silflex™ silicone rubber, polyester mesh, and braided polyester cords. The polyester mesh jacket on the stem provides long-term fixation through bony ingrowth into the mesh. The braided polyester cords facilitate immediate and long-term stabilization by attachment to the flexor carpi radialis tendon or the index metacarpal.

Finger Joint Implant*

The Sutter Finger Joint Implant is a total joint replacement for the metacarpo-phalangeal and proximal interphalangeal joints. The prosthesis consists of Silflex™ silicone rubber molded over an inner layer of reinforcing mesh and polyester anchoring sutures. The stems are covered with polyester mesh to permit infiltration of bone and fibrous tissue. Over 15 years of clinical experience with this design has demonstrated long term functional stability.

*U.S. Patent Number 3,593,342



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[redacted]

Finger Joint Implant

Catalog Number	Size
MPIP-00	00
MPIP-10	10
MPIP-20	20
MPIP-30	30
MPIP-40	40

Sizer

Catalog Number	Size
MPIP-005	00
MPIP-105	10
MPIP-205	20
MPIP-305	30
MPIP-405	40

Finger Joint Broach

Catalog Number	Size
FJBR-00	00
FJBR-10	10
FJBR-20	20
FJBR-30	30
FJBR-40	40

[redacted]

Standard Stem Trapezium Implant

Catalog Number	Size
TR-10	10
TR-20	20
TR-30	30

Sizer

Catalog Number	Size
TR-105	10
TR-205	20
TR-305	30

[redacted]

Short Stem Trapezium Implant

Catalog Number	Size
STR-10	10
STR-20	20
STR-30	30

Sizer

Catalog Number	Size
STR-105	10
STR-205	20
STR-305	30

Trapezium Burr

Catalog Number
TB-1

[redacted]

Proximal Radius Implant

Catalog Number	Size
RH-10	10
RH-20	20
RH-30	30

Sizer

Catalog Number	Size
RH-105	10
RH-205	20
RH-305	30

[redacted]

Distal Ulnar Implant

Catalog Number	Size
UH-10	10
UH-20	20
UH-30	30
UH-40	40

Sizer

Catalog Number	Size
UH-105	10
UH-205	20
UH-305	30
UH-405	40

[redacted]

Carpometacarpal Implant

Catalog Number	Size
TMC-10	Small
TMC-20	Medium
TMC-30	Large
TMC-15	Replacement Head
TMC-25	Replacement Head

- All Sutter implants, except for the Carpometacarpal Implants, are shipped presterilized by gamma radiation.
- Sizers are not for implantation.

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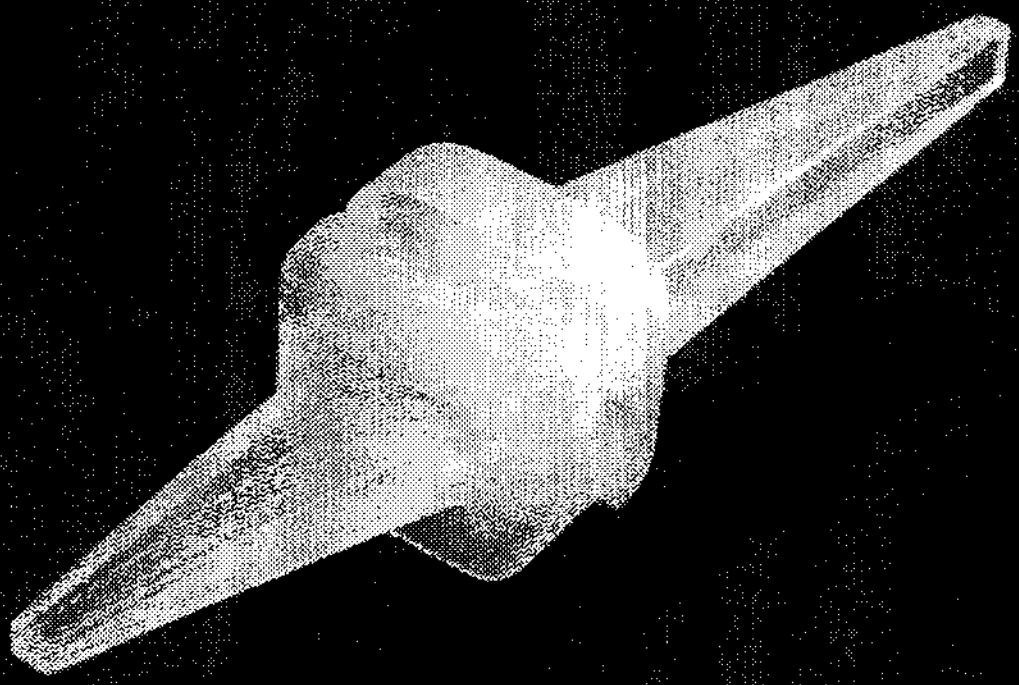
Now.
A full range of motion.
No volar impingement.
Same surgical technique.



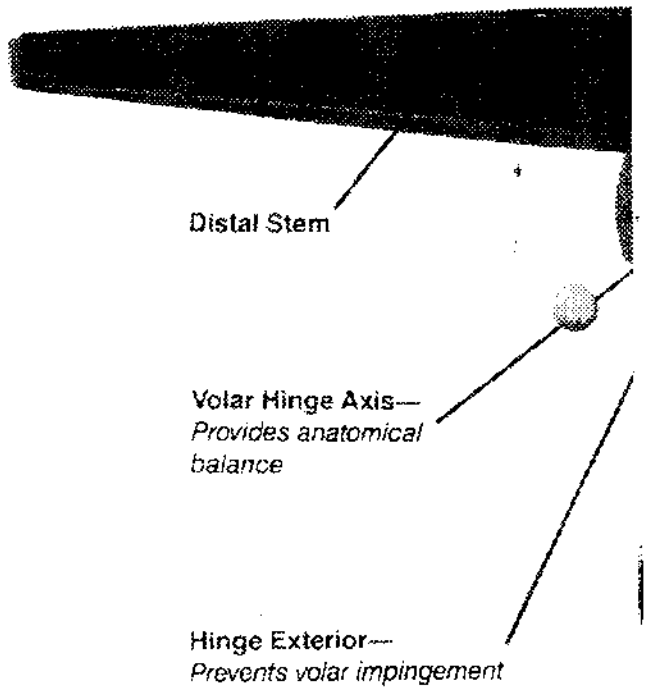
Introducing the Sutter MCP™ Finger Joint Prosthesis.

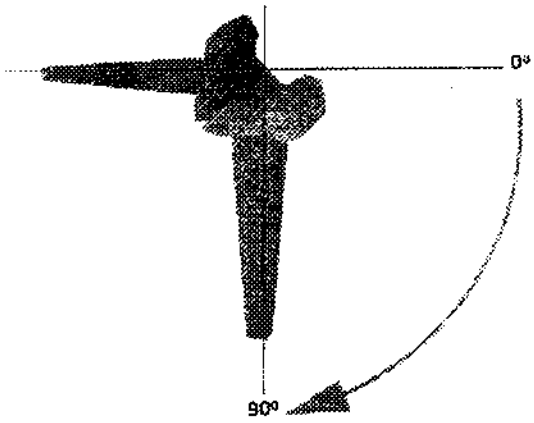
SUTTER CORPORATION

Biomechanically engine

► The same surgical technique as other silicone MCP implants

The surgical technique for the Sutter MCP™ Finger Joint Prosthesis follows the same protocol for other flexible hinge silicone implants currently in use. The technique requires neither sutures for fixation nor grommets for protection of the prosthesis.





Closely Duplicates Normal Elliptical Joint Motion

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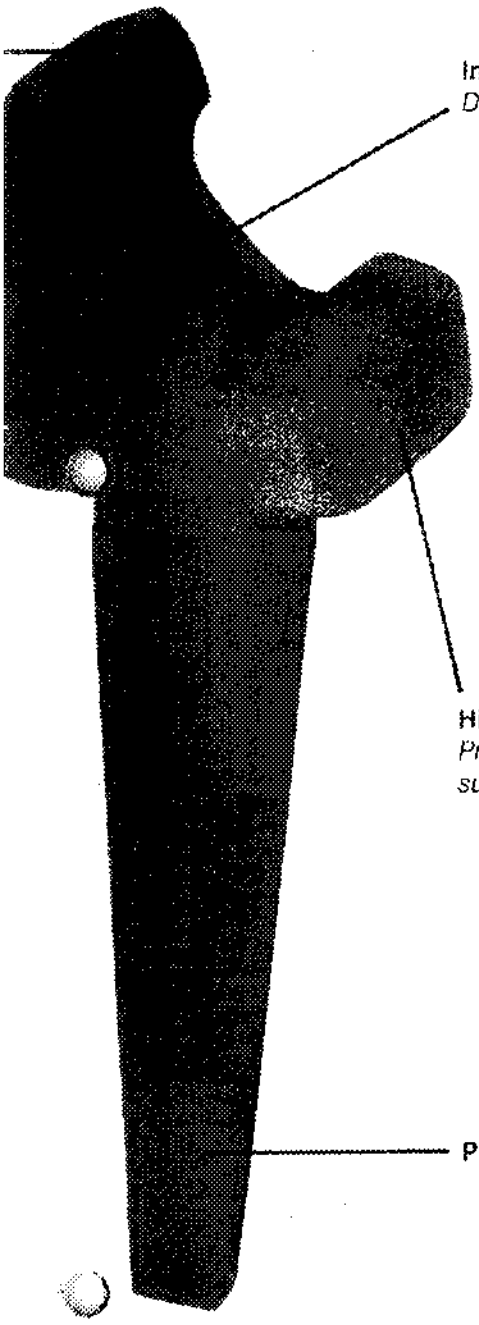
ered for superior results.



► The offset hinge axis provides a full range of motion

With the hinge axis in the volar position, the Sutter MCP Prosthesis maintains an anatomical balance between the flexor and extensor tendons thereby reducing extensor lag and providing well over 90° of flexion, without volar impingement. This offset of the hinge axis also creates an elliptical arc of motion similar to that of the anatomical MCP joint.

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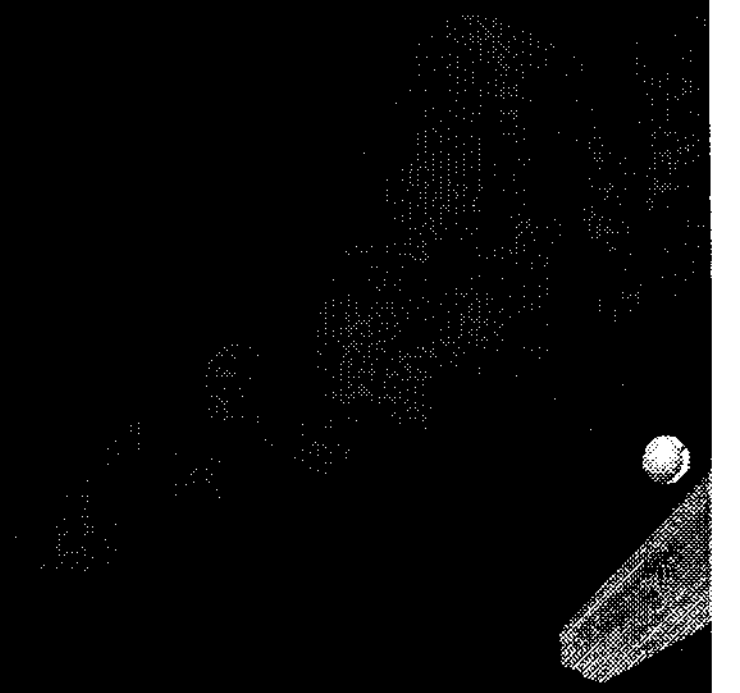
The Complete Sutte

Complete instrumentation and seven implant sizes

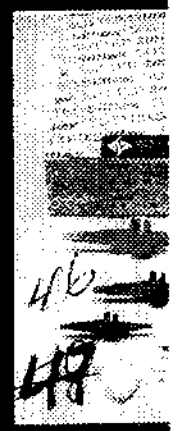
The Sutter MCP™ Implant System includes a complete set of 14 broaches, 7 implant sizers, a double-ended MCP rasp, MCP awl, and a custom sterilization tray. The System also includes implants ranging in size from the "00" to size "60." (See Ordering Information on back panel for complete list of sizes and dimensions.)

The MCP System also includes the surgical technique reference in print and video versions. The video is available in ½" VHS format.

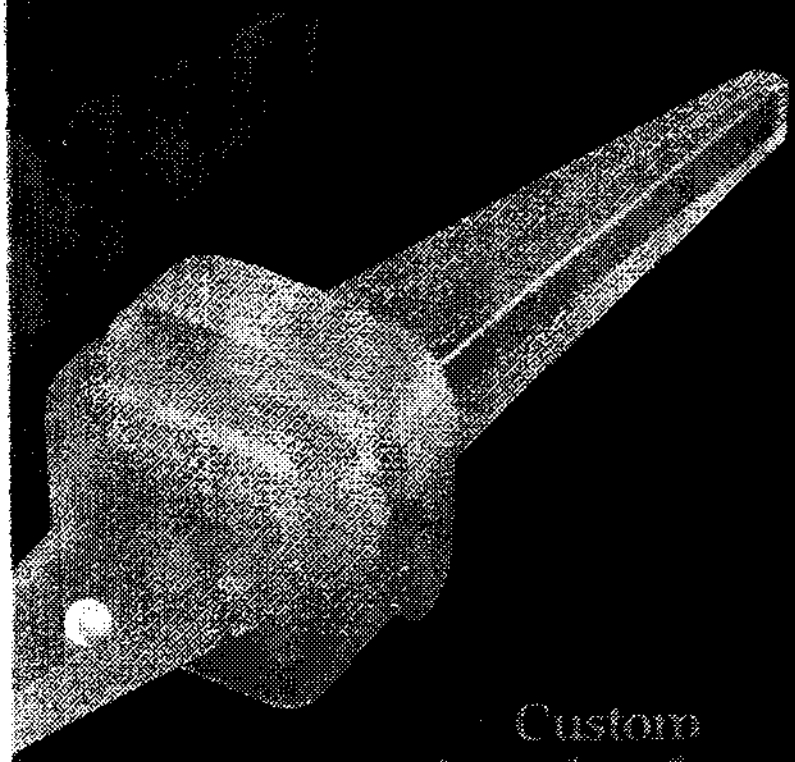


Color-coded sizers for quick visual reference

Sizers in the Sutter MCP Implant System are color-coded to coordinate with a large color marker which appears on each implant package. This color-coding system provides added convenience to the ease of set up and surgical procedure.



MCP Implant System



Custom broaches for better results

A full set of 14 custom MCP broaches is available. Each implant is supported by two broaches, a metacarpal broach and a phalangeal broach, for more efficient bone preparation. Broaches feature two-way cutting teeth for quicker and easier broaching of the intramedullary canal and light-weight, formed handles for superior procedural management. All broaches are color-coded to match sizers for fast and accurate identification.

Flexural durability through a superior material

With over five years of proven clinical performance, the Sutter Silflex® silicone hinge has demonstrated unmatched flexural durability in rigorous laboratory tests. Through machine testing, the prosthesis has been flexed from 0° to 90° and back to 0° at a rate of 315 cycles per minute, producing over 450,000 cycles per day. Today, the Sutter MCP Implant has been flexed over 50,000,000 cycles with no wear or tear propagation observed.

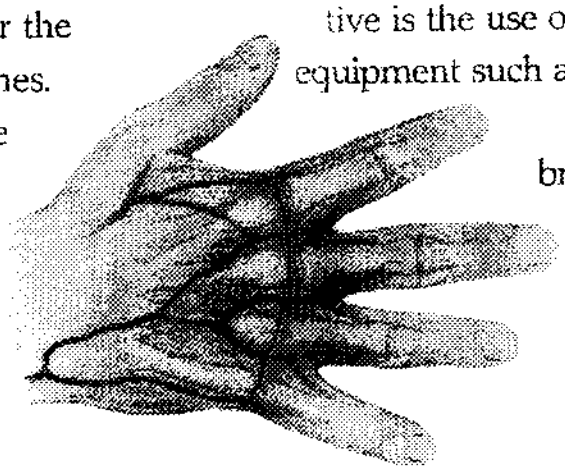
A simple technique

► Superior post-surgical results—durability and performance

The new Sutter MCP™ joint prosthesis, constructed of Silflex™ silicone, offers post-surgical results unavailable in any other finger joint implant. Its biomechanically engineered hinge block delivers a full range of motion and superior durability without the addition of grommets.

► Step One

A skin incision is made over the necks of the metacarpal bones. This incision can be a single transverse incision, or two longitudinal incisions, one between the second and third metacarpals and the other between the fourth and fifth metacarpals.

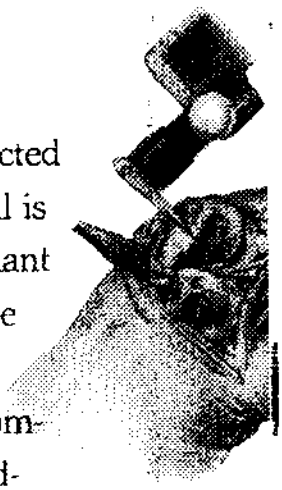


► Step Two

A blunt dissection is performed to expose extensor tendons and to preserve superficial veins and nerves.

► Step Three

The metacarpal head is resected and the intramedullary canal is prepared to receive the implant stem. This procedure may be performed by a variety of techniques with the most common being the use of a hand-held broach or awl. An alternative is the use of power equipment such as a small burr or oscillating broach head.



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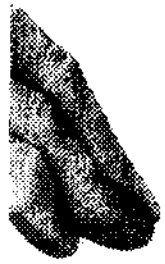
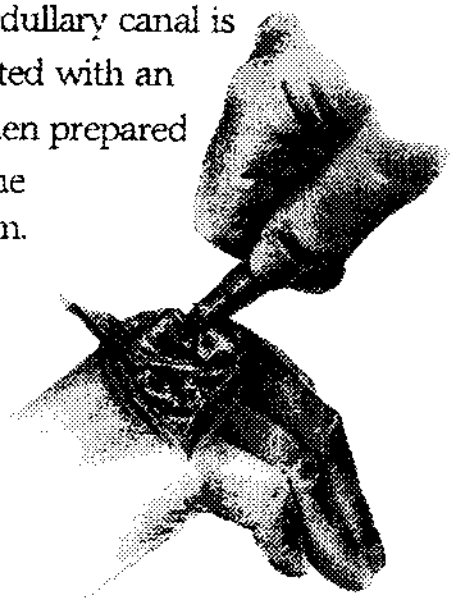
for long-term results

► Step Four

The intramedullary canal of the proximal phalanx is then prepared in the same manner as the metacarpal. Since resection of the proximal phalanx is not commonly done, preparation of the intramedullary canal is usually started with an awl, and then prepared to receive the implant stem.



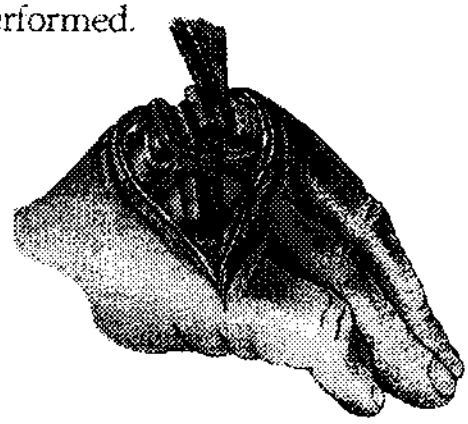


► Step Five

Implant size is determined by trial use of color-coded implant sizers. Once the proper size is determined, a range of motion is performed.

► Step Six

After size is determined and the intramedullary canals have been prepared, the implant is inserted into the metacarpal and then the proximal phalanx. A final range of motion is then performed.



► Step Seven

If necessary, ligament and tendon reconstruction and alignment are done at this time. Then the capsule is repaired and the wound is closed in the usual manner.

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Ordering Information

The Sutter MCP™ Finger Joint Prosthesis System

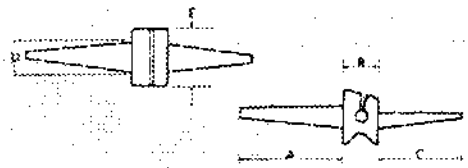
INDICATIONS

- Degenerative or inflammatory joint disease of the metacarpophalangeal joints.
- Dislocation or subluxation of the metacarpophalangeal joints.
- Painful metacarpophalangeal joints with limitation of motion.
- Ulnar drift not correctable by soft tissue procedure alone.

CONTRAINDICATIONS

- Psychologically unstable patient.
- Medically compromised patient.
- Infection.
- Inadequate bone stock.
- Irreparable flexor and extensor apparatus.

TYPICAL DIMENSIONS



SIZE	A	B	C	D	E
00	.618/15.7	.206/15.7	.48/35.2	.175/4.5	.352/8.9
10	.691/17.6	.240/6.10	.514/13.1	.197/5.0	.396/10.2
20	.768/19.5	.260/6.6	.602/15.3	.219/5.6	.440/11.3
30	.890/22.6	.280/7.1	.700/17.8	.246/6.2	.484/12.4
40	1.03/26.2	.308/7.8	.811/20.6	.276/7.0	.552/14.2
50	1.16/29.5	.340/8.6	.902/22.9	.310/7.9	.618/15.9
60	1.284/32.6	.384/8	1.000/25.4	.325/8.3	.648/16.5

SIZE – INCHES/MILLIMETERS

TO ORDER

Sizer

CATALOG NUMBER	SIZE
MCP-000	00
MCP-105	10
MCP-205	20
MCP-305	30
MCP-405	40
MCP-505	50
MCP-605	60

Implant

CATALOG NUMBER	SIZE
MCP-00	00
MCP-10	10
MCP-20	20
MCP-30	30
MCP-40	40
MCP-50	50
MCP-60	60

Broaches

CATALOG NUMBER	SIZE
MBR-M00 Broach	00 Metacarpal
MBR-P00 Broach	00 Phalangeal
MBR-M10 Broach	10 Metacarpal
MBR-P10 Broach	10 Phalangeal
MBR-M20 Broach	20 Metacarpal
MBR-P20 Broach	20 Phalangeal
MBR-M30 Broach	30 Metacarpal
MBR-P30 Broach	30 Phalangeal
MBR-M40 Broach	40 Metacarpal
MBR-P40 Broach	40 Phalangeal
MBR-M50 Broach	50 Metacarpal
MBR-P50 Broach	50 Phalangeal
MBR-M60 Broach	60 Metacarpal
MBR-P60 Broach	60 Phalangeal

Broaches, cont.

CATALOG NUMBER	
MBR-S Instrument/Sizer Set	
14 Broaches	
1 Awl	
1 Double-Ended Rasp	
7 Sizers	
1 Custom Sterilization Tray	

MISCELLANEOUS

Double-cratel MCP Rasp	RSP-001
MCP Awl	SAL-002
Custom Sterilization Tray	CST-003

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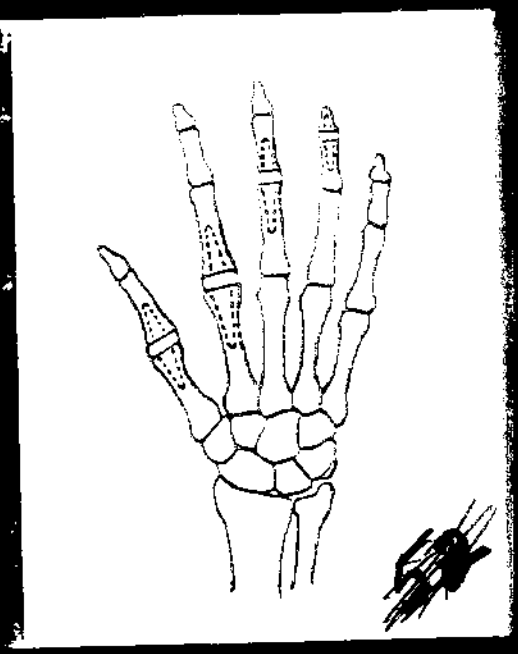


SILASTIC® BRAND Finger Joint Implant H.P.

(Swanson* Design)

DOW CORNING

WRIGHT

Description

A flexible, intramedullary-stemmed, one-piece implant developed to help restore function to hands disabled by rheumatoid, degenerative or traumatic arthritis.

Designed for metacarpophalangeal (MP), proximal interphalangeal (PIP) and distal interphalangeal (DIP) joint implant arthroplasty, this medical-grade high performance silicone elastomer implant serves to preserve normal joint space relationship during formation of the supportive capsule. Flexible, hinge-like construction helps maintain proper internal joint alignment with good lateral stability and minimal flexion-extension restriction.

The SILASTIC® Finger Joint Implant H.P. (designed and developed by Alfred B. Swanson, M.D.) is available in 11 sizes to adequately meet various operative requirements. A sizing set supplied non-sterile and not suitable for implantation is available for proper size determination during surgery.

High Performance Silicone Elastomer

The letters H.P. in the product name indicate the implant is fabricated from medical-grade high performance silicone elastomer. This elastomer shows greater resistance to tear propagation than conventional silicone rubber.[46]

Implant Design

The mid-section has been designed to flex easily while at the same time maintaining vertical stability. This load distributing flexible hinge in the mid-section of the implant acts as both a spacer and a flexible hinge mechanism. The absence of stress concentration during repeated flex loading contributes to the tolerance of the implant by the host and to the durability of the implant.

Specific Advantages

- Minimal irritation to bone and surrounding soft tissue.
- Pliable medical-grade silicone elastomer (softer than bone) unlikely to cause necrosis or bone resorption.
- Fabricated from medical-grade, high performance silicone elastomer.
- Design characteristics include: Intramedullary-stemmed, flexible one-piece hinge-like construction of homogeneous material with stiffness/flexibility balance of implant material, and proper compression-tension force distribution in midsection.
- No intramedullary permanent fixation required.
- Extensive testing has demonstrated high flexural durability (over 600 million flexion repetitions to 90° without evidence of material fatigue or fracture).
- Anatomical sizing (length, height, width) available in eleven sizes to meet various operative requirements.
- Visible on X-ray evaluation.
- Product sterilized; if resterilization is indicated refer to section "To Clean and Resterilize."

Clinical Advantages

1. Improves range of motion (especially extension)
2. Makes results more predictable, reproducible, and durable
3. Maintains joint space and alignment
4. Orients and supports joint encapsulation
5. Intramedullary stem gliding: less stress to bone and less stress to implant; allows joint to find its own center of axis of rotation
6. Early post-operative motion
7. Facilitates post-operative rehabilitation

Concept of Fixation by Encapsulation

The following explanation is furnished by Dr. Alfred B. Swanson for information purposes only. Each surgeon must, of course, evaluate the appropriateness of this explanation based on his own medical knowledge and experience.

Joint Resection + Implant + Capsule = New Joint

Regular joint resection arthroplasty works well in the hand if the joint space and alignment can be maintained.[7,13,28,29] This frequently requires excessive postoperative fixation with pins and external support. The fixation, if overused, will compromise the expected range of motion. In a considerable number of these cases, the joint space gradually narrows and stiffness and subluxation may result. Excellent results do occur however, and are related to the development of a supportive fibrous joint capsule organized during the time when a guarded range of motion is allowed. In finger joint arthroplasty, the proper amount of flexion-extension, appropriate lateral movement and reduction of dorsopalmar subluxation are difficult to obtain, but necessary for a good result. Therefore, one of the most important functions of a successful implant is to maintain proper joint alignment internally while allowing early motion as this new, functionally adapted, fibrous capsule matures.[19,33] By continuing to support the important fibrous capsule and acting to keep the joint surfaces apart, the implant further serves its useful purpose in the post-operative course. This important phenomenon has been named the "Encapsulation Process."

The intramedullary stems of the implant help to maintain alignment and prevent joint displacement. Orientation of the proper capsule is extremely important in the early stages of healing. The immediate post-operative positioning and control of joint movement during the six to eight week rehabilitation period are as important as the surgery itself and these are achieved by dynamic bracing and physiotherapy.

Because the implant becomes so well stabilized by the capsuloligamentous system, it is felt that no other fixation of the implant is required; in fact, it is contraindicated. Dr. Swanson's early experiences with permanent fixation of flexible implants with cross pins, cement, or Dacron cover on the intramedullary stems of the implants and some nonabsorbable suture fixations have led to early breakage of the implants.[30,37] In fact, lateral stability decreased in time because of bone absorption at the fixation site. Most of these implants have been removed, and it has been found that Dacron in a synovium-lined cavity can cause severe inflammatory reaction, which in turn enlarges the joint capsule and results in instability. An implant should cause no inflammatory reaction if it is to be long tolerated.

Stability of a reconstructed joint cannot be dependent on any implant if it is to be tolerated on a long-term basis. Long-standing host-implant reciprocal tolerance requires achievement of joint stability from the extrinsic capsular ligamentous and musculotendinous systems. The flexible implant concept respects this biological requirement. What appears to be a reasonable biomechanical model for an implant may not be tolerated physiologically because of failure of consideration of these facts.

The smooth flexible implant is completely included in the encapsulation process (Fig. 1). A slight amount of movement of the stems increases the life of the implant because forces that develop around the implant on motion are not concentrated in any particular area but rather spread over a broader section, and because the flexible hinge implants can find the best position with respect to the axis of rotation of the joint. This distribution of forces on the implant is also reflected at its interface with the bone or cartilage. The bone is less likely to react at the juncture with the implant if the forces are within the strain tolerance of the bone. Furthermore, the intramedullary stem of the implant has a supportive action on

the cut end of the amputated bone; it prevents the excessive resorption and remodeling phenomena that frequently occur after amputation, as noted in a 15-year study of the finger joint arthroplasty. The low modulus implant is softer than bone and has force-dampening characteristics that further protect the bone or cartilage and soft tissues.

Salvageability of an arthroplasty procedure must be one of the important considerations; this implies preservation of bone and soft tissues so that a secondary procedure can be performed. This requirement was of particular importance in the flexible implant arthroplasty procedure we designed. The capsuloligamentous structures around any flexible implant can be reconstructed to improve the stability, alignment, and durability of the arthroplasty, and revision procedures to further reinforce, release or realign the capsule and ligaments when necessary are easily performed. Because the implants are not firmly attached to bone, replacement of an implant for either infection, fracture, or subluxation is a relatively simple procedure. Furthermore, if a fracture of an implant develops or removal becomes necessary, a functioning resection arthroplasty remains. In case of fracture, the implant continues to function by maintaining the joint space and the integrity of the capsular space. In case of implant removal, the implant has fulfilled much of its mission as a spacer to support the development of the capsule-ligament system. The bone stock removal is minimal, and bone absorption practically never occurs, so that an arthrodesis procedure with a bone graft can easily be accomplished.

The results of metacarpophalangeal and proximal interphalangeal joint flexible implant arthroplasty have shown that this method can provide a pain-free, durable, mobile, stable, and salvageable arthroplasty. This method has received an overwhelming acceptance as the method of choice in most countries throughout the world.[1-6, 8, 9, 11, 13-18, 20-24, 26, 27, 47-49] The correction of the deformity is predictable if the operative and postoperative techniques are followed. The range of motion obtained has varied in clinics, depending in part upon their aggressiveness in the rehabilitation program. The average range of motion in our clinic for 1506 metacarpophalangeal joints was found to be from 4° of lack of extension to 67° of flexion. It is of interest to note that the range of motion on long-term evaluations has not changed significantly. The average range of motion in 493 operated proximal interphalangeal joints has been from 8° of lack of extension to 64° of flexion. Most of these cases were reconstructed for osteoarthritis or posttraumatic arthritis. This procedure also requires aggressive and detailed postoperative therapy. It should be emphasized that other surgical procedures necessary to balance the hand are equally important in flexible implant arthroplasties as in any arthroplasty.

General Indications

Any joint implant reconstruction requires consideration of the following general indications:

- Good condition of the patient.
- Good neurovascular status.
- Adequate skin coverage.
- Possibility of a functional musculotendinous system.
- Adequate bone stock to receive the implant.
- Availability of postoperative therapy.
- Cooperative patient.

Contraindications

- Physiologically or psychologically inadequate patient.
- Inadequate skin, bone and/or neurovascular status.
- Irreparable tendon system.

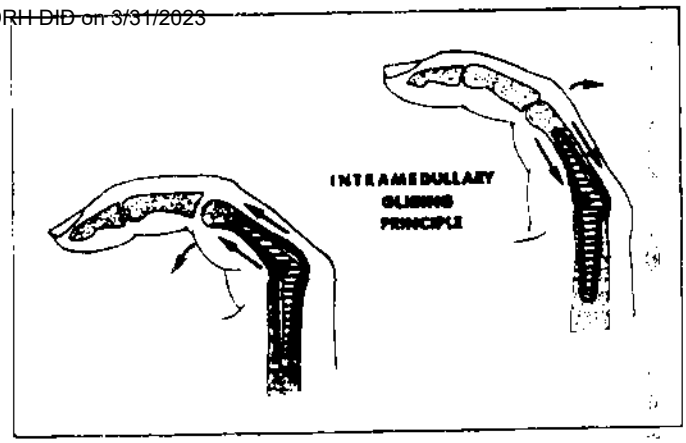


Fig. 1: *The stems of the Silastic® implant are included in the encapsulation process and the implant glides within the intramedullary canals a distance of 1 or 2 mm. on flexion/extension movements. This gliding allows a greater range of motion to occur and permits the implant to find the best position with respect to the axis of rotation of the joint. The gliding flexible implant is subjected to less stress and in turn causes less stress on the surrounding bone.*

Metacarpophalangeal Joint Implant Arthroplasty

Indications

Rheumatoid or Post Traumatic Disabilities with:

1. Fixed or stiff MP joints.
2. X-ray evidence of joint destruction or subluxation.
3. Ulnar drift, not correctable by surgery of soft tissues alone.
4. Contracted intrinsic and extrinsic musculature and ligament system.
5. Associated stiff interphalangeal joints.

Note: Severe and disabling flexor synovitis should preferably be treated before implant arthroplasty. After a reasonable rehabilitation period, the arthroplasties can be performed. Excessive manual labor and awkward weight bearing on hand(s) such as occasionally occurs in some crutch walkers should be avoided after surgery.

If crutches are absolutely necessary, platform crutches should be used. Lower extremity reconstructive surgery should be carried out first if feasible.

Surgical Technique

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only as a technique used by Dr. Alfred B. Swanson. Each surgeon must, of course, evaluate the appropriateness of the procedure based on his own medical training and experience.

Reconstruction of complex hands, those that have severe involvement of both MP and PIP joints or wrist joints, require special consideration. It is impossible in this data sheet to cover this topic in detail. Further study of this problem is strongly recommended in the appropriate references listed, including the recently published test book on flexible implant resection arthroplasty.[10,12,31,32,34,35,37,38,40-45]

Incision and Exposure

A long transverse skin incision is made on the dorsum of the hand over the necks of the metacarpals. The dissection is carried down through subcutaneous tissue to expose the extensor tendons. The dorsal veins which lie between the metacarpal heads are carefully released by blunt longitudinal dissection and are retracted laterally. The extensor hood is exposed to the base of the proximal phalanx. Its radial portion is

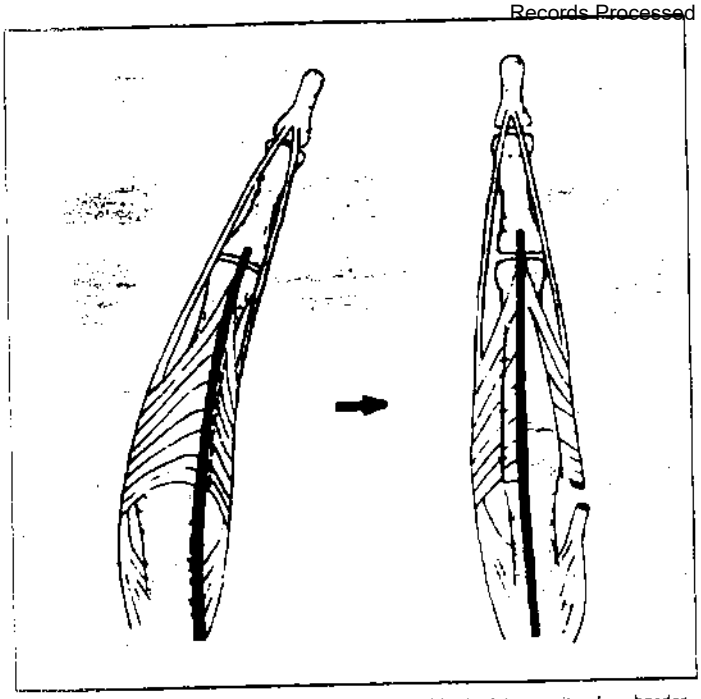


Fig. 2: *The dislocated extensor tendon is released by incision on its ulnar border. The ulnar intrinsics are released if tight. The sagittal fibers of the dorsal hood are reefed on the radial side to maintain the correction.*

usually stretched out and the extensor tendon dislocated ulnarward. A longitudinal incision is made in the extensor hood fibers parallel to the extensor tendon on its ulnar aspect (Fig. 2). In the little finger, the approach is made between the extensor communis and proprius tendons. The hood fibers and capsule are carefully dissected from the underlying synovium and retracted to the radial side. The joint is exposed and the head of the metacarpal identified.

Resection of Metacarpal Head

The neck of the metacarpal is exposed sub-periosteally and transected with an air drill, motor saw or bone cutting forceps leaving part of the metaphyseal flare (Fig. 3). Care should be taken to avoid splintering the bone. The head of the metacarpal is grasped and the collateral ligaments and capsule attachments are incised and preserved. The head of the metacarpal along with the hypertrophied synovial material is thereby removed en masse. Further involved synovia of the joint cavity and surrounding tissues is removed. A pituitary rongeur has been found to be useful for this purpose.

Soft Tissue Release

A comprehensive soft tissue release procedure must be done at this stage so that the base of the proximal phalanx can be displaced dorsally above the metacarpal. This may require incision of the palmar plate and collateral ligament attachments from the proximal phalanx. This release should be symmetrical and complete. Identify the ulnar intrinsic tendon at its point of insertion into the extensor mechanism. If it is tight, pull it up into the wound with a blunt hook and section at the myotendinous junction.

In some patients who have demonstrated evidences of a flexor synovitis, the flexor sheath can be incised longitudinally in its dorsal aspect. The long flexor tendons can be identified and pulled up gently into the wound with a blunt hook. The degree of involvement of the flexor tendons can be evaluated. In some cases a partial synovectomy and tendon sheath release or injection of corticosteroids is done through this incision.

The tendon of the abductor digiti minimi is exposed on the ulnar aspect of the fifth metacarpophalangeal joint, pulled into the wound with a blunt hook and sectioned. Care should be taken to avoid the ulnar digital nerve in the dissection. It is thought that this tendon eventually reattaches but in a lengthened position. The tendon of the flexor digiti minimi is preserved because of its importance to obtain flexion at the metacarpophalangeal joint of the little finger.

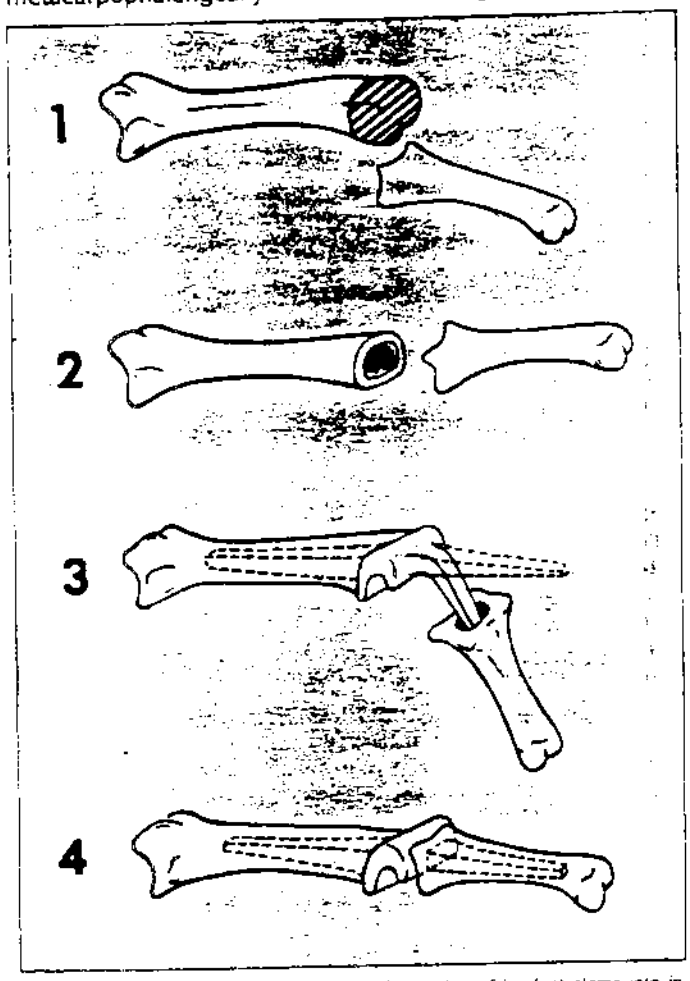


Fig. 3: *Resection of metacarpal head and insertion of implant stems into intramedullary canal. Use the largest implant that can be properly seated. The appropriate joint space should be obtained by bone removal and if necessary soft tissue release. Bone should be removed from the metacarpal head and also the base of the proximal phalanx particularly if it is eroded. A comprehensive soft tissue release should be done depending on the severity of the contracture.*

Preparation of Proximal Phalanx and Intramedullary Canals

Bony resection of the base of the proximal phalanx is not usually performed except for marginal osteophytes which might interfere with the implant. Occasionally in patients with osteoporosis and longstanding dislocation, deformities of the base of the proximal phalanx will be severe. In these cases, a shaping of the base of the phalanx may be necessary. The intramedullary canal of the metacarpal is prepared with a curet, broach or air drill with a special bur*. These burs have a smooth leader point which helps keep them in the canal and prevents inadvertent perforation through the cortex. The occasional constriction in the intramedullary canal of the proximal third of the proximal phalanx can easily be enlarged with the bur. Care should be taken to avoid too much reaming of the canal, especially in patients with thin bones. Test implants are used to select the proper size. The implant stems should fit well down into the canal so that the transverse midsection of the implant abuts against the bone

* Dow Corning-Wright

end. The largest implant possible should be used. Implants of sizes 4 through 9 are generally used. A rectangular hole is then made in the joint surface of the proximal phalanx with an osteotome, knife, broach or air drill. The intramedullary canal is reamed in the same fashion as the metacarpal to receive the distal stem of the implant selected for the metacarpal. This procedure is repeated for all digits. The intramedullary canal of the ring metacarpal is frequently quite small and requires careful preparation. Any sharp points or rough surfaces on the bone ends should be completely smoothed.

Implant Insertion

The wound is thoroughly irrigated with saline to remove debris. Blunt instruments should be used with a "no-touch technique" when inserting silicone finger joint implants. First the implant is firmly inserted into the intramedullary canal of the metacarpal and then by slight traction on the finger, the joint is distracted and the implant is flexed so that the distal stem can easily be inserted into the proximal phalanx. With the joint in extension, there should be no impingement of the implant. If there is, soft tissue release or bone resection has not been adequate.

Note

The implant should be handled with blunt instruments to avoid traumatizing its surface or contamination with foreign bodies. Reshaping of the implant should be avoided because modification might create mechanical weakness. Shortening of the end of the stem is permissible.

Extensor Hood Reefing

The radial portion of the sagittal fibers of each extensor hood mechanism is reefed in an overlapping fashion so that the extensor tendon is brought slightly to the radial side of the center of the joint. Three to five 4-0 Dacron sutures with a buried-knot technique are used. In certain cases of severe or long standing flexion deformity, the extensor tendons may become stretched and an extensor tendon lag may persist if not corrected. In these cases, the extensor tendon should be reefed not only transversely as described, but also longitudinally. Exceptionally, an extensor tendon tenodesis can be accomplished by suturing it to the dorsal base of the proximal phalanx through small drill holes.

Rheumatoid patients often present an inadequate first dorsal interosseous muscle or have a tendency for pronation deformity of the index finger and occasionally the middle finger; a reconstruction of the radial collateral ligament is then indicated. A distally based flap made of the collateral ligament and related structures is prepared by releasing the radial collateral ligament from the neck of the metacarpal and suturing it to the dorsoradial aspect of the neck of the metacarpal through small drill holes using 3-0 Dacron sutures. The radial capsule that has been preserved, may also be included in this repair (Fig. 4). The sutures are placed before the implant is inserted and are tied as the finger is held in supination and abduction. Note that the first dorsal interosseous muscle fibers which attach to the ligament become dorsally relocated with this repair. When the radial collateral ligament is inadequate, a palmar plate flap may be used to reconstruct this ligament (Fig. 5). This procedure has seemed to be important in correction of pronation deformities and provides some improved lateral stability for pinch. It seems to decrease flexion of the index metacarpophalangeal joint by 10 to 20 degrees by tightening the capsule, but this loss is outweighed by increased stability and a better correction of the pronation deformity.

Meticulous evaluation and correction of the balance of the capsuloligamentous and musculotendinous structures will be rewarded by improved results.

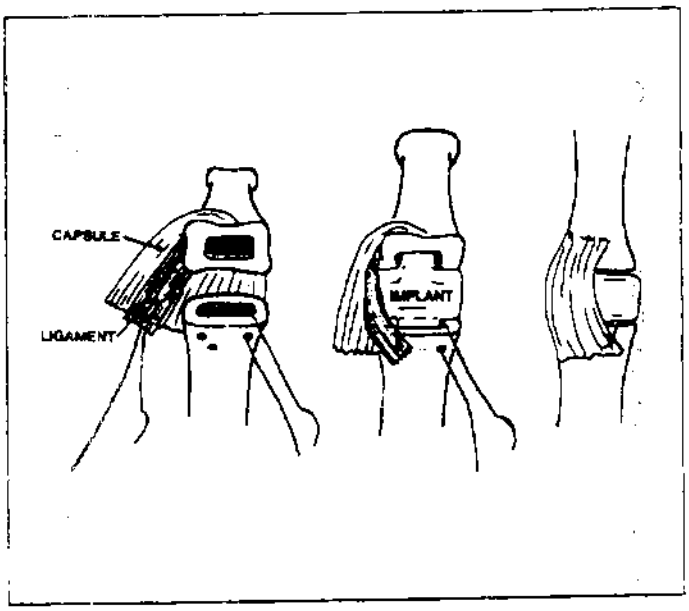


Fig. 4: *Radial collateral ligament reconstruction: A: The radial collateral ligament and joint capsule are incised from their attachment to the neck of the metacarpal. Two small drill holes (1 mm) are made on the radio-dorsal aspect and one small drill hole is made on the dorsal ulnar aspect of the neck of the metacarpal.*

B&C: *3-0 Dacron sutures are passed in the drill holes. After the implant is inserted, the radiocollateral ligament and capsule are firmly sutured to the bone.*

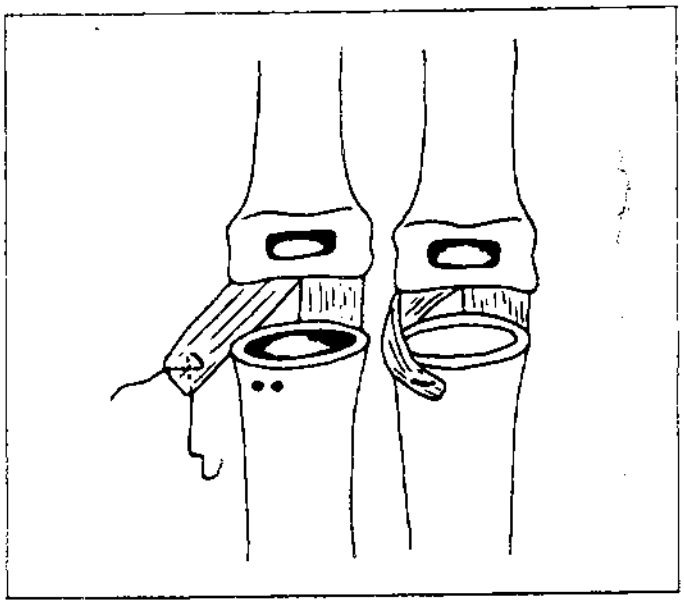


Fig. 5: *Collateral ligament reconstruction at the MP joint when the radial collateral ligament is inadequate: The palmar plate and its attachments are incised longitudinally through the middle. The sesamoid bone, if present, is resected. A distally based flap is made from the radial half of the palmar plate and collateral ligament, which are separated from the underlying intrinsic muscles and flexor tendons. This flap, 1.5 to 2 cm. in length, is attached to the radial aspect of the neck of the metacarpal through a hole in the dorsoradial cortex of the neck of the bone with nonabsorbable suture material.*

Closure and Dressing

The skin incision is closed with interrupted 5-0 nylon sutures; two small drains made from strips of silicone elastomer sheeting are inserted into the wound under the skin. A non-adherent dressing such as rayon is applied over the wound along with a Furacin or alternate gauze overlay. A voluminous hand conforming dressing is applied, gauze is placed between the fingers but not down into the clefts which might cause vascular constriction. A roll of Dacron batting is placed across the palm and is layered across the dorsal and palmar aspect of the forearm, wrist, hand and fingers. Sheet wadding or Webril is then applied. A narrow plaster splint is applied to the palmar aspect and the entire dressing is wrapped in a conforming bandage such as Kling.

Post-Operative Care and Bracing

The ideal motion would provide adequate flexion of the ulnar digits, allowing the surface of their pulps to touch the palm at the distal palmar crease for adequate grasp of smaller objects. Full flexion of the index and middle fingers is less critical for grasping as these digits are mainly used for pinch activities. A degree of spreading of the fingers into abduction, especially of the index finger, is important. Full extension at these joints is also important to perform normal hand activities and to maintain the balance of the distal joints. Chronic flexion deformity of the metacarpophalangeal joints can further aggravate hyperextension tendencies at the proximal interphalangeal joints. Pronation deformity of the index finger and occasionally the middle finger can be a problem in the rheumatoid hand and can, to some degree, be corrected in the postoperative program.

Immediate and continuous elevation of the hand and the forearm during the post-operative course is very important. The wound is usually checked on the second day and the drains removed. Swelling is generally minimal so use of the "dynamic brace" can begin on the third to fifth post-operative day. A light dressing is applied to the hand and forearm and the dynamic brace is fitted and adjusted enabling the patient to start finger movements in a protected arc. A ¼" felt pad is placed between the forearm and the brace.

Fig. 6: *An adjustable dynamic brace is placed over a slightly padded dressing after the third to fifth day. The patient is encouraged to flex joints within his limits of pain and fatigue.*

The rubber band slings are placed on the proximal phalanges to guide the alignment of the digits into the desired position (Fig. 6). The pull of the slings in the radial direction will usually require adjustment to prevent recurrent ulnar drift. The tension of the rubber bands should be tight enough to support the digits and yet loose enough to allow 70 degrees of active flexion; this is especially true of the little finger, which may have weak flexion power. The brace may require adjustment once or twice a day in the early postoperative course. Joint motion is measured with a goniometer and recorded.

The thumb outrigger is usually applied in all cases because of the tendency for the patient to bring the thumb over the fingers on flexion. This movement should be avoided because the pressure applied by the thumb to the index finger would be in the ulnar direction, thus aggravating the tendency toward ulnar drift deformity.

If there is a tendency toward medial rotation (pronation) of the metacarpophalangeal joint of the index or middle fingers, additional outrigger bars are applied to provide a supinatory force to the joint.

The extension portion of the brace is worn continuously day and night for the first 3 weeks, alternating with specific flexion exercises. The exercises are started 3 days after surgery. Exceptionally, if there is severe flexor weakness of the little finger with adequate extension, the extensor slings can be removed during the exercise periods.

During the second and third weeks, the extension portion of the brace is also worn continuously day and night. If there is severe flexor weakness and good extension, the extensor sling can be removed 1 to 2 hours a day to achieve greater active flexion of the metacarpophalangeal joints. The joints have a tendency to tighten up in the second week postoperatively. The patient is encouraged to flex his joints within his limits of pain and fatigue.

Patients who have normal proximal interphalangeal joints frequently will not gain the full expected motion at the metacarpophalangeal joint after arthroplasty because they tend to flex the proximal interphalangeal joint during their exercise program and thus relatively immobilize their metacarpophalangeal joints. To gain active motion of the metacarpophalangeal joints in these patients, we occasionally will tape small, padded aluminum splints on the dorsum of the proximal interphalangeal joints for the first three or four weeks after surgery which encourages the patient to localize all flexion force at the metacarpophalangeal joint.

At 3 weeks any residual flexor weakness should be energetically treated. The flexion cuff may be worn 1 to 2 hours twice a day to flex the metacarpophalangeal joints passively in some cases of flexor weakness. As this cuff is used, the figure eight elbow strap should be applied to prevent distal migration of the brace (Fig. 7). Other traction devices have also been designed to improve flexion in presence of adequate extension.

Fig. 7: *The flexion cuff may be used intermittently to assist flexion movements. Proper use of bracing is essential to insure an adequate range of motion.*

*Pope Brace Co., Greenwood, South Carolina

The extension portion of the brace is usually worn at night only, starting on the fourth postoperative week for another 3 weeks. In a few cases where there is a persistent extensor lag or a tendency for flexion contracture or deviation of the digits, continued part-time support by the use of the brace must be prescribed for several more weeks or even months. The patient should follow a continued exercise and stretching program for 3 months postoperatively to maintain the movement obtained in the earlier phase. After this time the final range of motion will have been established.

This most important rehabilitation program has been thoroughly described in previous publications and should be faithfully followed to obtain the ideal result[42](Fig. 8).

Fig. 8A: *Preoperative radiogram showing severe and typical deformities in a rheumatoid hand.*

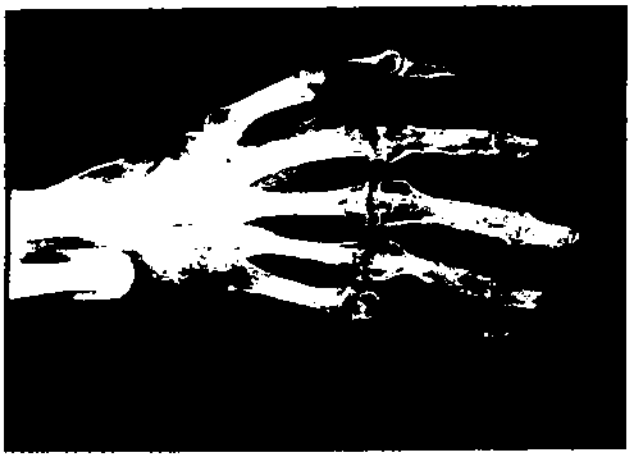


Fig. 8B: *Radiogram 4 years after implant arthroplasty of all MP joints and of the distal radioulnar joint. Note the excellent correction of deformities and acceptance of the implants.*

The Proximal Interphalangeal Joint

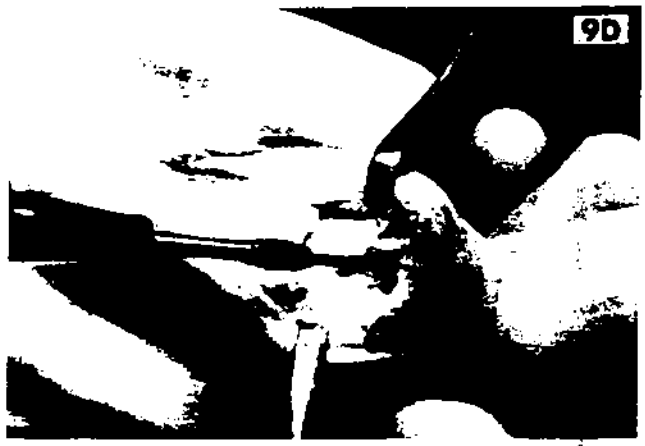
Indications

Rheumatoid, degenerative or post-traumatic disabilities with:

1. Destroyed or subluxated joints.
2. Stiffened joints in which a soft tissue release alone would be adequate.

Surgical Technique

Technique for a stiff PIP joint without collapse deformity (Fig. 9).



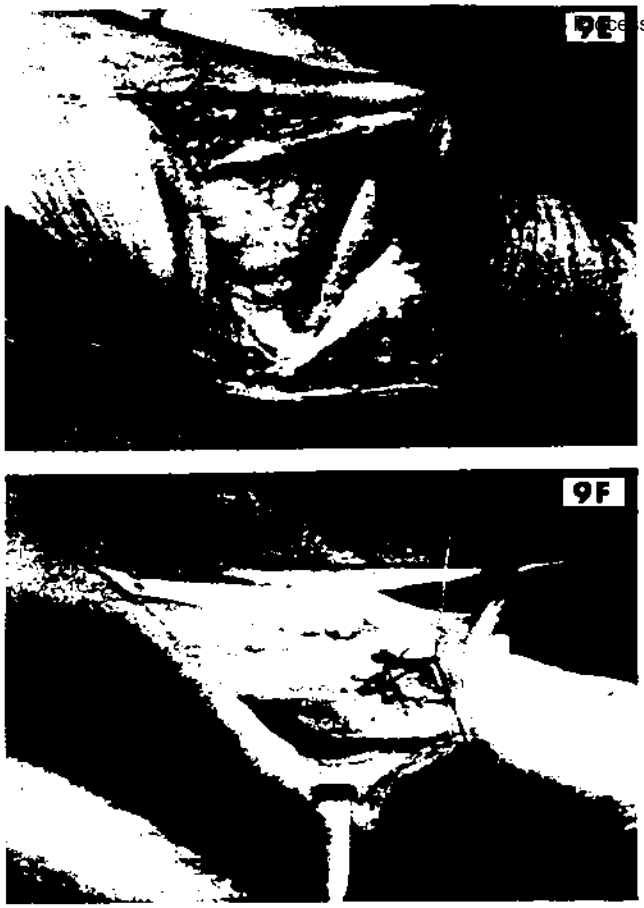


Fig. 9 A-F: **Technique for Implant Arthroplasty in a Stiff Nondeformed Arthritic Joint: A:** *The longitudinal "S" shaped incision is made over the dorsum of the PIP joint.* **B:** *The extensor mechanism is incised longitudinally and proximally from the base of the middle phalanx. Care is taken to maintain tendon insertion on the base of the middle phalanx.* **C:** *The split extensor tendon is retracted laterally and the head of the proximal phalanx is exposed. Using an air drill the head of the proximal phalanx is sectioned through the neck and removed. If the joint is tightly contracted, the bone may have to be removed piecemeal before the tendon can be safely retracted.* **D:** *To prepare the intramedullary canal a special bur with a smooth tip extension is used to avoid perforation through the cortex of the phalanx.* **E:** *A blue colored sizing unit is used to determine correct implant size. Sizes 0 through 4 are usually used for PIP arthroplasty. Implant in place with the finger in extension. Proper bone removal and soft tissue release must be done so that on extension there is enough space without impingement on the midsection of the implant.* **F:** *Using an inverted knot technique the extensor mechanism is reapproximated with 3-0 Dacron sutures. Arthroplasty for boutonniere and swan-neck deformities usually requires an individualized tendon reconstruction.*

Incision

A gentle "S" or preferrably "C" shaped incision is made over the dorsum of the joint so that the skin suture line does not lie directly over the tendon repair. In the little and index fingers, the incision is placed away from the presenting surface. The dorsal veins are respected. If associated flexor tendon surgery is also indicated, a mid-lateral incision or palmar incision is used. This allows accessibility to both the joint and the tendon.

Exposure

The extensor mechanism is exposed by sharp and blunt dissection avoiding injury to its surface. The central tendon is identified and incised longitudinally in a proximal fashion from its insertion at the base of the middle phalanx through the distal two-thirds of the proximal phalanx. In flexible deformities of the PIP joint, the extensor mechanism can be gently dislocated palmarward as the joint is flexed. The collateral ligaments are left intact when possible. If they are incised for joint exposure, they should be reattached. The insertion of each half of the central tendon into the middle phalanx should not be disturbed. However, in hypertrophic osteoarthritic joints, it may be necessary to section this attachment of the central tendon to excise bony spurs. The tendon is later reattached to the bone with a suture passed through small drill holes (1mm) made in the base of the middle phalanx. If the joint is contracted, the extensor mechanism cannot be readily dislocated and therefore the head of the proximal phalanx may be excised first by cutting it transversely at the neck with an air drill and then removing it piecemeal or it can be removed with the burring tool of the air drill.

Joint Release

Adequate release of the joint is essential for good results. If the joint is severely contracted, it may be released by removing bone from the proximal and middle phalanges. If this is inadequate, the palmar plate and collateral ligaments may be incised at their proximal insertion. However, the collateral ligaments should be reattached in a lengthened position passing the sutures through small drill holes (1mm) made in the dorsal aspect of the neck of the proximal phalanx (Fig. 10).

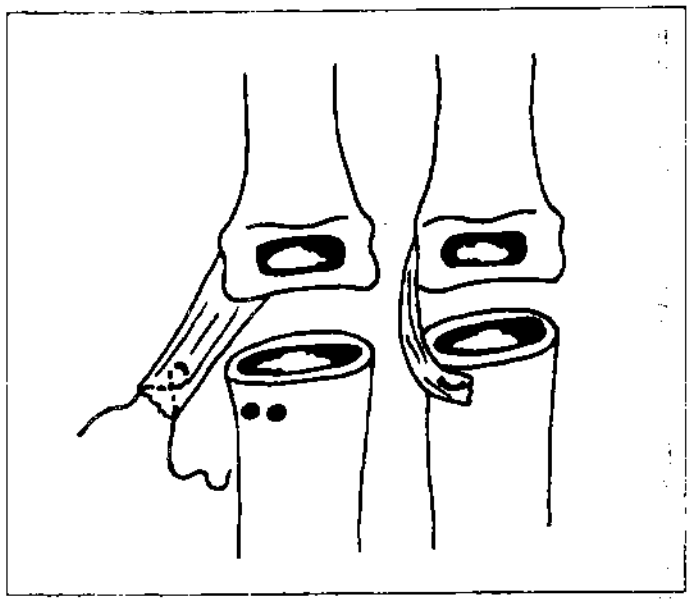


Fig. 10: *Technique for reattachment of the collateral ligament of the proximal interphalangeal joint to the neck of the proximal phalanx passing 4-0 Dacron sutures through two one millimeter drill holes made in the dorsal aspect of the neck of the proximal phalanx.*

A radial collateral ligament can be reconstructed in certain cases requiring correction of ulnar deviation or cases of increased radial instability as in the index finger. A distally based flap made of the radial collateral and accessory collateral ligaments is prepared. The flap is attached through a small drill hole to the radial aspect of the neck of the proximal phalanx, using nonabsorbable sutures. This procedure seems to limit flexion of the proximal interphalangeal joint slightly but can be important in the cases mentioned earlier.

Bone Preparation

After resecting the head of the proximal phalanx at the metaphyseal flare with a rongeur or on a side cutting bur, the intramedullary canal is prepared to receive the implant stem. It's first penetrated with a thin broach, then reamed into a rectangular shape to accept the implant stem with an air drill and smooth leader point bur. The intramedullary canal of the middle phalanx is prepared in a similar fashion. The base of the middle phalanx is usually not resected except in cases of severe joint contracture as mentioned above; osteophytes are trimmed if present.

Implant Section and Insertion

Using the sizing set, the largest acceptable implant is selected (sizes 0 through 4 and most often size 1). The midsection of the implant should seat well against the adjacent surfaces of the phalanges. With the joint in extension, there must be no impingement of the implant midsection by the bone ends; if this fit is not ideal there should be additional bone resection and/or soft tissue release. The bone ends should be smoothened to avoid sharp edges that could cut into the implant.

Prior to the insertion of the selected implant, the required sutures are placed in the drill holes made in the proximal phalanx for reconstruction of the collateral ligament system and, in the base of the middle phalanx for reconstruction of the central tendon.

Following wound irrigation with saline, the implant is inserted in a similar fashion as that described for the metacarpophalangeal joint.

Sizing Set

A reuseable sizing set containing one of each size implant is available to assist proper size determination during surgery. Numerically marked and blue in color for easy identification, the sizing set is supplied non-sterile and is not suitable for implantation. For use, follow instructions under section, "To Clean and Resterilize."

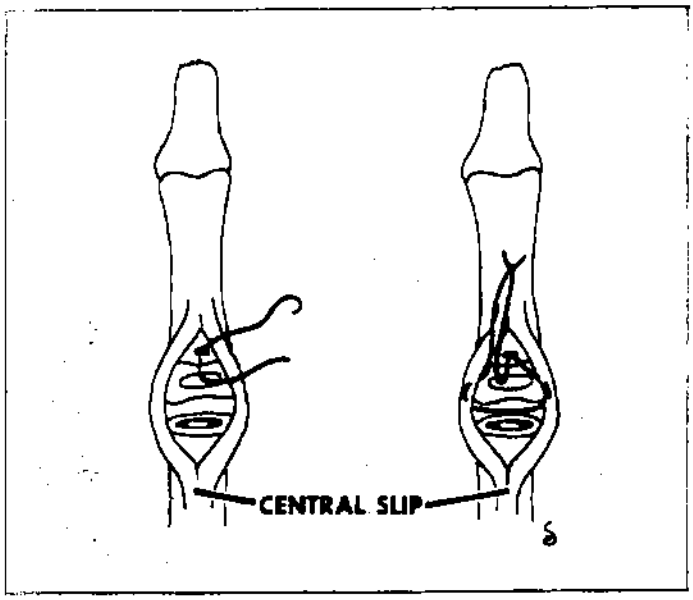


Fig. 11: *Technique for repair and reattachment of the central slip to the middle phalanx passing a 3-0 Dacron suture through a one millimeter drill hole made in the dorsal aspect of the middle phalanx.*

Closure

If sectioned, the collateral ligament is firmly reattached to the proximal phalanx using 4-0 Dacron sutures previously passed through small drill holes in the bone. The radial collateral ligament reconstruction, if used, is similarly secured to the proximal phalanx. The tension of the repair must be sufficient to obtain good lateral stability and alignment and to allow passive motion of the joint from full extension to 90 degrees of flexion.

The halves of the incised central tendon are drawn together and sutured to the base of the middle phalanx with a 3-0 Dacron suture previously passed through a drill hole in the bone (Fig. 11). The suture to the bone of the central tendon is especially important if the central tendon has been elongated, ruptured or divided. Wherever possible, tendons or ligaments must be sutured to bone to obtain a firm fixation.

At the end of the procedure, full passive range of motion should be present and slight traction on the joint should show an adequate joint space. The most common causes of failure of extension, are, inadequate bone removal and soft tissue release, failure to obtain proper tension of the central slip and scar formation.

The skin is reapproximated with 5-0 Nylon and small silicone rubber strips are used as drains. The hand dressing is applied similarly as that described for the metacarpophalangeal joint arthroplasty.

Extensor Mechanism in Collapse Deformities

Special consideration must be given to the extensor mechanism in collapse deformities of the digits. Adjustment of the unbalanced tension of the central and lateral tendons is essential to the correction of these deformities in resection implant arthroplasty of the proximal interphalangeal joints. Simply stated, in swan-neck deformity the central tendon is relatively tight as compared to the tension of the lateral tendons, and in the boutonniere deformity the central tendon is relatively loose as compared to the tension of the lateral tendons. Readjustment of the tension of these structures is important to avoid recurrence of these collapse deformities.

Swan-Neck Deformity

In swan-neck deformity, flexor synovitis is treated first and the hyperextension of the proximal interphalangeal joint is corrected through readjustment of the joint system. At least 10 degrees of flexion contracture of the proximal interphalangeal joint should be obtained and associated deformities of the contiguous joints should be corrected. In mild flexible deformity in weak hands, dermadesis of the proximal interphalangeal joint is indicated. In severe cases of swan-neck deformity, a fusion of the joint is preferred.

The technique for implant arthroplasty in a swan-neck deformity differs slightly from that for a nondeformed stiff proximal interphalangeal joint. The central tendon is separated from the dorsally displaced lateral tendons, which are allowed to relocate palmarward. The central tendon is step-cut transversely and dissected proximally, thereby lengthening it (Fig. 12). After insertion of the implant, the cut ends of the central tendon are reapproximated with interrupted sutures, with the knots buried. Occasionally, if the distal joint is severely flexed, it is fixed in a position of extension by an intramedullary Kirschner wire to increase the flex-

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ion force on the proximal interphalangeal joint during the early postoperative period.

A modification of the Littler procedure for the treatment of the swan-neck deformity can also be used in some moderately involved cases.

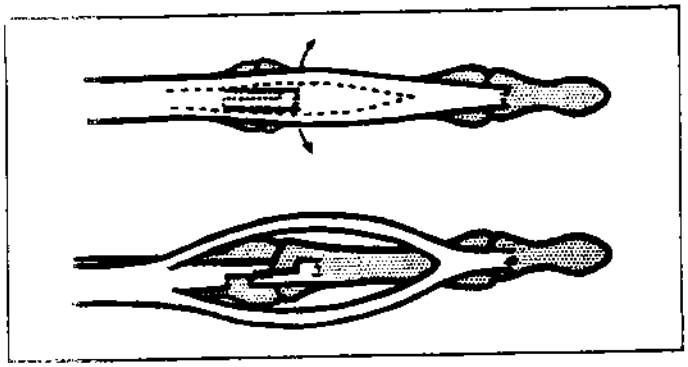

Fig. 12: *Technique for a stiff swan-neck deformity. The central tendon is separated from the dorsally displaced lateral tendons, which are allowed to relocate palmarward. The central tendon is step-cut transversely and dissected proximally, thereby lengthening it. After insertion of the implant, the cut ends of the central tendon are reapproximated with interrupted sutures, with the knots buried.*

Boutonniere Deformity

In a boutonniere deformity caused by rheumatoid arthritis, the central tendon has usually been relatively lengthened and the lateral tendons are usually displaced palmarward and the connecting fibers stretched out. Implant arthroplasty must be accompanied by reconstruction of the extensor mechanism. Two methods of reconstruction have been used. In one method the attachment of the central tendon to the base of the middle phalanx is repaired by suturing the stretched-out central tendon to the bone by means of a one millimeter drill hole in the base of the middle phalanx (Fig. 13A). The lateral tendons are released and relocated dorsally by suturing their connecting fibers or overlapping the fibers if they are redundant. In the alternative technique (Matev technique), a lateral tendon, usually the one on the radial side, is used to reconstruct the central tendon, attaching it to the insertion of the central tendon. The other lateral tendon may be reattached in a lengthened position distally (Fig. 13-B). Release of the lateral tendons may be required to correct hyperextension deformities of the distal joint if passive flexion cannot be accomplished after reconstruction. This release is usually done proximal to the insertion of the fibers of Landsmeer's ligament by sectioning the lateral tendons over the middle phalanx.

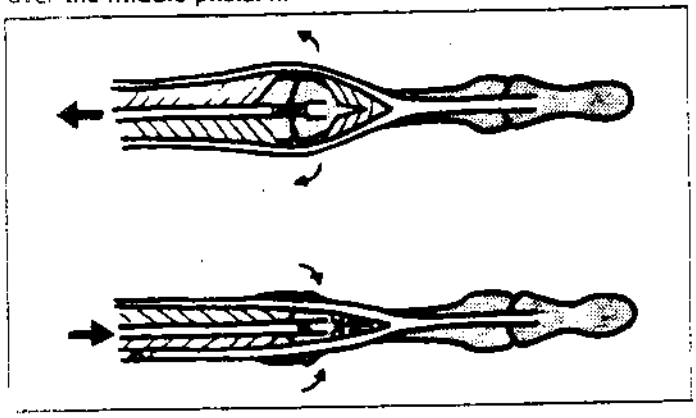

Fig. 13A: *The preferred method for repair of the extensor mechanism in boutonniere deformity. The lengthened central tendon is advanced and the lateral tendons are released and relocated dorsally by suturing their connecting fibers.*

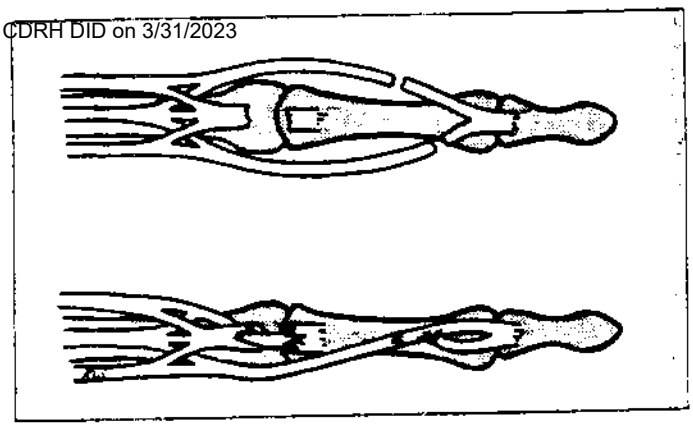

Fig. 13B: *Matev's method of repair of the extensor mechanism in a boutonniere deformity. A lateral tendon, usually on the radial side, is used to reconstruct the central tendon. The other lateral tendon is reattached in a relatively lengthened position distally.*

Post-Operative Care

The type of postoperative care depends on the situation presented.

Stiff Proximal Interphalangeal Joint

Active flexion/extension movements are started 3 to 5 days after surgery. The ideal range of motion would be full extension to 70 degrees of flexion. A small taped on padded aluminum splint to hold the digit in extension is worn mainly at night for 3 to 6 weeks after surgery depending on the degree of extensor lag present. The splint may also be applied slightly to the ulnar or radial side of the dorsum of the digit to correct any associated angulatory deformity. The exercises are performed with a variety of devices always taking care to support the metacarpophalangeal joint in extension. If necessary, after 3 weeks, passive flexion devices such as a flexor cuff or rubber band traction from a special wrist strap to finger nail hooks can be useful.

Swan-Neck Deformity

It is important in any of these tendon reconstructions for swan-neck deformities to obtain a permanent flexion contracture of the PIP joint of at least 10 degrees. For approximately 10 days the proximal interphalangeal joint is held in 10 to 20 degrees of flexion with a small, taped-on aluminum splint. Active movements are then begun and encouraged, and flexion exercises are performed while the proximal phalanx is supported. The flexor splint is still worn on a part time basis. After 2 weeks, gentle passive flexion exercises of the proximal interphalangeal joint are started if necessary. Hyperextension of the reconstructed joints must be avoided in the first three to six weeks so that a slight flexion contracture will develop and correction of the hyperextension deformity will be maintained.

Boutonniere Deformity

The proximal interphalangeal joint is maintained in extension for 3 to 6 weeks with a dorsal taped on padded aluminum splint. The distal joint should be allowed to flex freely. Active flexion/extension exercises are started from 10 to 14 days after surgery in alternation with the use of the extension splint at night; night splinting should be continued until the joint is stable and this may require 10 weeks.

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Fig. 14A: *Long-standing dislocation of proximal interphalangeal joint of little finger in young athletic man.* B: *Roentgenogram showing excellent position and tolerance of implant 3 years after surgery.* C and D: *Patient recovered full use of hand with excellent flexion and extension.*

The Distal Interphalangeal Joint

Indications

Degenerative or posttraumatic disabilities when preservation of joint motion is desired and, the following conditions are present:

1. Destroyed and painful joints
2. Stiffened joints in which soft tissue release alone would be inadequate
3. There should be adequate bone, ligamentous integrity, a potential tendon system and adequate skin and neurovascular system.

Surgical Technique

A "Y" shaped incision is made over the distal phalanx approximately 3mm from the base of the nail (Fig. 15-A). The skin flaps are carefully dissected as to avoid injury to the underlying extensor tendon and the dorsal nerves and vessels. The extensor tendon is incised transversely one centimeter proximal to the distal interphalangeal joint and carefully elevated from the bone; its distal insertion on the distal phalanx is preserved (Fig. 15-B). The dorsal capsule is incised transversely and the joint surfaces are exposed by sharply flexing the distal phalanx. In some cases, the dorsal half of the collateral ligaments are incised to facilitate the exposure; however, these ligaments are always retained to preserve lateral stability. With a side cutting or a rounded bur of the air drill, enough bone is removed from the base of the distal phalanx and the head of the middle phalanx to obtain a sufficient joint space to accomodate the midsection of the implant without bony impingement as the joint is fully extended. Lateral and palmar osteophytes or bony irregularities are carefully smoothed with a rounded bur. The intramedullary canals are penetrated first with a thin broach: their preparation in a rectangular shape to accept the implant stems is carefully completed with the special leader point bur of the air drill. The correct size implant, usually sizes 0, 1 or 2, is then selected. The cut bone ends must be smoothened.

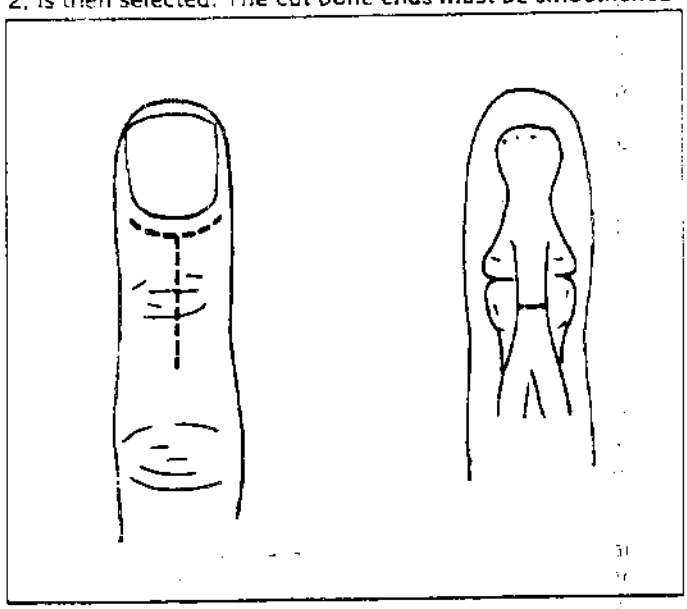

Fig. 15: *Technique for implant arthroplasty of the distal interphalangeal joint:*
Fig. 15A: *A "Y" shaped incision is made 3 mm. from the base of the nail and the skin flaps are elevated preserving the underlying tendon and the dorsal nerves and veins.*
Fig. 15B: *the extensor tendon is incised transversely one centimer proximal to the distal interphalangeal joint and carefully elevated from the bone.*

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Following irrigation of the wound with saline, the proximal implant stem is inserted in the intramedullary canal of the middle phalanx with a no touch technique and atraumatic instruments. As the joint is flexed, and slightly distracted, the distal stem is fitted in the distal phalanx. Perfect position of the implant is assured by gently pushing it in position with a rounded instrument as the joint is in full extension. The extensor tendon is then repaired with a Bunnel type "figure of 8" suture using 4-0 Dacron sutures inverting the knots. A few additional 5-0 Dexon sutures are placed to complete the reapproximation of the tendon ends. This tendon is easily damaged and must be handled with care throughout the procedure. The skin is meticulously reapproximated with interrupted 6-0 nylon sutures. Silicone strip drains are inserted subcutaneously. Following application of a non-adherent dressing, the distal joint is maintained in full extension with a dorsal padded aluminum splint. Occasionally a small 0.035" Kirschner wire can be carefully introduced through the distal pulp into the flexor tendon sheath to maintain full extension of the distal joint during the first 2 to 3 days of postoperative swelling: the proximal interphalangeal joint is not transgressed by this fixation.

The postoperative care is similar to that of a mallet finger. Using a dorsal half inch padded taped on aluminum splint, the distal joint and the proximal interphalangeal joint are maintained in full extension for the first 2 weeks. Following this, the distal joint only is immobilized in extension and the proximal interphalangeal joint is allowed to flex freely. After this time, use of the digit is resumed. Active extension and flexion exercises are prescribed. Rough activity is not recommended for these or the other finger joint arthroplasties.

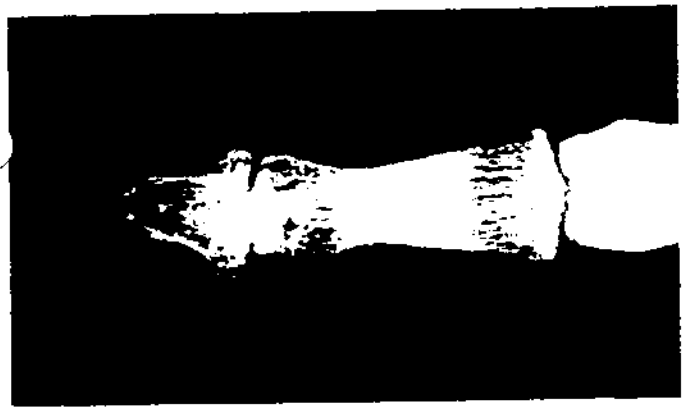


Fig. 16A: *Post traumatic painful arthritis of distal interphalangeal joint of 3rd digit of a 35 year old man who desired a surgical procedure which would provide movement as well as pain relief.*

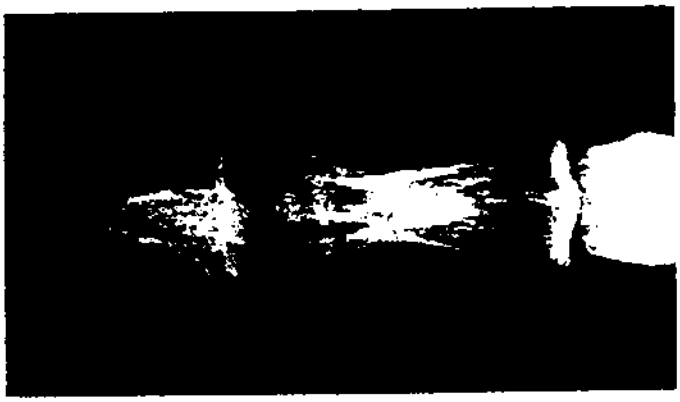


Fig. 16B: *Post-operative silicone flexible hinged implant resection arthroplasty of distal interphalangeal joint. Patient has a stable, painfree, functional joint with range of motion of -5° to 40°. This method offers an alternative to arthrodesis in selected cases.*

To Clean and Resterilize

The SILASTIC® Finger Joint Implant H.P. (Swanson Design) has been sterilized.

However in the event that the implant is contaminated prior to use and resterilization is indicated, the following sequential steps to clean and resterilize are recommended:

1. Scrub the implant thoroughly with a clean, soft-bristled brush in a hot water-soap solution to remove possible surface contaminants. Use a non-oily mild soap such as Ivory Flakes or Ivory bar soap. Do not use synthetic detergents or oil based soaps, as these soaps may be absorbed and subsequently leach out to cause a tissue reaction.
2. Rinse thoroughly with distilled water.
3. Wrap in a lint-free cloth or place on a clean open tray, and autoclave by one of the following methods:
   a. High speed instrument sterilizer - 10 minutes at 270°F (132°C).
   b. Standard gravity sterilizer - 30 minutes at 250°F (121°C).
   c. Prevacuum high temperature sterilizer - either 10 minutes at 270°F (132°C), or 30 minutes at 250°F (121°C).

Caution

Evidence suggests that repeated sterilization may affect the physical characteristics of the implant. Accordingly, resterilization in excess of three times is contraindicated.

The foregoing statement *does not* apply to the blue sizers where ultimate physical properties are medically irrelevant.

NOTE: Gas sterilization is not recommended for silicone rubber elastomers. Should this be the only available method of sterilization, it is essential to avoid inserting these implants within 10 days of the gas sterilization: otherwise severe tissue reaction might ensue from the vivo release of ethylene oxide.

Caution

Federal (United States) law limits this device to sale by or on the order of a physician.

A Clinical Case History

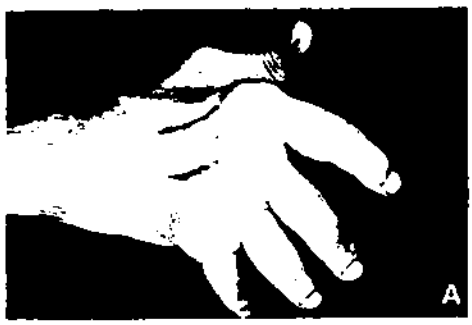
This 58 year old patient with an eight year history of Rheumatoid Arthritis had severe loss of function of the hands. He had marked ulnar drift and subluxation of the MP joints with extensor tendon subluxation and also Boutonniere deformity of the thumb. The patient had implant resection arthroplasty of the MP joints of the fingers and thumb. Postoperatively he was pain free and very pleased with his functional and cosmetic result. He was able to return to all his previous activities including playing the violin, which he had not been able to do since the onset of his disease.

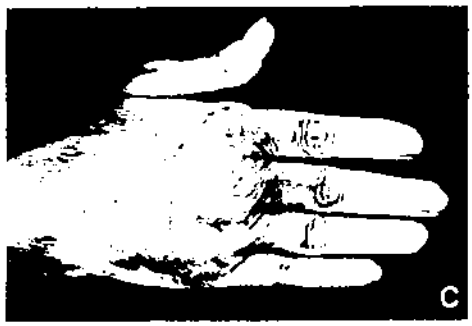
Fig: A, B; *Preoperative clinical views.*

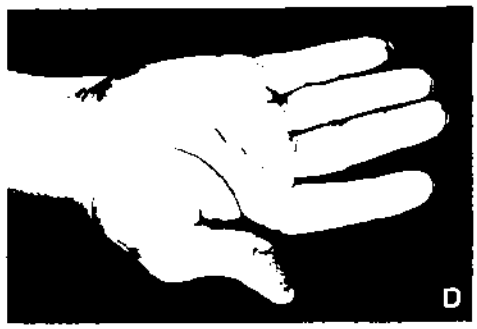
Fig: C, D, E, F; *Postoperative clinical views. Note the good correction of the deformities and the excellent range of flexion and extension of the digits.*

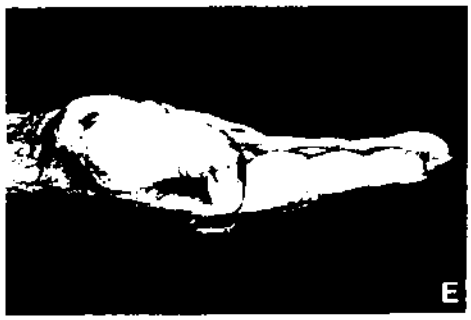
Fig: G; *Preoperative roentgenogram.*

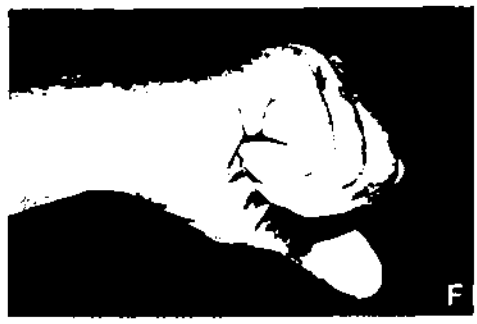
Fig: H; *Postoperative roentgenogram showing correction of the deformities and good tolerance of the implants.*











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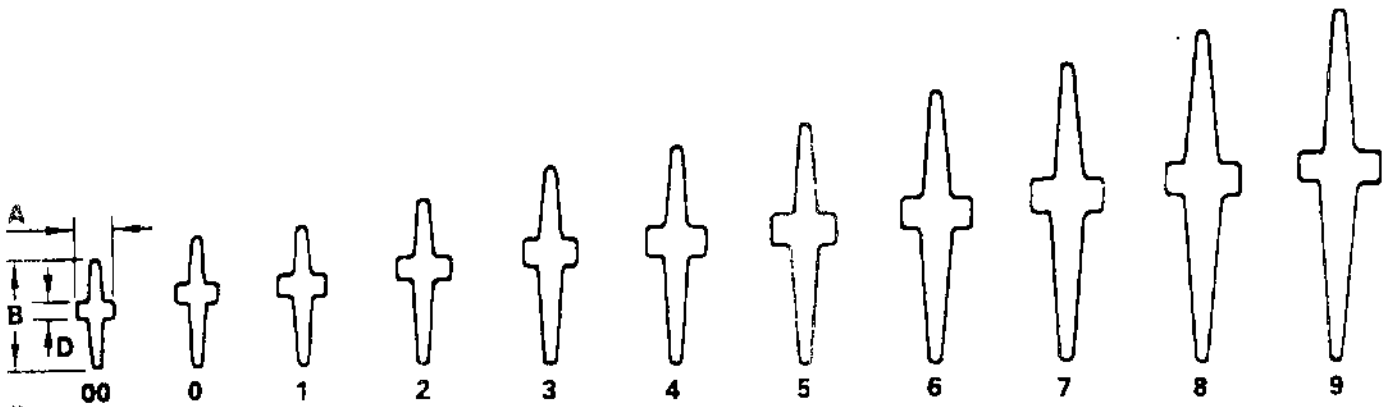
Typical Dimensions



	00	0	1	2	3	4	5	6	7	8	9
A	.31 (7.9)	.37 (9.4)	.45 (11.4)	.48 (12.2)	.51 (13.0)	.54 (13.7)	.58 (14.7)	.61 (15.5)	.64 (16.3)	.68 (17.3)	.72 (18.3)
B	1.00 (25.4)	1.16 (29.6)	1.25 (31.8)	1.45 (36.8)	1.70 (43.2)	1.94 (49.3)	2.19 (55.6)	2.44 (62.0)	2.68 (68.1)	2.93 (74.4)	3.17 (80.5)
C	.13 (3.3)	.16 (4.1)	.19 (4.8)	.22 (5.6)	.25 (6.4)	.28 (7.1)	.32 (8.1)	.33 (8.4)	.36 (9.1)	.37 (9.4)	.39 (9.9)
D	.12 (3.0)	.14 (3.6)	.18 (4.6)	.20 (5.1)	.20 (5.1)	.215 (5.46)	.22 (5.6)	.23 (5.8)	.25 (6.4)	.26 (6.6)	.27 (6.9)

Dimensions—inches
(Millimeters)

How Supplied

The SILASTIC® Finger Joint Implant H.P. (Swanson Design) has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
1 box	One each, Size 00	1470-0020
1 box	One each, Size 0	1470-0010
1 box	One each, Size 1	1470-0001
1 box	One each, Size 2	1470-0002
1 box	One each, Size 3	1470-0003
1 box	One each, Size 4	1470-0004
1 box	One each, Size 5	1470-0005
1 box	One each, Size 6	1470-0006
1 box	One each, Size 7	1470-0007
1 box	One each, Size 8	1470-0008
1 box	One each, Size 9	1470-0009
1 sizing set	One each, Sizes 00, 0, 1, 2, 3, 4, 5, 6, 7, 8, 9. Numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	1480-0000

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DOW CORNING
[redacted]
WRIGHT

P.O. Box 100 Arlington, TN 38002 901-867-9971

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Appendix D
Drawing

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date 3-15-94

From Mark Wright , Clerk-Typist, (CDRH, ODE, DMC) HFZ-401

Subject Premarket Notification Number(s) K931581|A1

To Division Director

The attached information has been received by the 510(K) Document Mail Center (DMC), on the above referenced 510(K) file(s). Since a final decision has been rendered, the record is officially closed.

Please review the documents(s) and return to DMC directed to my attention, with one of the statements checked below. Feel free to note any additional comments below. If there are any questions, please contact me on 594-3027.

✓ Information does not change status of 510(K); no other action required by DMC; please file. The Division should prepare a confirmation letter - example attached.

____ Additional information requires a new 510(K); please process.

____ Requests CLIA Categorization

Comments:

This information should be returned by 3-29-94.

Reviewed by: Mark N Melkerson

Panel: OR

Date: 3/15/94

Attachment

101

~~107~~ 1

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Re: Device Name
Dated:
Received:

Dear _____:

We have reviewed the information dated _____, regarding the 510(k) notification (K_____) previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

If you have any questions regarding the contents of this letter, please contact _____ at (301) 427-____.

Sincerely yours,

Division Director
Division of _____
Office of Device Evaluation
Center for Devices and
Radiological Health

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Facsimile Cover Sheet

To: Mark N. Melkerson
Company: DGRD/Orthopedic Branch
Phone: 301-594-2036
Fax: 301-594-2358

From: Louise M. Focht
Company: Sutter Corporation
Phone: 619-569-8148
Fax: 619-279-8249

Date: 03/08/94
Pages including this cover page: 4

Comments:

File K931588

Please let me know if there are additional questions or any information submitted is unclear. The original copy of the letter will be delivered Thursday March 10.

Thanks,

Louise Focht

103 104 3

SUTTER CORPORATION
SMALL JOINT ORTHOPAEDICS

9425 CHESAPEAKE DRIVE
SAN DIEGO, CA 92123
TEL. (800) 854-2216
FAX (619) 279-8249

March 8, 1994

510 (k) Number: K931588

Food and Drug Administration
510 (k) Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Attn.: Mark N. Melkerson DGRD/Orthopedic Branch

This document has been sent by FAX March 8, 1994 and a follow-up copy has been sent to be delivered March 10, 1994.

Dear Mr. Melkerson:

Thank you for your FAX and reference to the draft guidance for the preparation of premarket notification applications for orthopedic devices. The following information is provided in response to your questions regarding Sterilization of the Proximal Interphalangeal Joint Implant, and the information follows the outline of the draft guidance for orthopedic devices.

STERILITY INFORMATION, IMPLANT

Radiation Sterilization Method

1. Gamma Sterilization
2. Cobalt 60
3. Minimum dose 25 kGy[redacted]
4. Sterility Assurance Level 10E-6
5. Sterilization Validation according to AAMI Method 1 Routine audit is performed using AAMI Method 3B.
6. There is no claim in the labeling that the device is pyrogen-free.

For implants provided sterile the labeling is being changed to not recommend resterilization. The statement is being changed from the following:

Sterilization:

These implants are provided sterile in an undamaged package.
Warning: If either the implant or the package appears damaged, or if sterility is questioned for any reason the implant should not be used.

These devices may be removed from their package and resterilized by steam autoclaving at 270F(132C) for 15-20 minutes (fast cycle) or at 252F(121C) for 35-40 minutes (standard cycle). Ethylene oxide gas sterilization may be used but is not recommended because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer.

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Labeling for implants is being changed to the following:

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Sterilization:

These implants are provided sterile in an undamaged package.

Warning: If either the implant or the package appears damaged, or if sterility is questioned for any reason the implant should not be used. Resterilization of this product is not recommended.

STERILITY INFORMATION FOR NON-STERILE DEVICES THAT MUST BE STERILIZED PRIOR TO USE

STERILITY INFORMATION, SIZER (The sizer is used as a trial)

ETHYLENE OXIDE GAS STERILIZATION METHOD. (labeling is being changed to not recommend ethylene oxide gas sterilization, see below)

1.	Temperature	54°C ±1°C
2.	Humidity	60% ±10%
3.	Gas concentrations	6-7 psig of 12/88 Ethylene Oxide/dichlorodifuoromethane.
4.	Exposure time	4 hours
5.	Aeration cycle	18 hours

STEAM STERILIZATION METHOD

1.	Cycle	Standard Gravity
2.	Temperature	250°F (121°C)
3.	Exposure time	35-40 min.

1.	Cycle	Prevacuum
2.	Temperature	270°F (132°C)
3.	Exposure time	15-20 min.

Labeling for trials is being changed from:

Sterilization:

Instruments and sizers may be sterilized using either steam or ethylene oxide gas. Ethylene oxide gas is not recommended for silicone elastomer because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer.

Labeling for trials is being changed to:

Sterilization:

Instruments and sizers may be sterilized using steam. Ethylene oxide gas is not recommended for silicone elastomer because of the aeration time necessary to dissipate the absorbed sterilant from the silicone elastomer. The product may be resterilized using an autoclave by one of the following methods: Standard

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