# Records Processe by CDRH DID on 3/31/2023



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

Director Quality Assurance

Sutter Corporation 619-569-8148 x 2213

Enclosures:

Appendix A Proposed Labeling Appendix B Surgical Technique

ours M. Forht

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
)ate:	2/8/6-	
rom:	DMC (HFZ-401)  et: Premarket Notification Number(s): K9315-8  Division Director: OR /DCRND	×/AZ
ubjec	et: Premarket Notification Number(s): 11 / 51 5 5	
o:	Division Director.	
	The attached information has been received by the 510(k) DMG submission(s). Since a final decision has been rendered, this re-	C on the above referenced 510(k) ecord 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);  DMC; please add to image file. (Prepare K-25) THIS DOES N  OWNERSHIP. PLEASE BRING ANY TRANSFER OF OW	no other action required by the IOT APPLY TO TRANSFER OF
	Additional information requires a new 510(k); howev incomplete: (Noitify company to submit a new 510(k);[Prepare	er, the information submitted is e the K30 Letter on the LAN]
	No response necessary (e.g., hard copy of fax for the tr 510(k) statement, change of address, phone number, or fax nu	ruthful and accuracy statement, mber).
	CLIA CATEGORIZATION refers to laboratory test syste Division of Clinical Laboratory Devices (HFZ-440	m devices reviewed by the
	Information requires a CLIA CATEGORIZATION; the ast the original 510(k) or may change as a result of the addition letter)	he complexity may remain the same nal information (Prepare a CAT
	Additional information requires a CLIA CATEGORIZ. submitted is incomplete; (call or fax firm)	ATION; however, the information
	No response necessary	
	This information should be returned to the DMC within 10 within memorandum.	orking days from the date of this
	Reviewed by:	
	Date: Quo. ccm - 2/25/09	ζ
D	oraft #2 : 9/8/99	Dyr 1
D	raft #3: 1/3/00	2)

### Records Processed by CDRH DID on 3/31/2023 DEPARTMENT OF HEALTH & HUMAN SERVICES

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

k812691 - Silicone Implants Re:

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.

## $Page\ 2-Mr.\ Mike\ Simpson \\ \quad \ \ \, \text{Records Processed by CDRH\ DID\ on\ 3/31/2023}$

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

Sincerely yours, Headen S Rozene

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, 14<sup>th</sup> 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
Musculuskektal Clinical and Regulatory Advisers, LLC
505 Park Ave., 14th Vloor
New York, New York 10022
(212) 583-0250 x148
(212) 750 2112

### CONFIDENTIALITY NOTE

This electronic message contains privileged information intended only for the use of the individual or entity named above. If the reader of this electronic message is not the intended recipient or the employee or agent responsible for delivering it to the intended recipient, you are hereby notified that any forwarding, storing, printing, dissemination or copying of this electronic message is strictly prohibited and may be unlawful.. If you have received this electronic message in error, please notify the sender immediately by telephone at 212-583-0250 ext. 148 or by reply email and delete this message immediately. Thank you



1(931588/A-

**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:

- 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.
- A complete copy of all product regulatory files has been provided to Small Bone Innovations, LLC by Avanta LLC.
- 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.
- 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, 14<sup>th</sup> Floor New York, NY 10022 (212) 583-0250 ext. 148 dguthner@mcrallc.com

HX

resident) Small Bone Innovations

npson

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

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
	(0)(4)		
Braun-Cutter CMC (Avanta CMC)	Total Trapezio-Metacarpal Pros.	PMA	P960053
uHead	Ulnar Head Implant	510K	K982268
011000	Ulnar Head Implant	510K	K010786
rHead	Radial Head Implant	510K	K982288
111000	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
Externor Fixator	External Fixator	510K	K981716
GRS Carpal Tunnel	Anatomically Guided CT Release	510K	K943873
Carpal Fusion	Carpal Fusion Plating System	510K	K030881

CDRH PRE	DEPARTMENT OF HEALTH AND FOOD AND DRUG ADM MARKET REVIEW SU	INISTRATION		EET	Form Approva OMB No. 9010 Expiration Dat See OMB Stat	0-0120 e: Septemb	
Date of Submission	User Fee Payment				ssion Document		
01/31/2005							
SECTION A		TYPE OF SI					
PMA Original Submission Premarket Report Modular Submission Amendment Report Report Amendment Licensing Agreement	PMA & HDE Supplement Regular (120 day) Special Panel Track (PMA Only) 30-day Supplement 30-day Notice 135-day Supplement Real-time Review	Original PD Notice of C Amendmen	OP Completion	510(k Original Sub Traditiona Special Abbreviate section I, I Additional In Third Party	mission: I ed (Complete Page 5)	Pre-510( Pre-IDE Pre-PMA Pre-PDP Day 100 Agreeme	eting (K) Meeting Meeting A Meeting P Meeting Meeting Meeting Meeting ent Meeting nation Meeting
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Original Submission Amendment Supplement	Humanitarian Device Exemption (HDE)  Original Submission Amendment Supplement Report Report Amendment	Original Su		Class III Desi (De Nor Original Sub	ignation vo) mission	513(g) Other	e submission):
Have you used or cited Star SECTION B Company / Institution Name Small Bone Innovations,	SUBN	Yes No	CANT OR SP	please complete a ONSOR Registration Numb	na a de la constanta de la con		
Division Name (if applicable)	(4)			(including area co 83-9700	de)		
Street Address	- 184		FAX Number (i	including area code	)		
505 Park Avenue, 14th F	Floor		( 212 ) 8	26-9509			
City			State / Province	е	ZIP/Postal Co	ode Cou	untry
New York			NY		10022	US	SA .
Contact Name	100	*******					
Michael Simpson							
Contact Title	- Herricanus		Contact E-mail	Address		1. 8. 93	10 500 %
President			msimpson@				
SECTION C Company / Institution Name	APPLICATION CORRES	SPONDENT (e.	g., consultan	t, if different fro	om above)		
Musculoskeletal Clinical	Regulatory Advisers, LLC.						
Division Name (if applicable)				r (including area co			
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New York			NY	A.	10022		SA
Contact Name						1.5	
Donald W. Guthner							
Contact Title		-3WW	Contact E-mail	Address			
Vice President			dguthner@r	mcrallc.com			
FORM FDA 3514 (12/03)	THE THE PERSON OF THE PERSON O		1		*** **	PAGE	E 1 OF 5 PAGES

PSC Media Arts (301) 443-1090 EF

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:	Change in design, component, or specification:  Software / Hardware Color Additive Material Specifications Other (specify below)	Location change:  Manufacturer Sterilizer Packager  Report Submission: Annual or Periodic
Manufacturing Sterifization Packaging Other (specify below)  Response to FDA correspondence:  Other Reason (specify):  Pection D2  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	Labeling change: Indications Instructions Performance Shelf Life Trade Name	Post-approval Study Adverse Reaction Device Defect Amendment  Change in Ownership
	Other (specify below)	Change in Correspondent Change of Applicant Address
	Correspondent / Applicant	Conditional Approval
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	Design / Device Informed Consent Manufacturer Manufacturing Process Protocol - Feasibility Protocol - Other Sponsor  Report submission:	Deemed Approved Deficient Final Report Deficient Progress Report Deficient Investigator Report Disapproval Request Extension of Time to Respond to FDA Request Meeting Request Hearing
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	Design / Device Informed Consent Manufacturer Manufacturing Process Protocol - Feasibility Protocol - Other Sponsor	Deemed Approved Deficient Final Report Deficient Progress Report Deficient Investigator Report Disapproval Request Extension of Time to Respond to FDA Request Meeting
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	Design / Device Informed Consent Manufacturer Manufacturing Process Protocol - Feasibility Protocol - Other Sponsor  Report submission: Current Investigator Annual Progress Report Site Waiver Report	Deemed Approved Deficient Final Report Deficient Progress Report Deficient Investigator Report Disapproval Request Extension of Time to Respond to FDA Request Meeting
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	2	3	4			safety and effectiveness information 510 (k) summary attached
	6	7	8			510 (k) statement
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SECTION G		JCT CLASSIFICATION			PPLIC	
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FORM FDA 3514 (12/03)

PAGE 4 OF 5 PAGES

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

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

7

# A V A N T A

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, 14<sup>th</sup> 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
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Braun-Cutter CMC (Avanta			1
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
	Modification to Radial Head		
rHead Recon	Implant	510K	K023604
Wrist	Wrist Implant	510K	K021589
	Distal Radius Fracture Fixation		
SCS Dorsal Plate	Plate	510K	K943853
	Distal Radius Fracture Fixation		0.1844.000
Dorsal Buttress	Plate	510K	K990596
	Distal Radius Fracture Fixation	E4014	1/004745
SCS Volar Plate	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.

9369A Carroll Park Drive, San Diego, CA 9212/ USA (858) \$52-8580 ((800) 778-8837 / (858) \$52-9945 (fax)

9369A Carroll Park Drive, San Diego (858) 452-85807 (800) 778-8837 (4858)

MADE IN USA

WARNING: CLEAN, NOT STERILE:



### PRODUCT INSERT LINSTRUMENTS AND SIZERS L

TAUTION: United States Federal Law restricts this device to sale by and on the older 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 instrument tation 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 comers 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.

### 110

Av opaedics Corporation warrants that this product meets the manufacturer's specifications and is free from mai, iniq 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 me 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 tow-
- els or sponges with deionized or distilled water to keep solled instruments moist prior to cleaning.

  Manually scrub with a clean, soft-bristled brush or soft cloth in mild detergent following the delergent manufacturers
- memoring scruu write a clean, sort-bristied 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. Utrasonic cleaning is recommended for instruments with internal surfaces or crevices which may be hard to clean manually.
- which may be hard to clean manually.

  -- pri neutral dealers (pt 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 pt by rinsing with water or neutralizing agent. Highly alkaline or acidic cleaners (used in some mechanical westers) 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 lodine.

  - Use of water soluble lubricants is recommended for instruments with moving parts or those intended to be assembled
- intraoperatively to another instrument.

- intraoperatively to another instrument.

  Rinse thoroughly with deionized water or distilled water.

  Ory 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
- Silicope 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° when parts have been cleaned to the instructions above. Other similar steam cytes and detailing 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% (132-135°C)
Wrapped Prevacumm Steam Sterilization 6 minutes minimum @ 270-275% (132-135°C)
Unwrapped Prevacumm Steam Sterilization 4 minutes minimum @ 270-275% (132-135°C)

For further information on the above cleaning and sterilization recom Ava. \*hopaedics, 9369A Carroll Park Dr., San Diego, CA 92121 mmendations please contact 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

MADE IN USA

WARNING CLEAN NOT STERILE



### Pale of Nation INSTRUMENTS AND SIZERS

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

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.

- 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. 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 sterifity by tearing surgic
- gloves.

  If an instrument tip becomes bent, chipped, or otherwise damaged the instrument should be replaced or repaired befor further use. Attempts to straighten bends are not advised as the metallumical integrity of the metal may be compromis in the process, and the instrument may subsequently break during use.

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 t ne of the surgical procedure.

### CLEANING INSTRUCTIONS

- New instruments are packaged clean, not sterile and should be assumed to be contaminated. Instruments must cleaned and sterifized before each use.
- For your safety, be familiar with the procedures for handling contaminated materials at your facility before follows these instructions.
- Clean instruments as soon as possible after use and avoid allowing soited instruments to dry. Immerse, use damp to
  els or sponges with deionized or distilled water to keep soiled instruments moist prior to cleaning.
- es or sponges will elevance or unsense water to expense instituteurs more prior to exempt 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 (3007/149/C maximus should be used to ald in cleaning. Ultrasonic cleaning is recommended for instruments with internal surfaces or creviwhich may be hard to clean manually.
- tral cleaners (pH 6.0-8.0) are recommended for longer life of the instruments. If acidic or alkaline solutions ptr neutral cleaners (pr 6.0-6.0) are recommendations for neutralizing the pH by rinsing with water or neutralizing age tighty 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 containing chloridates, bromides or indoine.
   Use of water soluble lubricants is recommended for instruments with moving parts or those intended to be assemble.
- 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
- Silicone elastomer sizers may develop a static charge which attracts particulate matter. Sizers may be kept in sti 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

ended 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 104 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.

Access 00071495. Wrapped Gravity Steam Sterilization 20 minutes minimum © 270-275€ (132-135°C) Wrapped Prevacumm Steam Sterilization 6 minutes minimum © 270-275€ (132-135°C) Unwrapped Prevacumm Steam Sterilization 4 minutes minimum © 270-275€ (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



### **ENGLISH**

### CAUTION

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

### DESCRIPTION

ists of plates and acrews for the treatment of the distal radius.

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

The immeded use of the distal radius fracture fixation pists 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 angula-tion or fragmentation of bone, Failed fracture fixation with or without bone graft, Ostootomy and repair of distal indius makenion with or without bone graft.

### CONTRAINDICATIONS

- Active or latent infection Octeoporosis, insufficient quantity or quality of bone/soft tissue Material sensitivity If suspected perform tests prior to surgery
- tients with mental or neurological conditions who are unwilling or expeble 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. Cereful patient selection, education and courseling by the surgeon and relabilisation cone 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 dismage can occur when the implant is subjected to increased loading associated with delayed union, norunion, or incomplete hashing.

- increased backing esosciated with delayed union, nonunion, or incomplete healing.

  Improper insertion of the device during implantation can increase the possibility of loosening and migration.

  A poor mealt may be obtained if the fracture is not properly reduced or the device is not properly assembled.

  Explantation of this device may be necessery.

  Warning: This device is not approved for screw attachment or fixation to the asterior elements (pedicles) of the cervical, thoractic, or lumbur spine, cotification in accordance with the California fixing Water and Toxic Enforcement Act of 1986 (Proposition 55): This product contains a chemically known to the State of Celifornia to cause canner, and/or birth defects and other reproductive toxicity.

### PRECAUTIONS

- NECAUTIONS

  An implant should never be reused. Previous stresses may have created imperfactions 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 steriffity is questioned for say reason, the implant should not be used. This is a single use device it is not intended for m-use. Pe-sterifization is not recommended for the implant. Pe-sterifization of the commended for the implant. Pe-sterifization of the commended instruments provided may be performed by following the instructions for use.

- instruments provided may be perceived by notice to use.

  Caution should be taken as to enoid nicking, scratching or other damage during handling of this device.

  Meliculous preparation of the implant site and selection of the proper size increase the potential for a successful outcome.

  The stainle products should be removed from its sterile package only after it is determined that the implant will be used on the patient.

### ADVERSE EVENTS

- erse events published in the literature should be reviewed prior to using
- hardest events processed if we include structure to be revenued to the service.

  Metal sensitivity reaction have been reported following metal implantation.

  Additional possible adverse events may include fracture of the bone, infection, pain and soft issue initiation.

SURGICAL PROCEDURES

A manual is available describing detailed sergical procedure for use of this device, is the responsibility of the surgeon to be familiar with the procedure before use these products. In addition, it is the responsibility of the surgeon to be familiar wirelevent publications and consult with experienced associates regarding the procure 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 tracture healing. However, due to the many biological, seechanical and physiochemical factors which street 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

EMILIZATION
The implant is provided sterile in an undamaged package. If either the implant or the package appears diamaged, expration 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

LIMIT IEO WARHANT Y
Avanta Orthopsedics Corporation warrants that this product meets the manufacturer's specifications and is fine from manufacturing defects at the limit not distinct.
warranty specifically exclude defects resulting from masse, abuse or improper hands of the product subsequent to receipt by the purchaser. Avanta Orthopsedics not warrant the outcome of the surgical procedure.

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### PACKUNGSBEILAGE

### ACHTUNG

Nach dem Bundesgesetz (Vereinigte Staaten) list dieses Medizinprodukt auf Verl Vertrieb sowie Anwendung durch einen Arzt oder in dessen Auftrag beschränkt.

### BESCHREIBUNG

Das Medizing talen Radius. dukt besteht aus einer Platte und Schrauben zur Behandlung des dis-

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

- ANWENDUNGSGEBIETE

  Das Fixierungsplattiensystem für distale Radiusfraktur dient der internen Fixierung von 
  Freikuren und Osteotomien des distalen Radius. Dazu gehören:
  Dislocierte und nicht-dislosierte Fraktur, die mit oder ohne Abwinkelung bzw.
  Fragmentierung des Knochens einbergehen karn
  Fehigeschigenen Frakturflisterung mit oder ohne Knochentransplantat

  Osteotomie und Reparatur der Fehiheilung des distalen Radius mit oder ohne

- Aktive oder attente infektion
  Osteoponee, unzureichende Menge oder Qualität des Kivochena/Welchgewebes
  Empfendichkeit gegenfüher dem Material wenn ein diesbezüglicher Verdacht
  besteht, aind vor dem chirurgischen Eingriff entsprechende Tests durchzuführen
- Sepsis

  Patienten mit mentalen oder neurologischen Erkrankungen, die nicht gewillt oder nicht fähig sind, die postoperativen Behandkungsanweisungen zu befolgen

- WARNHIWEISE (Siehe auch den Abschnitt Informationen zur Patientenberatung)

  Dieses Medizinprodukt ist für den in dieser Packungsbeilage beschriebenen Verwendungszweck bestimmt.

  Sonfällige Patienterususverkt, Edulation sowie Beratung dunch den Chirurgen und den Leistungsweibeter für Perkahlitation sind besondere wichtig.

  Starke Belastung und übermeßlige Mobilität können zum Ausfall des Medizinproduktes fimplantativensgen) führer. Die Patienten sind derauf hinzurverisen, dass ach des Ausfallnisko des Medizinproduktes bei übermäßiger Resenouschaum erhötit.

- heodzinproduktes (implantativasjeri) futnite. Die Pausent sind des Bedeisproduktes bei übermäßiger Bearspruchtung erhöht. 
  Bruch oder Beachäußigung des Medizinproduktes können eintreten, wenn das Innolarint bei verzögenter Fraktunteilung, Pseudarthrose oder unvollständiger heilung einer erhöhten Belastung ausgewetzt wird. 
  Umsechgeraßige insertion des Medizinproduktes während der Implantation kann das Lockeurunge- oder Kürgnichnersteilung eine sinnolaristes erhöhten. Ein echlechtes Ergebnie kann erdortekten sinnolaristes erhöhten. Ein schlechtes Ergebnie kann erdortekten werden, wenn die Fraktungserstett wird. Es kann erforderlich sein, dieses Implantat zu entfernen. Warnthinweis Deses Modizingerät ist nicht um Verschraubung oder Fixierung an postenioren Elementen (Pedikel) der Halswirbei-, Brustwirbei- oder Lendermytektsalie zugehässen. 
  Mittelbung gemäß dem Gesetz für sauberes Frinkwasser und zur Bekämpfung totsicher Stoffe des Bundesstates Kalifornien (Californis Safe Drinking Water and Toxic Ernorement Act) von 1896 (Proposition 65): Dieses Produkt anthält eine Chemikalien, von der/denen dems Bundesstatut von Kalifornien bekannt ist, dass sie Krebs und/oder Geburtsschäden und andere Reproduktionstoxizität erzeugt/erzeugen.

### VORSICHTSMASSNAHMEN FÜR DIE ANWENDUNG

- PRSICHTSMASSNAHMEN FÜR DIE ANWENDUNG
  Das Innigiantst darf nie wiederverwendet werden. Durch frühere
  Beanspruchungen können Störungen und Defekte entstanden sein, die zum
  Ausfalt des Mediziproduktes führen können.
  Das Innigiantat werd steril in unverwenterte Verpackung geliefert. Wenn eine
  Beschädigung des Innigiantates oder der Verpackung vorzulegen acheint, das
  Verfalldsbum Überschriften oder des Steinlikst aus eigendeinem Grund in Frage
  gestelt ist, darf das Implantat nicht verwendet werden. Bei diesem Implantat hatdelt es alch um ein Medizingrodukt für einmaßgen Gebrusch, ein ist nicht zu
  Wiederverwendung bestimmt. Die Resterilisation des Implantates wird nicht empfoblien.
- fohlen.

  Bei dem Umgang mit diesem Medizinprodukt ist darauf zu achten, dass Einkerburgen, Kratzer oder sonstige Benchänigungen vermieden werden. Sorgifätige vohrenbeitung der krompatationsstatel und die Wahl der richtigen Größe des Implantatios artichten die Erfolgsansstichten der Implantation.

  Das atenie Produkt ist erst aus seiner sterlien Verpachung zu entniehmen, wenn erstechnische als, dass das implantat bei dem Patienten eingesetzt wird.

### NEBENWIRKUNGEN

- Die in der Literatur veröffentlichten Nebenwirkungen sind vor Anwendung dieses Medizirprodukte zu beschren. Es wurde über Empfindlichkeitsreaktionen auf Metall nach Metallimplantation berichtet.
- Als weitere Nebenwirkungen können Knochenfrakturen, infektionen, Schmerzen

### CHIRURGISCHE VERFAHREN

CHINUTISISICE VENTANHEN

Ein Handbuch mit einer ganauen Beschreibung des chirungischen Verfahrens zur Arwendung dieses Modzinproduktes ist verfügbar. Der Chirung ist deiter verantwortlich, sich vor Arwendung dieses Modzinproduktes mit dem Verfahren vertraut zu machen. Der Chirung ist weiterbin dafür verantwortlich, die enschlägigen Publikationen sorgfältig zu iseen und alsch mit Berufskolagen 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 Nabenwirkungen sind dem Patienten die nachfolgenden Informationen zu vermitteh:

Die erwartete Lebensdauer dieses Medizinproduktes ist zwar achwer zu bestimmen, aber sie ist begrenzt. Die Bestandteile sind aus Frendstoffen gefertigt, die zur Erleichterung der Heitung ener potenzielen Frankrie in den Körze implantiert werden. Auf Grund einer Veitzalb biologischer, mechanischer und physikalisch-chemischer Fisitoren, die diese Medizinprodukte besinfschtiger, kann jedoch nicht erwartet werden, dass diese Bestandteine auf unbognonte Zeitsuer derselben Aktivitätsstufe und Beiastung wie der normale gesunde Knochen stand-balten.

- STERILISATION

  Dieses Prochet wird mit Ethylenoxid (EO) sterifisiert.

  Dies Implantat wird sterif in unversehrter Verpockung geliefert. Wenn das Implant oder die Verpockung beschädigt zu sein scheiner, das Verfalldatum überschift oder die Steriftät aus impendenem Grund in Frage gestellt ist, darf das Implan nicht verwendet werden. Dies ist ein Medizinprodukt für einmeligen Gebrauch

EINTUESCHHANNTE GARANTIE
Avanta Orthopaedics Corporation gewährleistet, dass dieses Produkt die Spezifikationen des Herstelters ertillt und bei der Lieferung keine Herstellungsfehler aufweist Ausgeschlössen von dieser Giranties einst appeziell Fehler, die auf nicht bestimmungsgemäßlen Gebrauch, Abusus oder unsachgemäßle Hanchtabung des Medizinproduktes nach Eingang bei dem Käufer zurückzuführen sind. Für das Ergebnis des chinunglachen Verfahrens übernimmt Avanta Orthopaedics keine

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

### FRANCAIS

### **ENCART PUBLICITAIRE**

### 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 médicin.

### DESCRIPTION

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

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 pleque pour fination de fracture du racius distai est
le fination interne cles fractures et ostéotomies du racius distai. Cela comprend

- fracture avec ou sens déplacement, comportant ou non une angulation ou une fragmentation de l'os,
- Integrmentation de l'os, l'agrimentation de fracture avec ou sans greffe osseuse, exhotomie et réparation d'un cal vicieux du radius distat avec ou sans greffe

- CONTRE-INDICATIONS

  Infliction active ou laterite
  Catécopores, quantité ou qualité inauffisante d'os/de tissu osseux
  Alorgie au matérieu en cas de suspicion d'alorgie, faire des tests avant la chrungie
  Sepsis
  Patients qui, du fait de leur était mental ou neurologique, n'ont pas le voionté suffisiante ou sont incapables de suivre les instructions relatives aux soins post-

- AVERTISSEMENTS (voir aussi la section Conseils donnés au patient)

  Ce dispositif est uniquement prévu pour fufilisation décrite dans cet encart.

  La sélection rigouneuse des patients, l'information et les conseils donnés au patient par le chrungien et le prestataire de aceins de réhabilitation sont impor-

### PRÉCAUTIONS

- RECAUTIONS

  In le faut jamais réufiliser un implant. Les tensions précédentes peuvent avoir crée des imperfections risquent d'entraîner l'échtec du dispositif.
  L'implant est fourni stérile dans un emballage soellé. Si l'implant ou l'emballage paraît endormagé, à la date de peremption est depassée ou si la stérilité est mise en cause pour une easton ou une autre, il ne laut pas utiliser l'implant. C'est un dispositif à usage unique : l'a n'est pas prévu pour la reutilisation. In n'est pas recommande 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 méticuleures du site de l'implant et la sélection de la taille d'implant appropriée augmentent le potentiel de réussite.
  Les produits séries ne docivent être enievés de leur emballage stérile que ai le décision d'implantation a été prise.

- EFFETS INDÉSIRABLES

  Les effets indésirables publés dans la littérature doivent être revus avant l'utilisation du dispositif.

  Des résortions d'allergie au métal ont été rapportées suite à l'implantation du dis-
- positif.
  Les éventuets effets indésirables aupplémentaires sont notamment : tracture osseuse, infection, douleur et irritation des tissus mous.

PROCÉDURES CHIRURGICALES

Un maruel est disponible ; il décrit en détail la procédure chirurgicale permettant of tisser l'implant. La comaissance de cette procédure est de la responsablié chirurgien. Il incombe égaliement au chirurgien de se tenir au ouvrant des publicatis pertinentes et de consulter des confréres expérimentés au sujet de la procédur

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 difficie d'estimer la durée de vie prévue de ce dispositif, mais elle n'est pas llimitée. Ces composants sont en effet fabriquée dans des matériaux étrangers au corps humain et implantée pour leur potentie de guérison des fractures. Toutefois, en raison des nomhreur facteurs biologiques, mécaniques et physio-chiniques qui effectent ces dispositifs, les composants ne pouvent pas support-er le même niveau d'activité et les mêmes charges qu'un os sain pendant une période illimitée.

Ce composant est stérissé par oxyde d'éthylère.

L'implant est tourni stérile dans un embellage sosié. Si l'emplant ou l'emballage parait endommagé, si la date de peremption est dépassée ou si la stérité est mise en cause pour une raison ou une autre, il ne feut pas utiliser l'implant. C'est un dispositif à usage unique.

### GARANTIE LIMITÉE

Avertia Orthopassics: Corporation gerantit que ce produit est conforme aux spécifi-cations du tabricant et qu'il est ivre sans défeat de fabrication. Cette gerentie exclu-spécifiquement les défeats résultant d'une utilisation incorracte ou abusive, ou d'un manipulation incorrecte du produit postérieure à la réception per l'acheteur. Avent Orthopassics ne garantit pas l'issue de la chirugie.

Représentant en Europe : Medical Products International Europe, BV Schutweg 13e 5145 NP Waalwijk, Pays-Bas 31 (0) 415 563754

### **ESPAÑOL**

PROSPECTO DEL PRODUCTO

PROSPECTO DEL PRODUCTO

accessorios metálicos para la fijación óses.

### 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

se compone de una placa y de torniflos para el tratamiento del radio

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

### NDICACIONES

- Fractura dislocada o no dislocada, con o sin angulación o fragmentación del
- hueso; Fraceso de si fijeción de una fractura, con o ain injerto deso; Carloctomía y reparación con o sin injerto deso de una consolidación deficiente del radio distal.

### CONTRAINDICACIONES

- Infracción activa o latiente: Dissoponosia, centidad o calidad insuficiente del hueso / del tejido blando; Hiparenas bladad al material en caso de sospecha, efectuar las pruebas corre-apondientes antes de la cirugla;
- Despine Pacientes con afecciones mentales o neurólógicas que no están dispuestos a seguir las instrucciones para el cuidado postoperatorio, o que no sean capaces de inscerto.

- ADVERTENCIAS (Véase también et apertado "información pera el peciente")

  Este dispositivo está previsto para los usos descritos en el presente prospecto.

  Es importante una selección cuidadosa de los pacientes, sal como una apropia de información y assecimiento por parate del ciujano y del responsable de la reflabilitación.

  Los esturecos infensos o la movilidad excesiva pueden provocar el finaciso del dispositivo. Debe informarse a los pacientes de que las probabilidades de finaciso del dispositivo. Debe informarse a come consecuente a sobrecargas mecánicas excesivas.

  El dispositivo puede rempera o defianse si el implante se someste a un esturación addicional, asociado a una comodificación reterdada, a una seudoartrosa o a una consolidación incompeta.

  La inserción inadecuada del dispositivo durante la implantación quede aumentar

- contolidación incompleta. La inserción inadecuada del dispositivo durante la implentación puede aumentar la posibilidad de su aflojamiento y migración. Puede obtenerse un resultado instalisfactiorio el la fractura no se reduce correcta-mente o si el dispositivo no se monte correctamente. Puede ser necesaria la explantación de este dispositivo; Advertencia: Este producto no está autorizado para su fjación o unión mediante tomilios a los elementos posteriores (pediculos) de la columna cervical, dorsal o lamber.
- tonilios a los elementos posimientos quantidades en la California Sale Drinking Water and Toxic Enformement Act of 1986 [Ley sobre Segundad del Agua Potable y Agentes Toxicos del Estado de California, conocida también como Proposition 65]: Este producto contiene una o más productos quirnicos de los que el Estado de California, cabe que provocan cámber y/o defectos congénitos, y otros electos de Salfornia conocidade nenocluctiva.

### PRECAUCIONES

- RECAUCIONES Nunca debe cutilizarse un implante. Los esfuezos anteriores pueden haber provocado imperfecciones que podrán llever a un frecaso del dispositivo. El implante a es uministra estabil en un envase intalca. Si el implante o el envase-aparecen dafados, al ha transcurrido la fecta de caducidad o si por cusiquier motivo existen dudas sobre su esterilidad, el implante no debe utilizarse. Se trata de un producto desachable no previsto para su resutilización. No se recomienda
- de un producto desechable no previsio para en reunassensi.

  restaterizar e implante,
  pher à teneme buen cuidado pera evitur las meladuras, las rayaduras y otros
  anfos durante la manipulación de este dispositivo.

  La preparación meticulosa de la zons de implantación y la elección de un
  implante del ternaño correcto aumentan las posibilidades de éxito.

  Los productos estériles solo deben extraense de su envese una vaz que se determine que el implante va a utilizarse en el paciente.

### EFECTOS ADVERSOS

- TECTION ADVENSUOS

  Antes de utilizar este dispositivo deben estudiarse los efectos adversos descritos en la iteratura.

  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 manuel clonde se describe detalladamente la técnica quintrgica pars el uso de este dispositivo. Es responsabilidad del cirujano familiarizarse con la técnica antes de utilizar estos productos. Tamolin es responsabilidad del cirujano estar familiarizado con las publicaciones relevantes y consultar sobre la técnica con cole-pas experimentados antes del empleo de estos remodurba.

### INFORMACIÓN PARA EL PACIENTE (Vease también el apartado

Además de la información relacionada con los pacientes que figura en los epertados "Adveriencias" y "Efectos adversos", debe transmitirse al paciente la siguiente infor-

# Si bien resulta dificia de estimar la expectativa de vida de este dispositivo, ásta no es limitada. Sus componentes están fabricados con materiales ajenos al organ-ismo que se introducen en el mismo para facilitar el proceso de consolidación deas. Si embrago, debido a los numerosos factores biológicos, mecinicos y fisi-coquimicos que afectan a estos dispositivos, no es posible esperar que sus com-ponentes resistan durante un periodo ilimitado el nivel de actividad y los estuer-zos a los que está sometido un hueso normal aano.

### **ESTERILIZACIÓN**

- STEMELZACION Esta producto está esterilizado por áxido de etileno (ECI). El implante se asiministra estéril en un envase intacto. Si el implante o el envase aperacen defiacios, si ha transcumido la fecha de calcudad o si por cualquier motivo existen dudas soore su esterificiad, el implante no debe utilizarse. Este producto es de un solo uso.

### GARANTÍA LIMITADA

Avante Orthopeedics Corporation garantiza que este producto cumple las especifi-caciones del fabricante y que no presenta defectos de fabricación en el moervinto de su entrega. Esta garantila exculye específicamente los defectos derivados del uso incorrecto, abusa o manejo inadecusio del producto tras su recepción por el com-nection, altra orthopeedicio no garantiza el resusitado de la intervención pulvarigica.

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

## Records Processed by CDRH DID on 3/31/2023 NEDERLANDS

### BUSLUTTER

de botfixatiesystemen met toebehoren

### LET OP

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

BESCHRIJVING Dit product bestaat uit een plaat met achroeven voor behandeling van de distale

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

### INDICATIES

Het fixetieplastaysteem voor fracturen van de distate radius dient voor de inwerklifixatie van fracturen en osteotomieën van de distate radius. Dit kan het volgen

- All of niet verschoven fractuur die all of niet gepaard is gegaan met angulatie of Al of net verscrioven fractuur die al of niet gepaard is gegaant met angulatie of fragmentatie van het bot, Gefaalde fractuurfixatie, al of niet met een bottransplantaat, Osteotomie en herstel van een alechte consolidatie van de distale radius al of niet

- CONTRA-INDICATIES

  Actieve of intente infect

  Outsupprose, een onvo elheid of inferieure kwaliteit bot/zacht weef-
- zer Gevoeligheid voor het materiaal voer bij een vermoeden hiervan voorafgaand aan chirungie teets 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 cours

- AARSCHUWINGEN (zie tevens de rubriek Informatie betreffende counseling an de patiënt)

  Dit systeem dient uitsluitend voor gebruik zoals beschieven in deze bijsluiter. 
  Ean zorguvidige patiëntenselectie, voorlichting en counseling door de chirung en 
  de veriner ven revalidatiezog zijn betangstrijken, en counseling door de chirung en 
  de veriner ven revalidatiezog zijn betangstrijken, en crise leiden dat het product 
  faalt. Patiënter dienen erop he worden gestanscheerd dat er een verhoogde kars 
  bestaat dat het product faalt als er ie veel van wordt geverpd.
  Wanneer het insplantaat wordt blootgesteld aan een verhoogde belasting 
  veroorzaakt door vertrasgde consolidatie, geen consolidatie of onvolledige 
  genezing, kan het product tienen of beschandigd raken, 
  Onjuist intrengen van het product gedurende de implantatie kan de kans op losraken en migratie vergroten.
  Als de fractuer niet goed wordt gezet of het product niet goed wordt 
  samengesteld, kan dit een alecht resultaat tot gevolg hebben. 
  Explantatie van dit product kan nooktalkelijk zijn.
  Waarschweig. Dit product is niet geedgekand voor aanhectiving of lixatie met 
  behulp van achroeven een de achterelementen (pediculij van de cervicale, thoracale of lambale wenvelkoom.
  Werklaning outrom die wet van de Amerikaanse deelstaat Californië hazike veilig 
  drinkwater en tozorom die wet van de Amerikaanse deelstaat Californië hazike veilig 
  drinkwater en tozorom het de vet van de Amerikaanse deelstaat Californië hetwis en of mee 
  hetwelde het deze kanker 
  anvid geboortegetrieken en andeer reproductieve toxichen veroorzaken.

## VOORZORGSMAATREGELEN

- OPEZORGSMAATHEGELEN.
  Een inplantaat mag nooit opnieuw worden gebruikt. Eerdere belaatingen kunnen gebreien hebben veroorzaakt die ertoe kunnen leiden dat het product faall. Het implantaat wordt ateriel geleverd in een onbeschadigde verpakking. Inden het implantaat of de verpakking beschedigd biljet te zijn, de vervaktaam is verlopen of om welke reden den ook wordt getwijfeld aan de steriflient, dan mag het implantaat indt worden getwilkt. Dit is een product voor eenmalig gebruik en diert niet voor hergebruikt. Dit is een product voor eenmalig gebruik en diert niet voor hergebruikt. Dit is een van het implantaat wordt algereiden.
- dent item not hunger ander. Zorgutzleid is vereist ter voorkoming van kerven, krassen en andere beschiedigingen gedurende de hantering van het product. Een nauwkeurige voorbereiding van de implantatieplaats en keuze van de oorrecte afmetingen voor het implantaat vergroten de kans op een succesvol resul-

### COMPLICATIES

- JUNITELIA I I I ESTABLICA DE LA COMPICATION DE LA CAUTA DEL CAUTA DE LA CAUTA DEL CAUTA DE LA CAUTA DE

### CHIRURGISCHE PROCEDURES

Er is een handleiding verkrijbaar, waarin de chirurgische procedure voor het gebruik van dit product gedealieden 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 van deze producten vertrouwd te zijn met de reinversnie publiseate en om het advies in te winnen van ervaren collega's met betrekking tot de procedure.

## INFORMATIE BETREFFENDE COUNSELING VAN DE PATIÊNT (204

Hoewel de varwachte levenaduur van dit product moeilijk te schatten is, is deze beperkt. Deze componenten zijn gemaakt van Ischaamsveende materialen, die in het Ischaam worden geplaatst om het genezingsproces te beworderen. Vanwege de veie biologische, mechanische en fysiochemische Ischoren die deze producten beliviosoen, kan echter niet van de componenten worden verwacht dat ze voor onbeperkte tijd bestand zijn tegen het activiteitsniveau en de belast-ing van normaal gezond bot.

### STERILISATIE

- EMILIDATIE
  DIt product is gesterlissend met ethyleenoxide (ECs;
  Het implantaat word sterlie gelevend in een onbeschadigde verpakking, Indien
  het implantaat of de verpakking beschadigd blikt te zijn, de vervaldaaum is verlopen, of om welle neden dan ook wordt getwijfeld aan de sterlitet, aan mag het
  kniplantaat niet worden getwild. Dit is een product voor eenmalig gebruik.

### BEPERKTE GARANTIE

BEPERICIE GAKARCIE.

Aveata Orthopsedics Corporation gerandeert dat dit product op het moment van levering voldoet aan de apsocificaties van de fabrikaan en vrijs van habsingesfouten. Van
deze garantie zijn defectent die een gevolg zijn van verkeerd gebruik, misbruik of een
onjusies harstering edic sich office op de volgen van verkeerd gebruik, misbruik of een
onjusies harstering edic sich de perioduct na omvangst door de koper spoodfak uitigescheid.

Avanta Orthopsedics belief geen garantie op de uitbornst van de chinungische ingreep.

# Vertagemwoordiger binnen de EU: Medical Products International Europe, BV Schutweg 13a 5145 NP Waawijk, Nederland 0 416 563754

### ITALIANO

FOGLIO ILLUSTRATIVO

### ATTENZIONE

La tegislazione federale (Stati Uniti) impone la vendita, la distribuzione e fuso di questo presidio al soli medici o su loro prescrizione.

DESCRIZIONE:
Il presidio è costituito da una piestra e viti per il trattamento del radio di

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

### INDICAZION

uso previsto di questo sistema di fissazione a piastra è la fissazione interna di frat-re e osteotomie del radio distale, tra le quali:

- frattura acomposta o non acomposta con possibile argolazione o frammen-tazione dell'osso, fissazione fallita di fratture, con o senza innesto osseo, ostootomia e riparazione di malanione del radio distale con o senza innesto

- CONTROINDRCAZIONI

  Inflacione in atto o latente

  Ostoponosi, tessuto ossoc/mole insufficiente per quentità o qualità

  inpersonabilità ai materiale in caso di acapetta ipersonabilità, eseguire un test
  prime dell'intervento
- Sepsi: Pazienti che per condizioni mentali o neurologiche non vogliono o possono acquire le tetruzioni per le cure postoperatorie

## VVERTENZE (Si veda anche la Sazione relativa alle Informazioni per la

- VEHTENIZE: (Si veda anche la Sezione relativa alle fundimizioni per su noulenza al Pizierte).

  Il presidio è destinato unicamente all'uso descritto nel presente fogio Biustralivo. El importante chi il chirurgo e l'équipo di riabilitazione provvedano a selezionare attentamente i pazienti, educari a consigliari.

  Un sociesso di carlo o di mobilità possono comportare il tallimento del presidio. I pazienti devono essere avvettiti del imaggiore potenziare di fallimento del pre-sidio se sottoposto a sollectazioni occessive. Bi presidio più promperio ri namaree denneggiato se l'impianto viene assoggettato a carichi crescertti in essociazione con unione ritanteta, mancata unione o guari-nione incompotate.

- L'assexmento non corretto del presidio durante d'aspianto può avmentare la pos-sibilità et distacco e spostamento dello stesso.

  Si può diffener un risultato insoddistancita es la frattura non viene ridotta cor-rettamente o 8 presidio non è correttamente essembiato.

  In tali casi polrebbe rendersi necessario l'espianto del presidio.

  Avvoltanza importante: il presente presidio non è approvato per l'attacco o fis-sazione con viti degli elementi posteriori (poduncol) delle vertebre cervicali, toraccinho i combert.

  Notifica si conformità con la Legge del 1986 dello Stato della California sulla sicurezza dell'acqua potatabile e sulle sonstanza tossiche dichibirazione 65). Questo prodotto contiene uno o più sostanza orbiniche note allo Stato della California come possibili cause di cancro e/o difetti neonatali e di altri effetti tossici sull'at-tività riproduttiva.

- PRECAUZIONI
- IECAUZIONI
  Un impatino non deve mai essere riutilizzato. Le sollecitazioni subite in prece-denza possono aver dato origine ad imperfezioni che determinerebbero il falli-mento del presidio.
  Unipiento formo è sterile se in confezione integra. Non utilizzare l'impianto se to stesso o la confezione appasono danneggieti, se la data di scadenza è stara superata o se ori qualsiasi montre si è indott a dubiture della sua startifia. Il stara superata o se ori qualsiasi montre si è indott a dubiture della sua startifia. Il stara presionte presidio è monouso e non deve essere riutilizzato. Si aconsiglia la rateri-

- sente pressor e reconsular e nel vere se se esta e la contra como con la composita de la contra composita e presidio con pecauzione 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 steri devono essere prelevati dalla confezione starile solo dopo aver accertato l'uso effettivo dell'impianto sul paziente.

### EVENTI INDESIDERATI

- ENTI i intractivamenti.
  Prima di usere il presidio, eseguire una ricerca degli eventi indesiderati pubblicati dalla letteratura.
  Sono stati riferiti casi di reazioni di sensibilizzazione ai metalii in seguito
- Attri possibili effetti indesiderati: fratture ossee, infezioni, dolore e irritazione dei tessuti moli.

### PROCEDURE CHIRURGICHE

É disponibile un manuais che descrive nei dettagt la procedura chirungica da appli-care a questo presidio. È responsabilità del chirugo acquisire femisirati son la pro-cedura prima dell'uso di questi prodotti. È noltre responsabilità del chirungo anche acquisire familiarità con le pubblicazioni relative e consutiansi con colleghi esperti in merto alla procedura prima dell'uso.

### INFORMAZIONI PER LA CONSULENZA AL PAZIENTE ISI vedano anche le

Ottre 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, aebbene alla difficile da valutare, è consuniose limitata nel tempo. Si tratta infatti di elementi composti da materiale estranei all'organismo, ineeriti per la poincristice quanqione della frattura. A casso dei motti fattori biologici, meccanici e fisiochimici che influiscoro su questi dispositivi, mon si può lattavia pensare che essi possano maistere per un periodo di tempo llimitato a lineali di mittrità e carico uguali a quelli del normale osso sano.

- STERIL IZZAZIONE
- Cuesto prodotto è steritizzato in ossido di etilene (EC).
  Unesto prodotto è steritizzato in ossido di etilene (EC).
  Umpianto fornito è sterite se in contezione integra. Non utilizzare l'impianto se lo stesso o le confezione appaiono damneggiati, se la data di scadenza è stata superata o se per quelsiasi motivo si è indotti a dubitare della sua steritità. Il presidio è monouso.

GARANZIA LIMITATA GANAMAZIA LIMITATA

La Avanta Chrippeddica Corporation gerantisce che ili presente prodotto è conforme alle specifiche del produttore e che è esente de dietti di fabbricazione al momento delle coresogne. La presente genarizia estade specificamente i dietti derivaria di auso improprio o non corretto o de errori di manipolazione del prodotto successivamente al ricevimento de partir dell'acquirente. La Avanta Orthopaedica non gerantisce l'esto della procedura chiungica.

Agente per l'UE: Medical Products Inte Schutweg 13a 5145 NP Wasiwijk, Pr 31 (0) 416 563754 wilk, Paesi Bassi

### **ENGLISH**

### CAUTION

what invite federal (United States) law restricts this device to sale, distribution and use by or on he order of a physicien.

### DESCRIPTION

DESCRIPTION
This semi constrained joint proathesis consists of an ultra-high enciscular weight polyettydene (UHMWPs) distal component which is cemented to the shart of the prepared
metacorpal bone, and a cobact chromking proximal component which is cemented
into the prepared trapazium bone. The cobact chromking surface articulates with the
UHMWPs component to form a semi-constrained prostetule replacement of the TMC
joint of the hand. The implant is available in several sizes, each of which can be used
in spin or left hands. A range of trial sizes in seach high or either prepared
in bone preparation. This device is for cemented use only.

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

### INDICATIONS

The implient is indicated for total joint replacement in skeletally makine patients with pain or instability of the joint due to basina, infarminatory or department desease or revision of previous procedures, as an alternative to arthrodesic or reconstructive surgery.

### CONTRAINDICATIONS

- Active or latent infection

  Bone, musculative, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fection
- for the prosthesis. Skeletal Immeturity. Known sensitivity to materials used in this device.

WARNINGS (See also the Patient Courseling Information and Adverse Events

ction)
Patients should be made aware of the increased potential for device failure we accessive termands are made upon it. Strenuous loading, excessive mobility, articular instability eil may lead to accelerated wear and eventual failure by idening, fracture, or dislocation of the device.

### PRECAUTIONS

- RECAUTIONS

  Du not resterilize. The implant is provided stanle in an undamaged package. If all there the implant or the package appears damaged, expiration date has been exceeded, or if startility a questioned for any reason, the implant should not be used. Meticulous preparation of the impaint size and election 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 size is been prepared and properly sized. The properties of the pr

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

### int Replacement Related Risks

- eff Pepacerizen reserves, blood pern injury to surrounding nerves, blood vessels, fendons or soft tissue attifices night and weather related pain loss of motion replant fractive roution of implant accelerated were of the device components.

- acceptance are components loosening of the implant from the bones instability of the joint dislocation of the joint cement extrusion injury

- ning or shortening of the

- 3 per measurements of the implant decrease in range of motion allergio or other reactions to the metal or plastic materials additional surgery may be required for reoperation, revision or flusion of the control of
- for reoperation, revision or fusion or 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 Sale Drivining Water and Toxic Enforcement Act of 1996 (Proposition os). This product contains a chemical(j) known to the State of California to cause cancer, and/or birth defects and other resproductive 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 familier with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familier with relevant publications and consult with experienced associates regarding the

PATIENT COUNSELING INFORMATION (See also Warnings and Adverse Events Section) A patient brothure 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 esti-mate, 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 effect 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

### STERILIZATION

- This component has been startized by ethylene oxide or gamma radiation. Do not resterlize. The implant is provided sterile in an undamaged package, if either the implant or the package appears damaged, existation date has been exceeded, or if sterrithy is questioned for any reason, the implant should not be
- used. Trail sizer components are available to avoid having to open the sterile packar prior to prosthesis implentation. The implant should be removed from its ster package only after the implant site has been prepared and properly sized.

### 'ITED WARRANTY

The Development of the Indian Product meets the insurfacturer's specialists and is free from manufacturing defects at the time of definery. This warrantees and is free from manufacturing defects at the time of definery. This warrantee is specialistic product subsequent to receipt by the purchaser. Avanta Orthopsedics does not mart the outcome of the surgicial procedure.

### EU REPRESENTATIVE

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

asgesetz (Vereinigte Staaten) ist dieses Gerät auf Verkauf, Vertrieb dung durch einen Azzt oder in dessen Auftrag beschränkt.

### BESCHREIBUNG

BESCHREIBING
Diese tellgekoppelta (semiconstrained) Gelenkprothese hat eine distale Komponente aus ultrahochmolekularem Polyedhylen (UHMWPE), die in dem Schaft des präpariertem Metiscarpsakrochens zementiert verankert ist, und eine proteinale Kobalthochmonober fläche und UHMWPE-Komponente besteht zu Zwiechen Kobaltchromober fläche und UHMWPE-Komponente besteht eine gelenktige verbrichung (Kritulistich), une einem profestischen Errastz mit eilgekoppeltem (ausri-constrained) System für des Trapazio-Metiscarpai-(TMC-) Gelenk der Hand zu bilden. Diese hat die eingesetzt werden können. Für jeden implantatyp gibt es eine Pelette von Probeponthesen, zu gerannte Szaz, die sie Hillantich für die Präparation des Knochens verwendet werden. Dieses Gerät ist nur zur zernentierten Verankerung bestimmt.

- reraren Proximale Komponente aus Kobaltchrom gemäß ASTM F-75 Distale Komponente aus ultratiochmolekularem Polyethylen (UHMWPE) gemäß ASTM F-648

ANWENDUNGSGEBIETE

Des Implantat ist indiziert als Totalgelenkonsatz bei Patienten mit ausgereifter Skelettentwickung, die Infolge von Trauma, antzündlicher oder degenerativer Erkrankung oder Revision früherer Prothesen an Gelenkschmerzen oder Geienkschmetzen oder desenkschmetzen o

### GEGENANZEIGEN

- GEGENANZEIGEN

  Durch Knisitheit, Infektion oder #ühere Implantation angegriffene Knochen,
  Muskuktur, Sehnen oder angrenzende Weichteile, die keine sichere Unterlage oder
  Flüerung für die Prothese bieten können.

  Unreife in der Stelettentwicklung.

  Bekannte Überempfindlickeit gegenüber den in diesem Gerät verwenklaten.

WARNHINWEISE (Siehe auch Abschnitt \*Informationen zur Patientenberstung\*)

Patierten and auf das erhöltte Potenzial des Versagene der Prothese bei über-mäßiger Belastung hinzurweisen. Starke Belastung, übermäßige Mobiktät und Gebrikfinstablität können eile zu beschleunigten Verschließ und eventureilem Versagen durch Lockenung, Fraktur oder Dislokation der Prothese führer.

### VORSICHTSMASSNAHMEN FÜR DIE ANWENDUNG

- VORSICHTSMASSNAHMEN FÜR DIE ANWENDUNG

  Nicht nesterfalseren. Das Implantat werd atert in unversiehrter Verpackung geliefert. Wenn eine Beschlädigung des Implantates oder der Verpackung vorzuflegen scheint, das Verfaldatum überschritten oder die Steriflät aus irgendenem Grund in Frage pestellt ist duer des Implantat incht ververnotet werden.

  Sorgfältige Vorbereitung der Implantation der die Wahlder richtigen Größe des Implantation.

  Das Implantation erhöhen die Erfolgsaussichten der implantation.

  Das Implantation vorbereitung der implantation des Implantation in Implantation vorbereitung in Implantation des Implantations vorbereitung in Implantation des Implantations vorbereitung des Implantations in Implantation vorbereitung des Implantations des Implantat

### POTENZIELLE NEBENWIRKUNGEN

Allgemeine operationsbedingte Risiken

• Blutung • Infektion • Gebrauchsunfähigkeit der Hand • Arbeitsunfähigkeit • Tod

- rch Geienkersatz bedingte Riekten
  Schmerzen
  Verfetzung der umgebenden Nerven, Blutgefäße, Sehnen oder Werchteile
  Stelfigkeit
  Nachtschmerz um wetterbedingte Schmerzen
  Bewegungsunfähigkeit
  Impäerlatfriektur
  Rotetion des Impäerlatfes
  Beschleunigger Verschließ der Komponenten des Gerätes
  Lockerung des Impäerlates in den Knochen
  Gereinkriestablität.

- Gerenkinstabilität Dislokation des Gelenks Verletzung infolge von Zementextrusion

- Verletzung erroige von Zeineristunsund Unfaktion
   Verlangerung oder Verkürzung der Finger
   Amputation
   Schwächung der Knochen nund um das Implantat
   Verringerter Bewegungsradus
   Allemissche oder andere Reaktionen auf die Metall- oder Plastematerialien
   Ein zusätzlicher chrieugischer Eingriff kann zur Reoperation, Revision oder Fusion des Gelenks erforderfich sein.
   Die Operation kann zwer begonnen werden, aber der Gelenkersatz ist nicht durchführbar, wodunch es zur Fusion des Gelenkes kommt.
   Mitselung gemäß dem Gesetz für sauberes Tirrikwasser und zur Bekämpfung two-ischer Stoff des Bundesstaates Kalifornien (California Gale Orikting Water and Toxic Enforcement Act) von 1986 (Proposition 65): Dieses Produkt erithät eine Chemikalie (2. die nach Wissen des Bundesstaates Kalifornien Kreib und/oder Geburtsschäden sowie andere reproduktive Toxiztät verursachen kann.

### CHIRURGISCHE VERFAHREN

CHIRUNGISCHE VERREAHREN
EIn Handbuch mit einer genauen Beschreibung des chirurgischen Verfahrens für den
Ernsatz dieser Implantatprodese ist verfügber. Der Chirung ist disht versnivertilich,
sich vor Anwendung dieses Medizingrodulten mit dem Verfahren verfraut zu mechen.
Der Chirung ist westehn dafür versnivertilich, die einschlägigen Publikationen
sorgitätig zu lesen und sich mit Berufskollegen zu beration, die Ertehrung in der
Americkung dieses Verfahrens gesammelt haben.

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

en den Patienteninformationen in den Abschnitten Warnhinweise und enwirkungen sind dem Patienten die nachfolgenden Informationen zu vermitteln:

- Die erwartete Lebensdauer der Komponenten des Totalgelenkorsatzes ist zwar sichwer zu bestimmen, aber sie ist begranzt. Diese Komponenten sind ein Fremdistoffen geltertigt, die zur potenzießen Wiederherstellung der Mobilität und zur Veringenung der Sichnezen in den Körper implantiert werden, zur Grund einer Visitzer folologischer, mechanischer und physikalisch-dtemisicher Faktoren, die diese Prothesen beeinflussen, kann jedoch nicht erwerhet werden, dass die Komponenten auf unbegrenzte Zeitsauer demselben Aktivitätsgrad und derselben Belastung standhalten wie der normale gesunde Knochen.
  Unerwünschte Wirkungen dieser Prothese können möglicherweise Reoperation, Revision oder Fusion des betroffenen Gefenka erforderlich machen.

### STERILISATION

STERILISATION

Dose Komponente wurde mit Ethylenoxid oder Gammabestrahlung steritisiert.

Nicht resteritisieren. Das Implantati wird steril in unversehrtet Verpackung geliefert. Wern eine Beschädigung des Implantatis oder der Verpackung vorzullegen scheint des Verlaidskum überschritten oder die Steritität aus inpedienen Grund in Frage gestellt st, darf das Implantat nicht verwendet werden.

Probeprobeen, so genannte Sizer, sind verfügbar, um zu vermeiden, dass die sterie Verpackung vor der Implantation der Prothese geöffnet werden mass. Das Implantat darf verst aus der sehreln Verpackung entonnemen werden, wenn das Implantatisger vorbereitet und für die Größe des implantatisg richtig dimersioniert ist.

EINGESCHRÄNKTE GEWÄHRLEISTUNG

Avanta Orthopaedics, Inc. gewährleistet, dass dieses Medizinprodukt die 
Spezifikationen des Horsteilers erfült und bei der Lieferung keine Hensteilungsfehler 
aufweist. Dese Gewährleistung schließt speziels Fehler aus, die auf nicht-bestimmungsgemüßen Gebrauch, Abzaus oder unsachgemäße Hendhabung des 
Medizinproduktes nach Eingang bei dem Käufer zurückzuführen sind. Avanta 
Orthopaedics übernimmt keine Gewährleistung für das Resultat der chinurgischen 
Nationale.

### EU-VERTRETER:

tional Europe BV Schutweg 13A 5145 NP Wash 31 (0) 416563 754

### FRANÇAIS

ATTENTION a des États-Unis d'Amérique exigent que la vente, la distribution et t appareit solent assurées ou prescrites par un médecin.

DESCRIPTION DESCRIPTION

Cette profisio articulaire semi-contrainte se compose d'une pièce distale en polyethylène à poids motéculaire ultra élèvé (UHAMPe) qui est cimentée à l'aux de l'os métaurarpies prépare et d'une ploice proximals en cobalt-chrome qui est cimentée à l'os du protes prépare. La surface en cobalt-chrome s'articule sur la pièce en UHAMPe pour former un remplacement profiétique semi-constrict de l'articulaire un tapado-métacarpienne de la main. L'implain est disponible en plusieurs talles, checune d'eles étant utilisable à la main droite ou gauche. Une série de calibreurs d'essai est disponible pour d'auxe le per d'implain, en tant qu'éssaisance à la préparation osseuse. Ce dispositif est prévu exclusivement pour la cimentation.

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

### INDICATIONS

INDICATIONS

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

### CONTRE-INDICATIONS

- nt englierature tendora ou tiseu mou adjacent compromis par une maladie, une infection ou une implantation satérieure qui ne peuvent pas fournir un support adéquat ni permetire la fixation de la prothèse.
- inteccon ou une impartation senimente qui n adéquat ni permetire la fization de la prothèse immaturité du squelette. Allergie avérée aux matérieux de ce dispositif.

AVERTISSEMENTS (voir ausai la section Corseile donnée au patient)

Il faut informer le patient de l'augmentation du risique d'échec du dispositif en cas de sollicitations excessives. De fortes charges, une mobilité excessive et une instabilité réculaire peurent scolléer l'auser du dispositif et entraîner un échec éventuel par relâchement, fracture ou dislocation.

### PRÉCAUTIONS

- Ne pas nestéritiser. L'implant est fourni stérile dans un emballage scellé. Si l'im-plant ou l'emballage paraît endommagé, si la date de péremption est dépasaée ou ai la stérlité est mise en cause pour une raison ou une autre, il ne teut pus
- utieser l'implient.

  Une préparation méticuleuse du aité de l'implient et le aélection de la taile d'impliant appropriée augmentent le potenties de réussite.

  It taut enievre l'implient de son emballage strie luniquement sprès le préparation et le dimensionnement correct du site de l'impliant.

  Les impliants doivent être manipulée avec des instruments à bout mousse pour ne pas rayer, couper ou entailer le dispositif et ne pas perturber les performances de l'impliant.

# EFFETS INDÉSTRABLES ÉVENTUELS Risques généraux lés à la chirurgie saignements infection

- ques lés au remplacement de l'articulation douleur lescen traumatique des nerfs, vaisseaux sanguins, tendons ou du tissu mou environnants

- environnants indeur occurre et lide aux conditions météorologiques perte de mobilité fracture de l'implant control de l'implant coston de circulation l'auxilion de l'implant coston de circulation l'auxilion de l'implant comparent du doigt amputation de l'implant comparent de l'implant d'implant d'implant
- hason de l'articulation il se peut que l'on commence une chirurpie mais que l'on ne puisse pas remplacor 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 1989; ce produit contient un agent chirinique (;) connu dans l'État de Californie pour causer le cancer et/ou des malformations néonataise et autre toxicité êée à la reproduction.

PROCÉDURES CHITRURGICALES

Un marquel est disponible ; il décrit en détail la procédure chieurpicale permettant d'utiliser l'amplant. La connaissance de cette procédure est de la responsabilité du
nimigne. Il incombe également au chinurgion de se tenir au courant des publications
pertinentes et de consulter des confrères expérimentés su sujet de la procédure à

CONSEILS DONNES 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 controlue 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 ès ne sont pas inusables. Ces composants cont en effet fabriqués dans des matériaux étrarigers au corps humain et implantés afin de restaurer la mobilité ou de réduire la douleur. Toutréles, en raison des nombreux lacteurs biologiques, mécaniques et physio-chimiques qui affectent ces dispositifs, les composants ne pouvent pas aupporter le même réveau d'activité et les mêmes charges qu'un os saint pendant une période illimitée.

  Des effets indésirables peuvent nécessiter la néopération, la révision ou la fusion de l'articulation concernée.

### STÉRILISATION

- vesser i impain.
  Des calibreum d'essail sont disponibles : ils évitent d'ouvrir l'embellage 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

GARANTTE LIMITEE: Avanta Orthopaedics, Inc., gerantit que ce produit est conforme aux apécifications du fabricant et qu'il est limé aena défaux de fabrication. Cette garantie exclut spécifique-ment les défauts résultant d'une urblastion innoveractio ou abuvane, ou d'une mempula-tion incorracte du produit postérieure à la réception par l'acheteur. Avanta Orthopaedics ne garantit paus l'issue de la chiragie.

REPRÉSENTANT EN EUROPE :

### ESPAÑOL

islación federal estadounidense, este producto sólo puede ser vendido, utilizado por un médico o por orden de un médico.

### DESCRIPCIÓN

DESCRIPCIÓN

Esta protesia ericular estrairrestrictiva está integrada por un componente distal, hacho de un polietileno de paso molecular ultra elevado (UHIAMPE), el cual detecementarea a la didéria del former metacarginen previamente preparada, y por un amponente proximal de cobelto-cromo que debe cementarse al trapeznides carpinabilemente preparado. La superficia de cobelto-cromo articula con el componide UHIAMPE, constituyando un dispositivo de sustitución protesias aeministra en varios termaños, cada uno de los cuales puede ultiturane para marca derechas o tiguierdes. Se dispone además de una gianta de protesia de prueba de distribus tamentes para cual ten de inspetante con el proposito de syuder a la preparación del huseo. Este dispositivo ha sido constructo solamente para usarse como protesia comentada.

remeres
Componente proximal de cobalto-cromo, ASTM F-75,
Componente distal de policièreo de peso molecular ultra elevado (UHMWPe),
ASTM F-646.

### INDICACIONES

REUNCACIUNES

Este impliente está indicado para la sustitución total de la articulación en pacientes
con esqueleto macturo, que presenten dolor o inestabilidad de la articulación, causados por traumatismo, inflemación o enfermedad depenentiva, como estralamo para
la revelación quiriogica de procedimientos previos, como una alternativa frente a la
artrodesia o a la cirugia reconstructora.

### CONTRAINDICACIONES

- n I roumbrouxoutories.
  Presencia de hueso, musculatura, tendones o tejidos bisnidos adyscentes com-netidos por enfermedad, Infección o implantación previa, que no puedan propor-ar una sustentación o una fijación adecuada para la protesis;
- immadurez del esqueleto;. Hipersensibilidad conocida a los materiales que componen este dispositi

ADVERTENCIAS (Ver también el apartado "información pera el paciente")

Se deberta advertir a los pacientes sobre el mayor riesgo potancial de fallo de dispositivo cuardo det en sometido a esignicina mocalinas exceelvas. Los estueros intermos, la movilidad exceeiva y la inestabilidad erricular pueden causar un des gaste acelerado y conducir al fracaso del implante por aflojamiento, fractura o dislocación del dispositivo.

- PRECAUCIONES

  No reesterilizar. El implante se suministra estéril en un envase intacto. Si el implante o el envase aparecen darlados, si ha transcurido la techa de caducidad o al por cualquier motive existen dudas sobre su esterilidad, el implante no deberá uti-
- arse.

  La preparación meticulosa de la zona de implantación y la elección de un plaente del tamaño correcto aumentan las posibilidades de éxito.

  El implante debe extraerse de su envase estáril ablo después de haber concluido preparación de la zona de implantación y de haber determinado el tamaño correc-

### POSIBLES EFECTOS ADVERSOS

Resgos relacionados a la cirupia en general « Sangramiento » Infección « Pérdide de la función de la mano « Discapacidad per manente « Muerte

- Daño a los nervios, vasos sanguineos, tendones o a los tejidos blandos o undantes.

- sundantes
  Rigidez
  Doior noctumo o relacionado a los cambios climáticos
  Pérdide de la movilidad
  sectura del implante
  statación del implante
  Desgaste acelerado de los componentes del dispositivo
  Riogiamento del implante desde el hueso
  Inestabilidad de la articulación

- Dislocación de la articulación Lesión por la salida del ceme

- inteccion.
  Alergamiento o acortamiento del dedo
  Amputación
  Reretacción dese aimetador del implente
  Restacción del aimpo de movilidad
  Restacción del riago de movilidad
  Restacción del riago de movilidad
  Pesacciones allegicas u dos tipo de resociones al metal o a los materiales plasticos
  Puede escestianse la cirugia adicional para la reoperación, la revisión o la fusión
  as erticulación.
- Es posible que una vez iniciada la intervención, no pueda implantarse la prótesis,
- Es posible que una vez iniciada a intervencion, no juedos iniçamanos os provisos obligando a efectuar una fusión artícular.

  Notificación de acuerdo con lo establecido en la California, Salta Draiking Water and Toxic Enforcement Act of 1986 (Lay sobre Seguridad de Agua Potable y Agentes Toxicos del Estado de California, conocida también como Proposición 55). Este producto contriene una o más eustancias químicas de las que el Estado de California salbe que provocan cáncer y/o defectos congenitos y otros efectos de toxicidad.

### TÉCNICAS QUIRÚRGICAS

Tecreticas durinteriorios. Establicate en el tecnica quintigica para el uso de este depositivo. Es responsabilidad del cirujario familiarzarse con la técnica entre de utilizar estos productos. También es responsabilidad del cirujario estar familiarizado con las publicaciones relevantes y consultar sobre la técnica con cole-gas experimentados antes del empleo de asota 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 infor-

Si bien resulta difícil de estimar la expectativa de vida de este dispositivo, ésta no es iemitada. Sus componentes están fabricados con materiales ajenos el organismo que se introducen en el mismo para facilitar el proceso de corsolidación óses. Sin embargo, deboto a los numerosos factores biológicos, metarinos y fisicoquimicos que afectan a estos dispositivos, no es posible esperar que sus componentes resismo disante un periodo limitado el nivel de actividad y los estuezos a los que está sometido un huseo normal seno.
Los efectos adversos de este dispositivo pueden requerir reoperación, revisión o la fusión de la articulación comprometida.

### ESTERILIZACIÓN

STEHILIZACION Este misco esterilizado por óxido de etileno o por radiación gamma. Este procura El implante se suministra estári en un envase infacto. Si el mighante el consecuente diadecio, si ha transcurrido la fecha de caducidad o si por judiçuer motivo existen ducias sobre su esterificiad, el implante no debará utilizarse.

Se suministra componentes de prueba en cantidad suficiente para que no sea nece-aerio abrir el envese esteril antes de le impiantación de la prósesis. El implante debe extraerse de su envase estéril atolo después de haber concluido la preparación de la zona de implantación y de haber determinado el tamaño correcto.

### ARANTÍA LIMITADA

Ha Othopsedics. Corporation garantiza que este producto cumple tas especifi-nes del fabricante y que no presenta defectos de fabricación en el mocamito anierga. Esta garantia acictiye específicamente los defectos derivados del uso incorrecto, abusico o mánicje insidezcuado del producto trais su recepción por el com-prador. Aventa Orthopsedicia no garantiza el mesultado de la intervención del purugica.

# REPRESENTANTE EN LA UE:

### Records Processed by CDRH DID on 3/31/2023 NEDERLANDS

### WAARSCHUMING

Volgens de tederale wet (Verenigde Staten) mag verkoop, distributie en gebruik al passtavinden door of in opdracht van een arts.

BESCHRIJVING

Deze seni-constrained gewichtsprothese bestaat uit een distaie component van uitrainoog moleculair gewicht polyeithyleen (UH-MWP), welke aan de schacht van het voorbereide metacerpale bot wordt gelijmd, en een kobalt-chromen proximiste component welke in het voorbereide handwordtsbeneile wordt gelijmd. Het kobalt-chromen oppervlak is door een gewichtt verbonden met de component van UH-MWP om zo een seni-convrained prothetische vervanging van het duimzadeligewricht van de hand le vorman. Het emplantaat is verfrigbaar in verschliende meten, die allemaal kunnen worden gebruikt in de rechter of linkerhand. Woor ek type inciantaat is een senie protentaat verfrigbaar ist huip bij het voorbereiden van het bot. Dit instrument is uitskuitend voor gelijmd gebruik.

- ASTM F-54 distale component van kobatt-chroom
  ASTM F-648 distale component van uitrahoog moleculair gewicht polyethyleen

MELTIFICATION

Het incinitate is bestemd voor vervanging van het complete gewricht in patiënien met een volgroeid skalet met pijn of instabiliteit in het gewricht door trauma, inflammatoire of degeneratieve zandooningen of voor revisie van eerdere ingrepen, els alternatief voor afrodese of reconstructieve chilurgie.

### CONTRA-INDICATIES

- Door ziekte, infectie of eerdere implantatie sangetest bot, musculatuur, pezen, of ornigigend zacht weetsel, welke niet genoeg steun of bevestiging voor de prothese launen bieden.
- nen bieden. Onvolgroeidheid van het skalet. Bekende gevoeligheid voor de in dit instrument gebruikte mate

WAARSCHUWINGEN (zie ook het hookdstuk informatie voor patientvoorichting)

Patienten denen ie worden gewezen op die verhoogde kara dat het instrument et begeeft warneer et hoge eisen aan worden gestadt. Zware belsting, overmatige beweeglijdheid en gewichtsinstabiliteit kunnen allemaal leiden tot veranekte sitage en uiteindelijk kan het instrument het begeven door losraken, breken of dislocatie.

### VOORZORGSMAATREGELEN

VOORZORGSMAATHEGELEN

Nich herstrikserer. Het implantaat wordt storiel geleverd is een onbeschadigde verpakking heiden dreel het implantaat ofwel de verpakking beschadigd blijkt te zijn, de vervaklatum is deverscheden, of om welke neden dan ook aan de storikteit wordt getwijfleid, mag het implantaat niet worden gebruikt.

Een neuwiseurige voorbereiding van de implantatieplaats en de keuze van de juste maat implantaat mag pas uit zijn steriele verpakting worden gehaald zoors de implantaatienst is voorbereiden de leuise afwiktingen heeft.

Ont te voorkomen dat er in het instrument worde gehaat, gesneden of gekentd moeten implantaaten met stompe instrumenten worden gehaatden, dit om de werking van het instrument niet nadelig te beinvloeden.

### MOGELIJKE BIJWERKINGEN

Risico's die bij het vervangen van een gewricht kunnen optrec

- op in so green de proposition de pro

- nachteijke en weeralhankelijke pijn verifes van beweging breken van het implantaat rotatie van het implantaat versnelde slijtage van componenten van het instri kans dat het implantaat looraakt van de botten instabliëtet van het gewicht dislocatie van het gewicht dislocatie van het gewicht letsel door arkruis van het kleefmiddel infecties anger of korter worden van de vinger ampurtakte boherzwiskking rondom het implantaat

- empertable
  bothers/wakking rondom het implantaat
  vertandering van het bevergingsbereik
  allergische of andere reacties op het metaal of op plastic materialen
  aanvullende chirurgie kan nodig zijn voor heroperatie, revisie of fusie van het
- gewicht

   wanneer u begint met chirurgie voor een gewrichtsvervanging, kan dit niet uitlopen op een fusie van het gewricht

   kenniegeving in overeenstemming met de California Safe Drinking Water and
  Toxic Enforcement Act (verordening van de Amerikaanse deelstaat Californië Inzake
  veilig drinkwater en toxische bardhaving) van 1986 (opmerking 65): Dit product bevat
  een chemische stoff) waarvan in de deelstaat Californië bekend is dat hij kanker
  veroorzaakt, en/of geboortebeperkingen en andere reproductieve toxischait.

CHIRURGISCHE PROCEDURES

Er is een handleiding verkrijgbaar waarin gedetaliteerd de chirurgische procedure voor het gebruik van deze implertatie-instrumenten word beschreven. Het is de verantwoordelijkheid van de arts dat hij vertrouwd is met de procedure voordat hij daze producten gaat gebruiken. Daarnaast is het de verantwoordelijdheid van de chirurg dat hij voorafgaand aan het gebruik op de floogle is van nielvante 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 paliëntgerelateerde informatie in de hoofdstukken Waarschuwingen en Biwerkingen dient de volgende informatie te worden medegedeeld aan de patiënt.

Hoswel de verwachte levensduur van componenten voor een complete gewichtsvervanging moeilijk te schatten is, is deze beperkt. Deze componenten zijn gemaakt ven vreemde materialen, die in het lichaam wooden gepalantst voor mogeline herstel van de mobiliteit of vermindering van pijn. Varwege de vele bologische, mechanische en fysiochemische factoren die invided op deze instrumenten uitzelfenen, kan gehten niet van deze componenten worden verwacht dat zij gedurende onbeperkte lijd bestand zijn tegen het activiteitsniveau en de belasting van normaal eerond bot.

delige effecten van dit instrument kan heroperatie, revisie of fusie van het gewricht nodig zijn.

STERILISATIE

Deze component is gesterificieerd door middel van ethyleonoxide of gammastraing.

Niel hersterificieren. Het implantaat wordt steriel geleverd in een onbeschadigde verpaaking, indien ofwel het implantaat ofwel die verpaking beschadigd bijlit te zijn, de vervaldzum is overschreden, of om welke reuden dan ook aan da steriniefet wordt gatwijfeld, mag het implantaat niet worden gebruikt.

Prochinaatiomponentein zijn verkrijdpaar om te voorkomen dat de steriele verpaking voor de implantatie van de prottesse moet worden geopend. Het implantaat mag pas út zijn steriele verpaking worden gehaald zodra de implantatieplasts is voorbereid en de juiste afmeringen heeft.

Avanta Orthopsedics, Inc. garandeert dat dit product beantwoordt aan de specificaties van de fabrikant en op het moment van ievering geen productiefourien bewat. Uitgestoten van deze garande zijn met name gebreken als gevolg van verkeerd gebruik, misbruik of een onjuiste bediening van het product nadult het door de koper e ontvangen. Avanta Orthopsedics geeft geen garantie op het resultaat van de chirurgische procedure.

EU-VERTEGENWOORDIGER, Medical Products International Europ Schulweg 13A 5145 NP Waalwijk 31 (0) 416363 754

### ITALIANO

### ATTENZIONE

a legislazione lederale (Stati Uniti) impone la vendita, la distribuzione e l'uso di uesto presidio al soll medici o su loro prescrizione.

### DESCRIZIONE

DESCRIZIONE

Cuesta protesi semi vincolata dell'articolazione è costituita da un componente distale
in polietilene di peso motecciare utimiseggem (JHAMVPe), cementato aul corpo del'osso meticarpale prepensio, e da un componente prossimale in cromo-cobalto
comentato nell'osso trapazio preperato. La superficie in cromo-cobalto si erticole con
il componente in UHAMVPe formando una sostituzione protesio a seni vincolata delfarticolazione TMC della mano. L'impianto disponibile in numerose misure, ognuna
delle quali può essere utilizzata nella mano destra o sinistra. Per ogni tipo d'impianto
a disponibile una vista germa di califoratori di prova, che representano un valido
assisio nella preparazione dell'osso. Questo presidio è destinato unicamente all'uso

- teriali
  Componente proasimale in cromo-coballo ASTM F-75
  Componente distale in polietilene di peso molecolare ultraleggero (UHMWPe)
  ASTM F-648

### INDICAZIONI

Translational ("Emplanto per la sostituzione totale in pazienti con sviluppo acheletrico completo con dolore o instabilità dell'articolazione in segunto a traumi, partotoje infi-armatione o degenerative o per la revisione di procedure precedenti, in alternativa all'artodesi o alla chirurgia ricceltruttiva.

CONTROINDICAZIONI

Ossa, mascolatura, tendini o tessudi molti adiacenti compromessi da patologia, infeccioni o impareti precedenti che non sono in grado di fornire supporto o fisaazione adequati per la protesi,
Immaturità acheletrica.

Accertata ipersembilità ai materiali ufilizzati in questo presidio.

AVVERTENZE (vedere anche la sezione Informazioni per la consulenza ai pazienti)

1 pezierti devono essere avvertiti del maggiore potenziale di fallimento del presidio se sottoposto a solicoltazioni eccessive. Un eccesso di carico o di mobilità e l'instabilità eritopare sono tutti fattori che possono accelerare l'usura e comportare il
possibile fallimento del presidio per distacco, trattura o spostamento dello atesso.

- PRECAUZIONI

  Non risterilizzare l'impianto. L'impianto torvito è sterile se in confezione integra.
  Non utilizzare l'impianto se lo atesso o la confezione appacno danneggiati, se la data di acadenza è statta superata o se per quelsiasi motivo ai è indotti a dubitore della sua
- rina.
  Una proparazione meticolosa del alto d'impiento e la sceta della misura corretta
  l'impianto stesso aumentano le probabilità di sello positivo dell'intervento.
  L'impianto deve essere prelevato dalla confezione sterile solo dopo aver preparamisurato correttamente i atto dell'impianto.
- to e insurrato communente si sito des imparato.

  Gil implanti devono essere manegolati esclusivemente con l'ausilio di strumenti amussati per evitare di graffiare, tagliare o scalifire il presidio, in modo da non compromettere le prestazioni dell'impianto.

### POTENZIALI EFFETTI INDESIDERATI

- Perdita dell'uso della mano

- chi cometati alla sostituzione dell'ericolazione
  Dotore
  Lessoni dei nervi, vasi sanguigni, tendini o tessuti molli circostanti
  fligidità
  Dolore notturno e comeiato alle condizioni atmosferiche
  Perolita di motilità
  Frattura dell'impianto
  Rotazzone delli mipianto
  Usura soceleriata dei componenti del presidio
  Distanco dell'impianto dalle casa
  instabilità dell'eriboolazione
  Spostamento dell'aricolazione

- Spostamento dell'articolazione Lesione dell'estrusione di ce

- Infazione

  Infazione

  Infazione

  Allungamento o accordimento del dato

  Allungamento del consistento del dato

  Amputazione

  Indebolamento dell'ampiezza di movimento

  Demnuzione dell'ampiezza di movimento

  Reazioni allergiche o di altro tipo ai materiali metallici o plastici

  Può enderia inecessario un ulteriore intravvento chiaupico per seconda operazione, revisione o fusione dell'articolazione.

  Può essere avvisto un intervento chimupico, senza però potere eseguire alcuna sositiuzione dell'articolazione.

  Nodifica in conformità con la Lagge del 1986 dello Stato della California sulla acurezza dell'acqua postabile e sulle sostarioza chiache fotchiarazione 55): Questio prodotto confinee uno o più sostariaz chimiche note aio Stato della California come possibile cause di carcino e/o difietti ineonatale e di altri effetti tossici sull'attività riproduttiva.

# PROCEDURE CHIRURGICHE

# Precolezione Comprovatorio. É disponible un manuale c'he descrive nei dettagli la procedura chrungica da appli-care a questo presido. É responsabilità del chrungo acquisire familiantà con la pro-cedura prima dell'uso di questi prodotti. É ionibre responsabilità del chrungo anche acquisire familiarità con le pubblicazioni relative e consultansi con colleghi espeni in

INFORMAZIONI PER LA CONSULENZA AI PAZIENTI (vedere anche la sezione Avverteruzi)

È disponibile un opissolo per i pazienti da utilizzare per la relativa consulenza.

Otre alle informazioni relative al paziente contenute nelle eszioni Avverten

Effetti indesiderati, devono essere trasmesse al paziente le seguenti informazio

• La durata prevista di questo presidio, sebbene sia difficile da valutare, è comunque limitata nel tempo. Si unita infatti di elementi composti da materiali estranei all'organismo, insertip per ficilitarei il processo di giunzigione. A causa dei molti fattori biologici, imeccanici e fisicolimici che influiscono su questi dispositivi, non si pub luttivario entrare che essi possano resistere per un periodo di lempo llimitato a leveli di attività e carico upuali a quelli del nomale osso sano.
L'eventuale insorgenza di effetti indisciperati di questo presidio possono richiedere un secondo nitervento, la revisione o la fusione dell'articolazione coinvolta.

STERILIZZAZIONE

Il prodotto è steritizzato in oasido di etilene o ai raggi gamma.

Non ristrizzate l'impiento. L'impiento ternito è sterite se in confezione integra. Non utilizzare l'impiento se lo stesso o la confezione appacono darnaggieti, se la data di soadenza è stituti superstat o ae per qualessie motto a il indotti a dubtiene della sua

steriita.

Sono disponibili calibratori di prova per evilare di dover aprire la confezione si ile prima dell'impianto della protesi. L'impianto deve essere prelevato dalla confezio aterile solo dopo aver preparato e misurato cometamente il sito dell'impianto.

### GARANZIA LIMITATA

GANGANICIA LIMITATA
Avanta Chrispoedica, inc. garantisce che il presente prodotto è conforme elle specifiche del produttore e che è essente da difetti di rabinizzazione al momento della cossegna. La presente guarazia e escuside specifici franciare i difetti derivanti da uso mproprio o non corretto o de emori di manipolazione del prodotto successivamente al ricevimento da prate dell'eculurente. Avanta Chrispoedicis non garantisce l'estito della

AGENTE PER L'UE: Medical Products International Europe BV Schutweg 13A 5145 NP Waalwijk

19-0356 Rev E



# A V A N T A HER THIS PRESENCE OF STREET ASSESSMENT OF STREET ASSESSMENT

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### EU AFGEVAARDIGDE

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latertals: Statelless Steel F 316 L, ASTM F 138, ASTM F 138 ASTM A 564 Statelless Steel 17-4PH

EU Representative Medical Products International Europe, BV, Schurweg 13a, 5145 NP Wasiwijk, The Nethorlands 31 (9) 416 563754

19-0365 rev C

CE

# A VANTA A NTA A ORTHOPARDICS 6369 Control Pair Orthe, Since A, San Diego CA 92121 USA (858)452-85802 (858)452-9945 (fax)

Avanta TMC Triumb Prosthesis
pezic-Metacarpal TMO Daumenprothese von Avanta
Prothese de pourse trapezo-metacarpierne Avanta
Erolesis trapeciometacarpiana del pulgar, Avanta TMC
avanta trapeziometacarpale dumprothese
Protesi del police Avanta TMC

PRODUCTINSERT

### **FNGI ISH**

### CAUTION

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

### DESCRIPTION

DESCRIPT FIJIN
This semi constrained joint prosthesia consists of an ultra-high molecular weight polyethylone R/HMVP-id distal component which is cemented to the start of the prepared
metacerpel bons, and a cobalt chromium proximal component which is cemented
into the prepared trapezum bone. The cobalt chromium surface articulates with the
RHHMVPs component to form a semi-constrained prosthetic replacement of the TMC
joint of the hand. The implant is available in several sizes, and of which can be used
in fight or left hands. A range of trial sizes for each type of implant is available to aid
in bone preparation. This device is for cemented use only.

- commun.
  ASTM F-75 cobalt chromium proximal component.
  ASTM F-648 ultre-high malecular weight polyethylene (UHM/WPe) distal component

### **INDICATIONS**

The implemt is indicated for lotal joint replacement in skeletally mature patients with pain or instability of the joint due to trauma, lattermatory or depondentive disease or revision of previous procedures, as an afternative to arthrodesis or reconstructive surgery.

- CONTRAINDICATIONS

   Active or intent infection,
   Bone, musculature, tendone, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fluation for the emphasises. infection, or sen-for the prostness, Skeletal immature, Known sensitivity to materials used in this device.

WARNINGS. (See also the Patient Counseling Information and Potential Adverse Events Section).

\* Petions should be made aware of the increased potential for device failure when excessive demands are made upon it. Stremuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loos-oning, facture, or disociation of the device.

### PRECAUTIONS

- RECAUTIONS

  Do not resterilize. The implant is provided sterile in an undameged package, if either the implant or the package appears damaged, expiration date has been exceeded, of sterility is questioned for array areas, 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 as been prepared and properly sized, including should be herefield with blant instruments to avoid scratching, cutting or utilizing the device so as not to advertisely affect line septem performance.

POTENTIAL ADVERSE EVENTS
Genoral Surgary Potated Pitaks
• bleeding • intection • lass of use of the hand • permanent disability • death

### Joint Replacement Retated Risks

- pain rigury to surrounding nerves, blood vessets, tendons or soft tissue

- stiffness
  night and weather related pain
  loss of motion
  implant fracture
  rotation of implant
  accelerated wear of the device
  components
  tostering of the implant from the
  bones restability of the joint

- dislocation of the joint cement extrusion injury intection langthening or shortening of the

- d \* permanent disability \* death amputation bore westerning eround the implant decrease in range of motion allegic or other nections to the motal or plestic materials additional surgery may be required for reoperation, revenion or fusion of the joint surgery may be started but a joint replacement cannot be done result-replacement cannot be done result-region fusion of the joint Notification in accordance with Authorities of the point California Sele Dinking Water and Tooks Enforcement Act of 1989 Proposition 55). This product con-tains a chemically 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 surgicor to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgicor to be familiar with relevant publications and consult with experienced associates regarding the iar with relevant public procedure before use.

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

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

- While the special of lie of the plaints. While the special of lie of the plaints. While the special of lie of total plaint project promote components is difficult to estimate, it is fixed. Times components are made of foreign materials, which are placed within the body for the potential materials of mobility or reduction of pain, however, due to the many biological, mechanical and physiochemical factors which affect these devices, the components carmed be expected to whistand the activity level and loads of normal healthy bone for an unlensed period of time. Adverse effects of this device may necessifate moperation, revision, or fusion of the avolved jobit.

### STERILIZATION

- This component has been sterikzed by ethylene oxide or gamma radiation. On not restertize. The implant is provided sterile in an undamaged packaga, if enter the implant or the package appears dranaged, expraison date has been exceeded, or if sterilify is quiestioned for any reason, the implant should not be
- used.

  Trial sizer components are available to avoid having to open the sterile package prior to prostite its implantation. The implant should be removed from its sterile package only after the implant size has been prepared and properly sized.

### TED WARRANTY

TEO WARMANTY
THEO WARMANTY
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THEO WITHOUT SPECIAL STREET SPECIAL STREET SPECIAL STREET SPECIAL STREET SPECIAL SPEC

### EU REPRESENTATIVE

Medical Products International Euros Schutweg 13A 5145 NP Waatwijk The Netherlands 31 (0) 416563 754 wal France BV

## Records Processed by CDRH DID on 3/31/2023

### BESCHREIBUNG

BESCHREIBUNG
Diese teilgekoppelte Gelenikprothese hat eine dietale Komponente sus ultrablochniciskulterem Polyethylen (U-HMVPE), die in dem Schaft des prägarierten
Melacarpashorchens zementent veranisert ist, und eine proxinate KoblichtomKomponente, die in den prägerierten Trapazirischen einzementliert ist. Zwischen
Kobaltchromberffäche und U-HMVPE-Komponente besteht eine gelenktigs
Verbindung (Artikulstion), um einen prothetischen Ersatz mit teilgekoppeltem System
titt des Trapazio-Metacarpal-ETMC-) Gelenik der Hand zu bilden. Das Impäantat ist in
merkeren Größen verfügbes, die alle in der michtlen oder inliene Hand eisgesetzt
werden können. Für jeden impäantatip gibt es ehn Paleitte von Protesprothesan, die
als Hilberteitt für die Präpaziarisch des Knochons vorwendet werden. Dieses Gerät ist
nur zur zementierten Verankerung bestimmt.

- Meterialien:

  Proximale Komponente aus Kobeltchrom gemäß ASTM F-75

  Distale Komponente aus ukrahochmolekularem Polyethylen (UHMWPE) gemäß
  ASTM F-948

ANWENDUNGSGEBIETE
Das Implantat ist indizent als Tolaigelenkersatz bei Petienten mit ausgereiter
Skiedsterhtwickung, die infolge von Trauma, entzündlicher oder degenerativer
Erkrankung oder Revision früherer Protinesen an Gellenkschmerzen oder
Gelenknistablick inden, und stellt eine Allenstirke zu Arthrodese oder misorstudieser

### GEGENANZEIGEN

- GENANZEIGEN
  Althe oder itsterne trijsklion.
  Durch Krankhelt, Infektion oder frühere implantation angegriffene Knochen,
  Mauladatus, Sentrem oder engrenzende Welchteile, die keine sichtere Unterlage
  oder Foierung für die Prothese bleten können.
  Unweite in der Skelettentwichlang.
  Bekannte Überempfündlichtet gegenüber den in diesem Gerät verwondeten

WARNHINWEISE (Siehe auch Abschnitt "Informationen zur Patientenberatung"

und Potenzielle Nebenwähungen?

Patenzielle Nebenwähungen?

Patenzielle Nebenwähungen?

Patenzielle Nebenwähungen?

Patenzielle Nebenwähungen?

Patenzielle Nebenwähungen.

Stands Balastung, übermäßige Nobilität und Gelenkinstablität können alle zu beschlesnigtem Verschließ und eventuellem Versagen durch Lockenung, Fraktun der Oblisklatinn der Prottiese führen.

- VORSICHTSMABNAHMEN

  Nicht restertfälleren. Das kripkartat wird alert in unversehrter Verpeckung gelefent. Wenn eine Beschädigung des implantates oder der Verpeckung vorzulegen scheint, des Verfalbatum überschriften oder die Steriffelt aus eigendennen Grund in Frage gestellt ist, darf das implantat nicht verwendet werden. Sorgfällige Porbereikung des Implantatages und die Wahl der richtigen Größe des Implantations wird der Problemation. Des kerkelbestellt des Problemations der Problemation oder Problemation. Des kerkelbestellt des Problemations von des
- Das Implantat ist erst aus seiner sterrien Verpackung zu entnehmen, wenn das Implantatiager vorbereitet und für die Größe des Implantats richtig dimensioniert 191, Bei der Handhabung des Implantats eind stumpfe instrumente zu verwenden, um Kratzer, Schrifte oder Kerben auf dem Implantat und eine damit verbundene Beeinträchtigung der Implantatielstung zu vermeiden.

### POTENZIELLE NERENWIRKUNGEN

Allgemeins operationsbedingte Risiken

Bittung + Infektion + Gebraucheunfähigkeit der Hand + Arbeitsumfähigkeit + Tod

### Durch Gelankersatz bedingte Risiker

- nch Gekenkersatz bedingte insteller Schmerzen Verletzung der umgebenden Nerven, Bildgefaße, Sehnen oder Welchteile Stefigkeit Nachschmerz und wetterbedingte Schmerzen Bewegungstunfähigkeit Implentathaktur Rotation des Implantats Beschieunigter Verschließ der Komponenten des Implantats Lockerung des Implantats in den Knochen Gelenkinstabilität
- Disiokation des Gelenks Verletzung infolge von Zementextrusion
- Verlängerung oder Verkürzung der Finges

- Amputation
  Schwächung der Knochen rund um das Implantat
  Verningerter Bewegungsradis
  Adergische oder Andere Residionen auf die Metall- oder Plasteniaterialen
  Ein zusätzlichen chrungischer Engridt kann zur Reoperation, Revesion oder Fusion
  des Gelenkis erforderlich sein.
  Die Operation kann zwar begonnen werden, aber der Gelenkensatz ist nicht
  durchklinhen, wodusch es zu Fusion des Gelenkes konntt,
  Mattelbung gemäß dem Gesetz für sauberen Trinkvesseer und zur Beldungtung
  toxischer Stoffe des Bundesstaates Kalfornien (Celfornia Safe Drinking Water
  and toxic Enforcement Act) von 1966 (Proposition 65): Deses Produkt enthalt
  eine Chemitäge (), die nach Wissen des Bundesstaates Kalfornien Fusion
  und/oder Gaboritsschäden sowie andere reproduktive Toxizität verursachen kann.

### CHIRURGISCHE VERFAHREN

CHIRUNGISCHE VERRANITIEN
Ein Handbuch mit einer genausen Beschreibung des chirungischen Verfahrens für den
Einsatz dieser Impänistaprothese ist verfugber. Der Chirung ist dahr verantwortlich,
sich vor Anwendung dieses Medicinarodukses mit dem Verlahmen vertraut zu machen.
Der Chrung ist weinerhin dahr verantwortlich, die einschlägigen Publikotionen
songfählig zu lesen und sich mit Berufskollegen zu beraten, die Erfahrung in der
Awendung dieses Verfahrens gesammelt haben.

### INFORMATIONEN ZUR PATIENTENBERATUNG (Siehe auch Warntinweise und Polenzielle Nebenwirkungen) Eine Pattentenbrochtire zur Verwendung bei der Beratung der Patienten ist vertügber.

Neben den Patientenkriormationen in den Abschnitten Warnhinweise und Nebenwirkungen sind dem Patienten die nachfolgenden kilormationen zu vermitteln:

- Dis erwartete Lebensstatier der Komponenten des Totslegleinkersatzes ist zwaschwer zu bestimmen, aber sie sit begrenzt. Diese Komponenten sind auFriendstatter gefertigt, der zu potrazitien Weiserherseitligung der Mobilität und
  Friendstatter gefertigt, der zu potrazitien Weiserherseitligung der Mobilität und
  einer Weiserhall Bautgeicher, mechanischer und physikalisch-chemischer Fatturen,
  die diese Protinisen bestiffussen, kann jedoch nicht erwartet werden, dass die
  Komponenten auf unbegrenzte Zeitfatzer demselben Aktivitätsgrad und
  derseitben Beteitung standhallen wei der normate gesunde Krochen.
  Unerwünscher Weiserung dieser Protinise könner möglichterweite Reoperation,
  Revision oder Fusion des betroffenen Gelenke erkorderlich machen.

### STERLISATION

- FERELSATION
  Diese Komponente wurde mit Ethylenoxid oder Gammebestrahlung sterilsiert.
  Nicht restorfisieren. Das Implantat wird steril in unversichtler Verpackung gefelent.
  Vern eine Beschädigung des Implantats oder der Verpackung vorzuliegen
  acheint, das Verfalldatum überschritten oder die Steräftät aus Inpendeniem Grund
  in Frage gestell ist, darf das ministrats nicht verwendet werden.
  Probeprotiesen sind verfüglisch, um zu vermeden, dass die sinde Verpackung vor
  der Implantation der Protinses geöffen werden muss. Das Implantat zur erst aus
  der sterilen Verpackung entnommen werden, wern das Implantatioger vorberentet
  und für die Größe des Implantats nichtig dimensionen ist.

### EINGESCHRÄNKTE GEWÄHRLEISTUNG

EINGESCHRANKTE GEWAHRLEISTUNG 
Avanta Orthopaedics, Inc., gewährleistet, dass dieses Medizinprodukt die 
Soezilikatorien des Henstellens erüllt und bei der Liefenung knien Henstellungstehler 
aufweist. Diese Gewährleistung schließt spazzleif Fehler aus, die auf nicht-bestimmungsgemäßen Gebrauch, Abauss oder unsachgemäße Handhabung des 
Medizhunduktes rach Engang bei dem Käufer zurückzufüren sein. Awsitat 
Critischaedies überninnti keine Gewährleistung für das Resultat der chrugisischen

### EU-VERTRETER:

is International Europe BV Medical Products International I Schutweg 13A 5145 NP Washvijk, Die Nederla 31 (8) 416563 754

### FRANÇAIS

DESCRIPTION

Chele prothèse aniculaire senvi-contrainte se compose d'uns pièce distale en polyethyène à polés inoteculaire utira élevé (UHMWPe) que est cimentale à l'aux de los métacarpien prépare et d'une pièce proximale en cobalt-chronne qui est cimentele à l'os du trapitze prépare, La surface en cobalt-chronne s'articule sur la pièce en UHMWPe pour tomme un remplacement prothétique semi-constricté de l'articulation trapitze ordiscemente en email. L'implain est disponible en plusieurs tailes, cha-cune d'elles étant utilisable à la main droite ou gauche. Une aétre de calibreurs d'essi est disponible pour chaque bye d'implaint, en tats qu'assistance à la préparation osseuse. Ce dispositif est prévu exclusivement pour la canentation.

- péce proximale coben-chrome ASTM F-75 pièce distate en polytitytime à poids moléculaire ultra élevé (UHMWPe) ASTM F-648

### INDICATIONS

INDICATIONS

(Emplant est indique pour le remplacement de l'articulation totale chez les patients dont la croissance est terminée et qui souffrent ou sont atteints d'issabblié articulaire du à un traumatisme, une maladie inflammations ou dépéndation ou une révision des procédures préoblemées, en tant que solution de remplacement d'une arthrodèse

### CONTRE-INDICATIONS

- JM INE-Photocasticutos
  Infection active ou staine, to describe ou series, consistente, tendons ou tiesu mou sejacent compromis par une materiae, une
  infection ou une implematation antinheure qui ne peuvent pas fournir un support
  sidequat ni premettre la fusation de fa prothèse.
  Immaturité où sousiette.
  Allergie avérée aux matériaux de ce diapoetiff,

MISES EN GARDE (voir aussi les sections Conseils donnés au patient et Effets

indéstrables éventuels.

Il au l'interner le patient de l'augmentation du risque d'échec du diapositif en cas de solicitations accelsives. De fortes charges, une mobilité accessive et une instabilité articulaire peuvont accelérer fusure du dispositif et entrabler un échec éventuel par rélichement, larciture ou dislocation.

- PRÉCAUTIONS

  \* Me pas restérilleer. L'implant est fourni sterile dans un emballage scelé. Si l'implant ou l'emballage parait endommage, ai la dets de péremption est dépassée ou si la stérillé est mise en cause pour une ration ou une autre, it ne faut pesutifiéer l'implant.

  Une présentain méliculeuse du être de l'implant et la sélection de la taille d'implant appropriée augmentent le potentiel de réuseite.

  8 l'aut enlaver l'implant de son emballage stérile uniquement après la préparation et le dimensionnement commet du site de l'implant.

  Les implants dovent être manipulés avec des instruments à bout mousse pour ne pas raye, couper ou entaitler le dispositif et ne pas perturber les performances de l'implant.

# EFFETS INDÉSIRABLES ÉVENTUELS Risques généraux tés à le chirurgle • salgnements • infection

- perte d'usage de la main incapacité de travail définitive

- sques ses au remplacement de l'articulation douleur lésion traumatique des nerfs, valisseaux sanguns, tendons ou du tissu mou environnants raideur raideur nocturne et lèse aux conditions météorologiques perte de mobilité fracture de l'implant rotation de l'implant usum sociétrée des composants du dispositif

- retation de l'implant 
  usure accidère des composants du dispositif 
  relàchement de l'implant (dissohement des as) 
  natabilité de l'articulation 
  blessure par échusion de ciment 
  infection 
  blessure par échusion de ciment 
  infection 
  relacions articulation 
  dissolution 
  articulation 
  articulation 
  articulation 
  d'iminishen d'amplitude de mouvement 
  réactions allegiques ou autrour de l'implant 
  diminishen d'amplitude de mouvement 
  réactions allegiques ou autrour aux matériaix métalliques ou phistiques 
  une chaurgie additionnable peut être requise pour la réopération, la révision ou la 
  fission de l'articulation
- une charugie additionnale peut être requise pour la respiratori, la révision du la fusion de l'articulation. Rés peut que l'en commence une chirurgie mais que f'on ne pusse pas remplecer Farriculation, ce qui entraîtait une fusion de l'articulation. Notification conforme à la Proposition 65 de Celifornie (Californie Sale Drinking Water and Tosic Enforcement Act, acte assicutativa de la protection de l'esu potable contre les produits toxiques, approuve en 1986); ce produit contient un agent chinique (;) connu dans l'Esta de Californie pour causer le cancer et/ou des malformations reconstation et autre toxicole fiée à la responduction.

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
chiragien. Il incombe également au chirurgien de se tenir au courant des publications
pertinentes et de consulter des contrêtes expérimentés eu sujet de la procédure à

CONSEILS DONNÉS AU PATIENT (voir aussi Mises en garde et Effets indésira-

břes eventuels) Une brochure à l'attention du patient, contenent des conseils, a été realisée Outre l'information relative au patient qui est contenue dans les sections Avertissements et Ettets indésirables éventuels, le patient doit recevoir l'information

- It est difficile d'estimer la durée de ve prévise des composants de remplacement d'articulation totale, mais êts ne sont pas inusables. Ces composants sont en effet tabriqués dans des matériaux étrangers au coops human et implantés afin de restaurer la mobilité ou de réduire la douleur. Toutefois, en racon des nombreux facteurs biologiques, mécaniques et physio-chimiques qui effectent ces disposi-tifs, les composants ne peuvent pas supporter le même invesu d'activité et les mêmes charges qu'un os sain pendant une période literatée. Des effets notaisrables pouvent nécessiter la réopération, le révision ou la fusion de l'articulation concernée.

STÉRILISATION

- ERRUSATION

  Ce composant a éta stérilea à l'oxyde d'éthylène ou aux rayons gamma.

  No pas restérilear, L'implant est fourni stérile dans un embatique socile. Si l'implant ou l'enballage parail endormenage, si la data de péremption est dépassée ou si la stérilité est mise en cause pour une reson ou une autre, il ne faut pas utiliser l'implant.

  Des calibreurs d'essai sont disponibles : lè evitent d'ouvrir fembatique stérile avant l'implantation de la prothese. Il tout enlever l'implant de son embatique stérile uniquement après la préparation et le dimensionnement correct du sée de l'implant.

### GARANTIE LIMITÉE

GANANTIE LIMITIEE.

Avanta Orthopsendos, Inc., gavantii que ce produit est conforme aux spécifications du fabricant et qu'il est livré sans déraul de fabrication. Cette garantie exclut a pécifiquement les détauts resultant d'une utilisation incorrecte ou abustive, ou d'une méripolation incorrecte de grandit pas déviners à la réception par l'acheteur. Avanta Orthopsedoc or garantit pas finaude à chanagle.

REPRÉSENTANT POUR L'UE :

### **ESPAÑOL**

### DESCRIPCIÓN

DESCRIPCIÓN

Esta prótesia articular semimentricitva está integrada por un componente distat, hacho de un poletilemo de paso unolacular utira elemado (LiHAMPRe), el cual debe cementarea e la deficia del praner metacarpo perviamente prepuzada, y ou un componente proximal de cobalto-como quiu debe cementarse al trapecio carpiamo debidamente prepuzado. La superios de cobalto-como attouta con el componente de UHAMPRe, constituyendo un dispositivo de sustitución profésica semimentariorixa para la enticulación trapeciometacarpiana del pulgar. Esta implante se suministra en varios terrendo, cada uno de los couses puede utilizarse pera la mano derecira o la erda. Se dispone ademise de una gama de medidores de prueba de distribución foro para cada lipo de implente, con el propósito de syudar a la preparación del ao. Este disposativo ha sido construido solamente para userse como protesta-camentada.

steriales:
Componente proximal de cobelto-cromo, ASTM F-75;
Componente distal de polietikono de peso molecular ultra elevado (UHM/WPe),
ASTM F-648.

### INDICACIONES

Esta implante está indicado para el reemplazo articular total en pacientes con estructura dose madura, que presenten dolor o inestabilidad en la articulación, causados poi insumatismo, enfermedades refinantarios o defenerativos o nevisión quirdigica de procedimientos previos, como una stemativa frente a la artrodesta o a

### CONTRAINDICACIONES

- NRTH/IMPRITIES INTEREST.

  Introción activo o internis.

  Compromiso de los hussos, músculos, tendones o tejido blando adyscentes a cause de padologías, infección o implante previo, que ofescan una austentación o usa fisición admouladas para la proteés;

  (internaciona: nesa;

  Hipersansibilidad conocida a los materiales que componen este dispositivo.

ADVERTENCIAS (viesse también les secciones información para el paci

incibes efection activersos)
Se deberá advertir a los pacientes sobre en inayor riesgo potencial de latin del dispositivo cuardo éste es sometido a exigencias medanicas excessivas. Los esfuerzos intensos, la movilidad excessiva y la inestabilidad artícular pueden causer un desgasate acelerado y conducto al fisaciso del implante por afiojamiento, tercitura o dielocación del dispositivo.

### PRECAUCIONES

- ECAUCIONES

  No reseteritizar. El implante se presenta estéril en un savase intacto, Si el imptante o el envisen están defiados, si ha tranocumido la fecha de valuez est por cualquier motivo se duida de su esteritidad, el implanta no deberá utilizarse. La preparación mediculosa de la zone de implantación y la efección de un implante del tameño sociouso sumenian las posibilizades de lavo, el implanta debe sacarse de la envise estár sido después de haber concluido la preparación de la zona de implantación y de haber determinado el tamaño ocumento.
- correcto.

  Los implantes deben manipularse utilizando instrumentos romos para evitar rayaduras, cortes o marcas que puedan alectar el funcionamiento del implante.

POSIBLES EFECTOS ADVERSOS
Riaggos relacionados con la cirupia en general

• Sangramiento • Infección • Perdida de la función de la mano • Discapacidad per-

- Riesgos relacionados con la sustitución articular
   Dofor
   Daño a los nervios, vasos sanguineos, tendones o al tejido blando circundantes

- Dotor
  Daño a los nervos, vasos sanguineos, tendones o al tejido blando circumdantes.
  Rigidez.
  Dotor noctumo o estacionado a los cambios climáticos
  Pérdida de la movilidad
  Fractura del implante
  Despaste acelerado de los componentes del dispositivo.
  Afrigamianto del implante desde al fueso
  inestabilidad de la articulación
  Dislocación de la articulación
  Dislocación de la articulación
  Dislocación de la articulación
  Listión por le extrusión del comento
  Intección
  Asigamiento o acortamiento del dedo
  Ampunicación
  Destitamiento óseo alrededor del implante
  Restricción del rango de movilidad
  Restricción del rango de movilidad
  Restricción del rango de movilidad
  Restricción del rango de movilidad.
  Restricción del rango de movilidad
  Restricción del rango de movilidad.
  Restricción del rango de movilidad.
- te articulación.

  Es posible que una vez lociada la intervención, no pueda emplentaria la prácesa, obligando a electuar una tusion artícular.

  Notificación de acuerdo con lo establectido por la California Sale Drinning Water and Toxic Enforcement Act of 1985 [Lay sobre Segurated de Agua Potable y Agentes Toxicos del Estado de California, conocida tambien como Proposición 65]: Este producto contiene una o más sustencias químicas de las que el Estado de California, abec que provocan cáncer y/o defectos congénitos y eltres electos de toxicidad reproductiva.

## PROCEDIMIENTOS QUIRÚRGICOS

RECCEDIMIEM TOS AUTOMOSCOS. vaire un minural que describe en detalle el procedimiento quinurgico para el uno de toto implantas. Es responsabilidad del cinujano familiarizarso con el codo dimiento testes de utilizar estos productos. Tambien en es responsabilidad del riujano minarzarse con las publicaciones relevantes y consultar con colegas experimentados secon del procedimiento antes del empleo de estos miscritars. untes de utiliza

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

Además de la información relativa al paciente que figura en las secciones Advartencias y Posibles efectos advarsos) se deberá transmitir al paciente la algu-iente Información:

- Si bien resulta dificid de estimar la duración prevista de este dispositivo, este no es immatata. Sus comportentes están labricados con materiales ajanos al oppariamo que se introducem en el nitrano para fecilita el proceso de control-tación dese. Sin embargo, detidos a los numerosos tactores biológicos, medidos y fisicoquímicos que afectar a estos dispositivos, no es de esparar que sus componentes resistan durante un periodo infination el intel de actividad y los esfuerzos a los que está sometido un hueso normal sano.
  Los efectos adversos de está espositivo pueden requerir una nueva operación, revisión o la fusion de la erriculación afectada.

### **ESTERILIZACIÓN**

- STERILEZACIÓN

  Este producto ha sido esterilizado por óxido de etiliano o por radiación gamma.

  No ressteritze: E implante se presenta esteril en un envese intacto. Si el implante el enveze estan dañados, si ha trinscurido la techa de validaz o si por cualquer motivo se duda de su atteridad, el simplante no debañ utilizarse.

  Se suministran componentea de prueba en cantidad suficiente para que no sea necesario abrir el envese estáril ambos de la implantación de la implanta de implantación de sertireste de se unavas estáril antes de la implantación de la preparación de la zona de implantación y de haber determinado el tamaño cor-moto.

### GARANTÍA LIMITADA

Avanta Ottopeacios Corporation garantiza que este producto cumple las espocial-ceciones del fabi ciante y que no presenta defectos de fabricación en el momento de 1º entrega. Esta garantia exchye especificamente los defectos delivados del uso l'ecida abuseo emispulación incometa del producto una vez recibido por al con-dició. Avanta Orhiopadeica no garantiza el resultado de la intervención quivangica:

## REPRESENTANTE EN LA UE: Medical Products International E Schutweg 13A 5145 NP Waahvijk, Paises Bajos 31 (0 416563 754

### Records Processed by CDRH DID on 3/31/2023

### BESCHRIJVING

BESCHRIJVING

Date semi-constrained gewifchtsprothese bestaat uit een dietale component van uiterknoog moleculair gewifcht polystityleen (IR-HMVP), webe aan de achacht van het voorbrereide metacerpale bot wordt gelijind, en een kabalt-chromen prostmate component weke in het voorbrereide handwordebenrijk wordt gelijind. Het slobat-chromen oppervlak is door een gewifcht verbonden met de component van UI-HMVP om ze een sammi-constrained prohetische voorwiging van het dourzackelgewicht van de hand te vormen. Het timplantaat is verkrijgbaer in verschillende maten, die alternaal isunen worden geltruikt in de rechter- of inkerhand. Voor elk type Implantaat is een arier profentaer verkrijgbaar als huip bij het voorbereiden van het bot. Dit instrument is uitstuitend voor gelijmd gebruik.

- renaem. ASTM F-75 proximale component van kobali-chroom ASTM F-648 distale component van uitzekoog moleculair gewicht polyethyleen (UHMWP)

### INDICATIES

Hel implantat is besternd voor vervanging van het complete gewricht in patiëri met een volgroeid aksele met pip of insabiliteit in het gewocht door trauma, infla matore of degeneratieve aendoorningen of voor revisie van eendere ingrepon, els alf nabel voor annodess of reconstructieve chirunge.

- CONTRA-INDICATIES

  Active of leterate infects.

  Door ziekte, trifectie of eerdere implantatie aangetast bot, musculatuur, pezan, of onliggend zacht weefset, welke niet genoeg steun of bevestiging voor de protisses kunnen bledden.

  Omologoechied van het skielet.

  Beklende gevoeligheid voor de in die instrument gebruikte meterlaken.

### WAARSCHUWINGEN (zie ook het hoofdstuk Informatie voor patiëntvoorlichting

Mogolijke Blewerkingeri)
Patienten dienen te worden gewezen op de verhoogde kans dat het instrument het begeet wenneer et is hoge eisen aan worden gesteld. Zware belasting, overmatige beweeglijkheid en gewrichtsinstabilieft kunnen atlemaal leiden tot verhan of distocatier.

- O'NORZORGSMAATREGELEN
   Nist harsterlifiseren, Het avplantaat wordt steriel geleverd in een onbeschadigde verpeidding, briden ofwel het implantaat overd et verpeidding, briden ofwel het implantaat niet over de verpeidding het oerscheden, of or welke neden dan ook aan de stefffelt wordt getveligtest, naag het implantaat niet worden gebruikt.
   Een nauwissarjae voorbereiding van de implantatielpatas en de keuze van de jusie maat implantaat vergroten de kans op een successool resultaat.
   Het implantaat meg pas uit zijn steriele verpelding worden gehaald zodra de implantatielpiaats is voorbereid en de justa afmetingen heeft.
   Om te voorkomen dat er in het instrument wordt gelvast, geeneden of gekenfd moeten implantation met stompe historienetten worden gehanteerd, dit om de werking van het instrument niet nadelig te beinvloeden.

### MOGELIJKE BIJWERKINGEN

- verties van gebruik van de hand blijvende invaliditet

### oo's die bij het vervangen van een gewricht kunnen opt

- co's us a ret versam per variety in the last of the la

- langer of korter worden van de vinger ampatatie

- amputatio
  bothez-welsking rondom het langkentaat
  vermindering van het bewegingsbereik
  altergische of andere nanctins op het metaat of op plastic materialen
  anvullende chinzgle kan nodig zijn voor heroperatie, revisie of fusia van het
  gewicht.
- gewicht, wanneer u begint met chirusgie voor een gewrichtsvervanging, kan dit niet uitkoen op een tusie van het gewricht kennisgeving in overeensterming met de California Sale Dinking Wester and luxic Entitrecement Act, heroricening van de Amerikaanse deelstaat California nizies veilig drakvester en toxische handhaving) van 1986 (opmissing 65). Dit product bevat een chemische stof(j) waarvan in de deelstaat Californie belend is dat hij kanker veroorzaaks, ervol geboortebeperkingen en andere reproductieve toxiotetit.

### CHIRURGISCHE PROCEDURES

Mogalijke Blywstangen)

Er is een patiëntentvochure verkrijgbaar die kan worden gebruikt om de patiënt voor te korten. INFORMATIE VOOR PATIÊNTVOORLICHTING (zie ook Waarschuwingen en

- krosweil de verwachte levensduur van componenten voor een complete gewichtsvervanging moelfijk te schatten is, is deze beparkt. Deze componenten zijn gemaakt van verende malerielen, die in het fichaan worden gesplaats voor moojelijk herstel van de mobiliet of vermindering van pijn. Vanwege de veie biologische, mochanische en Hysiochemische factoren die snivolde op deze instrumenten uitoelenen, kan echter niet van deze componenten worden verwecht dat zij gedorende onbeperkte tijd bestand zijn legen het activiteitenweau en de telesling van normaal gezond bot. Door neddege effecten van die instrument kan heroperatie, revisie of fusie van het betreffende gewicht nodig zijn.

- STERILISATIE

  Deze component is gestleriisbesed door middel van etitydeenoxide of gammastraling.

  Nich heistlerikseren. Hel implantaat wonst steriel geleverd in een onbeschadigde verpalking, bedrien ofwel hat implantaat ofwel die verpalking beschadigd blijkt te zijn, de vervalziataum is overschusden, of om welke erders dan ook aan die sterifikat wordt getwyfladt, mag het smilantaat niet worden gebruikt.

  Proefmastomponenten zijn verkrijgbaar om te voorkomen dat de steriele verpalking voor de kruplantatie van de protiese moet worden geopend. Het anplantaat mag pas uit zijn steriele verpalking worden gelnaakt zodra de kruplantatie pas de zijn steriele verpalking worden gelnaakt zodra de kruplantatie pas de zijn steriele verpalking worden gelnaakt zodra de kruplantatieplaats is voorbereid en de juste afmetingen heeft.

Avanta Orthopasdics, Inc., garandeert dat dit product beantwoordt aan de specificaties van de fabrikent en op het moment van leverrig geen productiefouten bevat. Uitgebilden van deze gazontie zijn met name gebreken als gevolig van verkeerd gebruik, misbruik of een ongiutse bediening van het product nadat het door de koper is ontvangen. Avanta Orthopaedics geeft geen garantie op het resultaat van de chikuspische procedure.

### EU-VERTEGENWOORDIGER Medical Products International Europe 67

medical Products into Schutweg 13A 5145 NP Waahwiik M wijk, Nederland 31 (0) 416563 754

### **ITALIANO**

### DESCRIZIONE

DESCRIZIONE

Questa portesia articolare seminiscolata è costituita de un componente distale in polietiame ad attissimo peso molecciare (LHRMVPR), cementato sul corpo dell'osco metacarpale preparata, e du un componente prossivale in crum-cobalto comentato rell'osco trapezio preparato. La superficie in crum-cobalto si anticola con il componente in UHRMVPs formando una assistizione protessioa senvinociata dell'articolazione trapezio-metacarpale della mano. L'impianto è disponibile in numerose misura, conune delle quile più essere utilizzata nolla mano destra o sinistra, Pere ogni tipo d'impianto è disponibile una vesta gamma di ceitzationi di prova, che rappresentano un valido sustio nella preparazione dell'osco, Cuesto precidio à destinato unicamente all'uso cementato.

- enas: Componente prossimele in cromo-cobalto ASTM F-75 Componente distale in polietiene ad attissimo paso molecolare (UHIMWPs) ASTM F-648

### INDICAZIONI

Empiano è indicato per la sostituzione totale dell'articolazione in pazienti con sviluppo acheletrico completo, che accusano dolore o instabilità dell'articolazione in seguito a traumi, patologie inflammatorie o degenerative o per la sevisione di procedure precedenti, in alternativa all'articolesi o alla chinurgia ricostruttiva.

- CONTROMDICAZION
- Interiore attito o laterite.

  Cissa, muscolatura, tendri o tessuti molii adlacenti compromessi de patologio, interiori o implanti prescedenti che non eono in grado di tomire supporto o fissazione adequati cer la protesi, immeturità schielotica.

  Accentata preseneibilità al materiali utilizzati in questo presidio.

AVVERTENZE (vedere anche le sezioni informazioni per la consulenza ai pazienti e Potenziali eventi avveriti .

Si raccomendo di informare i pazienti sulta maggiore probabilità di insuocesso, se gli impianti vengono sottoposti a sollecitazioni eccessive. I canchi particolarmente persenti, l'eccessiva mobilita e l'instabilità attrololere possono accelerare l'usur e provocare aventuali canni alta profesi per distacco, fisitiure o lassazione.

- PRECAUZIONI

  Non risteritizzare l'impianto. Non utilizzarlo se l'impianto stesso o la confezione sembrano desmeggiati, se è trascorse la data di scadenza o se si duota della siestità per quabilasi motivo.

- sterittà per qualstasi motivo.
  Una preparazione metiodosa del etto d'impiento a la scolta delle misura cometta
  dell'impianto atesso aumentario le probabilità di eato positivo dell'interento.
  L'impianto deve essere prolevato della conference sterie soto dopo aver pregnato
  e misurato contettamente il stro dell'impianto.
  Gli impianti devono assere maneggiati sectarivamente con l'austilio di strumenti
  surassati per evitare di graffiario, taglare o scallino il presidio, in modo da non
  compromettere le prestazioni dell'impianto.

### POTENZIALI EFFETTI AVVERSI

- intezione Perdita dell'uso della mano Invalidità permanenta Morte

### Rischi correlati alla sostituzione dell'articolazione

- chi corrolati alla sociituzione dell'articolazione
  Doiore
  Lesioni dei nervi, vasi sanguigni, tenden o tessuti molfi circostanti
  Figidità
  Dolore notturno e correlato alle condizioni atmosferiche
  Perdita di moltisia
  Frattura dell'ereparto
  Bertano dell'ereparto
  Usura accelerata del componenti del presidio
  Destacco dell'emplamio delle cess
  Instabilità dell'ereparto
  Usura accelerata del componenti del presidio
  Destacco dell'emplamio delle cess
  Instabilità dell'articolazione
  Lasione per l'ostruscione di cemento
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PROCEDURE CHIRURGICHE r nouvezona. O informacone. É disponible un manurie che descrive nei dettagli la procedura chirurgica da appli-care a questo presidio. É responsabilità del chirurgo acquisse familiarità con la pro-cedura prima dell'uso di quasti prodotti. È inolmi responsabilità del chirurgo anche acquisire familiarità con la pubblicazioni relativa e consultarsi con colleghi esperti in

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

- Oltre alle informazioni specifiche, riportate nelle sezioni Avvertenza ed Eventi avversi, si raccomenda di comunicare ai pazienti anche quanto segue: I componenti sostitulivi dell'eritoolazione hanno une durata limitata che, puriropporisuta difficile da stimites. Questi componenti sono realizzati con meterifali estrane, che vengono interdii nei corpo per riprattinare una potenziale indolfità a ridure ili dobte. Tuttava, considerando i numerosi latino biologici, meccanici e fisiochimici legati a questi dispositini, non si può partre dal presuposto che sano ni grado di sostenere il livelo di attività e i cracini del nomale osso sano per un penodo di tampo illimitato. L'eventutale insoperazi di effitti avversi potrabbe richiedere un secondo intervento, la revisione o la fusione dell'articolazione convolta.

STERILIZZAZIONE

ERILIZZAZIONE

Il prodetto è attor steritizzato con ossisto di etilene o raggi gamma.

Non ristoritizzare l'impianto, L'impianto fornito è atenia se la confezione è integra.

Non ristoritizzario se l'impianto stesso o la confezione sembrano damneggiatti, se è trascorsa la data di scadenza o se al dubtin della sterittà per qualsiasi motivo.

Sono disponibili calibratori di prove per evitamo di dover appre la confezione serie prima dell'impianto della provenia. L'impianto deve sessere prefevato della confezione sterile solo dopo aver preparato e misurato correttamente il salo dell'impianto.

GARANZIA LIMITATA QARIANIZIA LIMITATA
Avanta Orthopaedics, Inc., guardisce che il prevenire prodotto è conforme alle specifiche del produtture e che e sente da diletti di fabbricazione al momento della consegne. La presente garanzia escubio especificamente il difetti diervanti di uso enviroprio o non convetto o de errori di manipolizione del prodotto successivamente al nicevimento da parte dell'acquiverse, Avanta Orthopaedics non garantisce l'esito della

reconsidera dibitatione.

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



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BEORENZTE GARANTIE

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INDICATIONS
The Average PM Finger Prositions is indicated for user in antiroplasmy of the PIP park.

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CONTRADIDICATIONS

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WARNINGS (See site the Perior Courseling Indometion Section)

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- PRECAUTIONS

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### ADVERSE EVENTS

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For more conside one Table & Completions for US Persons in the Careod Forestance Section for recording schedule supply associated with the device

# POTENTIAL ADVERSE EFFECTS Committé Coppery Personné Status blanding blanding blanding blanding blanding blanding commander claudéry (Judy)

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CLINICAL EXPENSIONS
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CHRUROISCHE PROCEDURES

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### INFORMAZIONI PER LA CONSULENZA AL PAZIENTE de INTAFOR DE

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# PRODUCT INSERT

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PATIENT COUNSELING INFORMATION (See size Westerga)

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Lincheld P.L., Microempophetangesi anthropleaties: proeffette design constitutione. Hand Anthropleaties: Federation of European Societies for Surgery of the Hand. June 2000.

EU NEIRA DENTANT Melkel Princes Instructional Europe, Schuring 1 Ma. 51-55 NF Wangel, The Herbesterck 21 CS 416 595754

### FRANCAIR

DISPOSITIF HUMANITAIRE. La protince digitale Avenue MCP set sublee per le la subselle des Essen-line d'Amèrique sour subsetion en antregalente de l'antoide-rier MCP dans fou des tiese des survers.

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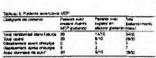
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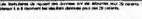
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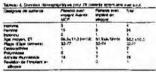
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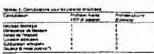
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\* 4 meters removates de la divier e mon sprie l'opérato

### Tableau L. Nombre de patiente americana direziona è chacue nes q

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REPRESENTANT EU Nedros Products Innoce Schulere 13a, 5145 NF Westerd, The Networks of 31 E2 415 565/164



19-0303 W/ PI

### FEDAROI

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DISPOSITIVO HUMANO.

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CONTRAMORIA CROMES

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Practicas en existención com principiros alternites.

ADVENTENCIA Privisos servicios si guestado de información dues el publicado Compas apracticas, mostificial accesar y trestabilidad estadar pueden constituir su deseguera existencia y com el encora o sibilor cualente par todigera, questrate o dis-tocarse el dispositivo, Los podentes sidente ser conscrivera de la probletad a uni-tiado de un filocolor querente apricialmente el de temporen assignadas sidentes allo de un filocolor querente apricialmente el de le temporen assignadas sidentes allo de un filocolor querente apricialmente de la temporen assignadas sidentes procesos de la conscripció de la construcción de la construcció

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### REACCIONES ADVERSAS POSISLES

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### Table 6. Numero de pazierose de los EEUU, finolerose en cada tabre del seguimento.

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### INFORMACIÓN PARA EL PACIENTE (viene serbido Acomismons)

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REPRESENTANTE EU
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VOORZONGEMENTATIONERS IN VOORZONGEMENT VERLES V

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### RESCURENCE COMPLICATION

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### DOTENTIAL E COMPLICATER

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Avers o'Drissanders, Inc., geranderer das dit product veliblest dass dir experimental
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### THEMO

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### EVENTI NEGATIVE

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### INFORMAZIONI PER LA CONSULENZA AL PAZIENTE IN TRUPOS NO

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EFFERLIZEZATION CONTRACTOR CONTRACT

ANALYZA LIMITATA
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Neticel Projects (Institutional Europa, Schulumy 13a,
1145 NP Neticologica, The Neptunlayale
31 EV 416 547754







### **ENGLISH**

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

This rifead Recon prosthesis consists of a cobalt chromium stem and the implant is designed to be snarried into the sheft of the proximal radius. The head of the implant articulates with the capitalium. The implant is evaluable in several sizes, each of which can be used in right or left heads. A range of trial sizers for each type of implant is available to add in bone preparation.

- reverse."
  ASTM F-1537 wrought cobalt chromkum molybdenum alloy for surgical implants.
  ASTM F-1590 bitanium powders for coatings of surgical implants.
  ASTM F-648 ultra-high molecular weight polyethylene powder fabricated form for

### INDICATIONS

NDICATIONS

lead Recon implant is intended for replacement of the proximal end of the radius.

Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, creptation and decreased motion at the radiohumeral and or proximal radio-uhar joint with:

a. Joint destruction or subhustion visible on x-ray

b. Resistance to conservative treatment

Primary replacement after facture of the radial head

Symptomatic sequelae after radial head resection

### CONTRAINDICATIONS

- An Interestructure Turkes
  Inadequate skin or musculotendinous system
  Growing patients with open epiphyses
  Previous open fracture or infection in or around the joint
  Known sensitivity to materials used in this device

WARNINGS (See also the Patient Courseling Information Section)

Sirenous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or discostion 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 aits may become intected, painful, avoide 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 when the patient's expectations or may deteriorate may be increased to proceed the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

### RECAUTIONS

- **IECAUTIONS**The implant is provided sterile in an underwaped package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility a questioned for any reason, the implant should not be used. Do not restardize, implants should be handled with blunt instruments to avoid scratching, outling or nicking the device so as not to adversely affect the implant performance. Polished bearing and bloper surfaces must not come in contact with hard or abrasive surfaces.

  The head and stern should not be implanted if the articulating surfaces are possibly demaged, this includes repeated attaching and detaching.

  The head of the prostlessis is impacted on to the ball of the after. Prior to assembly confirm that tyte articular surfaces are dry and free from contaminant.

### ADVERSE EVENTS

ADVERSE EVENTS
Potential adverse events reported with joint prostheses include pain, loosening, trachare delocation or infection. There have been some reports of patients with metal sensitivity needs consist chrome and/or transitivity needs in toneign body reaction of materials such as cobalt chrome and/or transitivity needs to the surposarial site. Injury to the surrounding neves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device.

### SURGICAL PROCEDURES

Surricular 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 distinct, it is the responsibilities 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 referent publications and constult 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-inclusif procedures such as soft itseue reconstruction or arthrodesis, prior to surgery is necessary. In addition to the patient related information confianced in the Warnings and Adverse Events sections, the following information should be conveyed to the patient: 1) Adverse effects may necessitate reoperation, evision, or fusion of the involved joint. If the patient is a soft in the patient components is difficult to estimate, if 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

STERILIZATION
This component has been sterilized by ethylene oxide or gamma rediation. 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 in questioned for any reason, the implant should not be used. Do not resterilize. Trial sizer components are available to exold having to open the sterile package prior to prostness implantation. The implant should be removed from its sterile package only after the implant size has been prepared and properly sized.

### LIMITED WARRANTY

Avanta Orthopaedics, Inc. warrants that this product meets the manufacturer's specifications and is fee from manufacturing defects at the time of delivery. The warrant psychiatric exclusive effects resulting from misuse, abuse or incrupers handling of the product subsequent to recept by the purchaser. Avanta Orthopaedics, Inc. does not warrant the outcome of the surpical procedure.

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

setz darf dieses Produkt nur von einem Azzt oder in dessen trieben oder eingesetzt werden.

BESCHREBUNG

Diese friead Rocon Prothese besteht aus einem Cobell-Chrom-Schaft und einem Cobell-Chrom-Schaft und einem Gelenkeinsatz aus Polyethylen. Der Schaft des Innientats ist zum Einsetzen in den Schaft des proximation Radius bestimmt. Der Kopf des Innientats als tim einem Kopf des Innientats als tim metmeren Größen erhältlich, die jewells für die finite oder die rechte Hand verwendet werden können. Zur Erleichterung der Knochespräparation ist ein Satz Probeimperates für geden mehrenatigt parhältlich.

- nostoria: Cobah-Chrom-Molybdan-Knetlegierung für chkurgische Implantata gen F-1537
- r-1537
  Täanpulver für Beschichtungen von chirurgischen Implantation gemäß ASTM F-1560
  - Pulvergefertigte Form aus uttrahochmolekularem Polyethylen (UHMW-PE) für chirurgische knolsıntate gemäti ASTM F-648.

### INDIKATIONEN

IDIKATIONEN

si Haad Roon Impientat ist zum Ersatz des proximaien Pladiusendes bestimmt:
Erzatz des Radiusköpfchens bei degenerativen oder posttraumatischen
Behinderungen mill Schmarten, Crepitatio und Bewegungseinschränkung am
Radiohumeral- und/oder proximaien Radiohumpelenk mit:

a. Radiologisch abchtbarre Gelenkzwestram goder Subbuouston
b. Resistenz gegenüber konservativer Behandfung
Primärersatz nach Fraktur der Radiusköpfchens
Symptomatisiche Folgeerscheirungen nach Radiusköpfchennesektion

### KONTRAINDIKATIONEN

- mit HAINDIKATIONEN Inadäquate Haut oder inadäquates Muskel-Sehnen-System Im Wachstum begriffene Patienten mit offanen Epiphysen Frühere offene Fraktur oder Infektion im Gelenk oder im Umkreis des
- nnte Überemofindlichkeit gegenüber den Implantatwerkstoffen

4. Bekannte Übernahrindichneit gegenüber den wepuransverkstorren WARNHINWEISE (Siehe auch Abschritt Patienteninformationen) Extreme Belastungen, übernahige Mobität und Gelenkinstabilität können zu frühzeitigem Verschleiß und eventuelen Versagen der Prothese durch Lockern, Berchen oder Verlagem führen. Der Pätient sollte über das erhöhte Riekte eines Versagens der Prothese bei Überbeanspruchung aufgektigt werden. Prothesen sind mechanische Produkte, der verschießen, ermüden oder brechen können. An der Innplantasionsstelle können Infektionen, Schmerzen, Schweilungen der Entschändigen auftreten. Das unvillegende Knochen- oder Weichteilgewebe krann in einem Zustand sein, der keinen ausreichenden Halt für das Innplantat bietet, oder kann sich mit der Zeit verschleichtern und dachurch eine hastabilität oder Delomität oder beides nacht sich ziehen. Der Notzen der Implantation kann unter Umständen den Erwartungen des Patienten nicht geracht werden oder mit der Zeit äbnahmen, sodass ein Revisionsegniff zum Austausch der Prothese oder zur Curchlüfuung alternativer Verfahren erforderlich ist. Ravisionseingriffe sind bei Prothesen nicht neiten.

VORSICHTSMASSNAHMEN

1. Die Profitiese wird ateril in einer unbeschädigten Verpackung geliefert. Sollte entweoer die Profitiese oder die Verpackung beschädigt, das Verfalldatum überschritten oder die Sterillät aus eigendelnem Grunde zweiferbart sein, darf die Profitiese nicht verwende werden. Die Profitiese nicht erneut aterfilleren.

2. Profitiesen aolten ausschließlich mit autmofen instrumenten gefasst werden, um krafter, Schrifte und Kerben auf der Profitiese zu vermeiden. Poliefer Gelienk- und Konuscoerflächen dürfen nicht mit harten oder abzeisiven Oberflächen in Kontakt

### KOMPLIKATIONEN

KOMPUIKATIONEN
Bekannta mögliche Komplikationen bei Gelenkprothesen aind Schmerzen,
Locksrung, Fraktur, Dislokstion oder infektionen. Bei einigen Patienten tratan
überempfinichteiten gegen Metall nach dem Gelenkeszt auf. Die Impalnation
von Materialen wie Coball-Chrom und/oder Titan kann zu Francikforpernealtionen in
der Limgebung der implemationsatelle fürmen. Darüber häuse können Verletzungen
der umgebenden Nerven, Blutgefäße, Bänder oder Weichteile auftreten.

### **OPERATIONSVERFAHREN**

OPERATIONS/VERT-APRIEN

En Operationsverlation zur Verwendung dieser Prothese ist erhältlich. Der Chirury
muss sich vor der Verwendung dieser Produkte mit dem Operationsverfahren vertraut
machen. Außerderen liegt es in der Verentwortung des Chirurpen, vor der Verwendung
dieser Produkte die relevanten Publikationen zu Rate zu ziehen und sich mit
erfahrenen Kollegen über des Operationsverfahren auszuziausschen.

erfahrenen Kollogen über das Operationsverfahren auszufausschen.

PATIENTENINFORMATIONEN (Siehe auch Warnin-weise)

Vor der Operation mass jeder Patient schriftlich über poteuzielle Komplikationen und
mögliche Alternativen aufgelüßet werden. Hierzu können auch Maßnahmen ohne
Prothessen, wie z.B. Weichteilekonstruktionen ober Arthrodenen zählen. Zustätzlich zu
den Patienteninformationen in den Abschnitten Warninweise und Komplikationen kötztlich zu
den Patienteninformationen in den Abschnitten Warninweise und Komplikationen können eine
neue Operation, einem Parvisionengriff oder eine Fusion des betroffenen Gesientse
erfordern. 2) Die Labersdauer der Gelenkersatz-Komponenten ist nur achwer
vorherzussgen, in jedem Fall aber begrenzt. Die Komponenten bestehen aus
körperfremden Material und werden in den Körper eingerflanzt, und die
Beweglichte möglichst wiederbetzustellen und Schrinezen zu verwingen. Aufgrund
zahlvelcher biologischer, mechanischer und physiochemischer Faktoren, die auf diese
Komponenten einwirken, können diese dem Aktivitätsniveau und der Besiehtung eines
gesunden Krinochers nicht über einen unbegrenzten Zelfraum standhalten.

### STERILISATION

STERILISATION
Deese Produkt wurde mit Ethylenoxid oder mit Hilfe von Gammastrahlen steriksiert.
Es wird steril in einer unbeschädigten Verpackung geleiert. Sollte entweder die Prothese oder die Verpackung beschädigt, das Verfaldatum überschritten oder die Sterlität aus rigendernen Ganude zweitighatt sen, darf die Prothese nicht verwendet werden. Die Prothese nicht verwendet werden. Die Prothese nicht erneut stanftsieren. Um die sterie Verpackung nicht zur Feststellung der nichtigen Größe der Prothese vor der (implantation offeren zu müssen, stehen Probeinsplantate zur Verfügung. Die Prothese der est dann aus der sterien Verpackung entormmer werden, wenn die Implantationsstelle ausreichend vorbereitet und die nichtige Größe der Prothese ermittellt wurde.

BEGRENZTE GEWÄHRLEISTUNG

Avanta Orthopsedics, Inc. gerantiert, dass dieses Produkt den Spezifikationen des
Herstellers entspricht und zum Zeitpunkt der Liefenung feis von Herstellungsfehlern
ist Diese Gewährleissungs schließt ausdrückfüch Schäden aus, die auf unsachigentäße
Behandlung, Missbrauch oder fallsche Verwendung durch den Berintzer
zuröckzufüren sind. Avanta Orthopsedics, Inc. gibt keine Gewährleistung für einen
Erfolg des chirurgischen Eingriffs.

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### **FRANÇAIS**

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

### DESCRIPTION

DESCRIPTION

Cette profitee rifered Recon consiste en une sige et une tête en cobalt-chrome ainsi
qu'en un module d'articulation en polyéthyène. La tige de l'implant est prévue pour
une rissertion d'anné le corps du radius proximals. La tifé de l'amplant a'articule sur le
conclyle de l'humérus. L'implant est disponible en plusieurs belles, utilisables du côté
droit comma du côté gauche. Une série de califoreurs d'esse est disponible pour
chique type d'implant, en tant qu'assistance à la préparation deseuse.

- térieux : Alliage de cobelt-chrome-motybdène façonné pour implants chirurgicaux (conforme à la norme ASTM F-1537) Poutres de titrare pour enrobages d'implants chirurgicaux (conformes à la norme ASTM F-1580) Forme de poudre de polyéthylène à poids moléculaire utire élevé trathé pour implants chirurgicaux (conforme à la norme ASTM F-648),

### INDICATIONS

L'implant ri-lead Recon est prévu pour le remolacement de l'extrémité proximale du

- impaint integer ressar ess purso.

  Remplacement de la téte radiale en raison d'incepacités dégénératives ou postaumetiques accompagnées de douieur, créptation et parte de mouvement de 
  articutation radio-humérale st/ou radio-unaire proximale avec ;

  a. Destruction de l'articutation ou subluosition visible aux reyons x.

  b. Résistance à un trattement conservates de 
  Remplacement primaire après fracture de la tête radiale.

  Séquéles symptometiques après résection de la tête radiale.

### CONTRE-INDICATIONS

- incompatibilité de la peau ou du système musculo-tendineux Patients en cours de croissance et syant des épiphyses ouverles Antécédent de fracture ouvernet ou d'infection dans ou autour de l'articulation Allergie svérée aux matérieux de ce dispositif

a. Asergie averee sur materiaux de oe dispositif AVERTISSEMENTS (Voir aussi la section Conseita donnés au patient). De fortes charges, une mobilité auxoesaive et une instabilité articulaire peuvent accédérer l'usure du dispositif at entrainer un dothec éventuel par relâchement, fracture ou dislocation. Il faut informer le patient de l'augmentation du risque d'âchec du dispositif en cas de adificiatione auxoesaives. Les implants sont des dispositifs mécaniques. En tant que tels, ils peuvent à'user ou se casser, Le aite d'un implant pout devent douloureux, à l'infecter, s'entier ou être le siège d'information. Il se peut que l'état de l'os adaccert et des tissus mous ne sermette pas le pose de l'implant ou as défériors avec le lamps, entrainant une instabilité, une difformité ou les deux. Il se peut que les aventages de l'implantation en répondent pas aux attenties du patient ou diminuent su fid ut brançs, nobessitant une chiurgie de révision afin de remplacer l'implant ou le resours à d'autres procédures. Il n'est pas rare de pratiquer une chiurgie de révision sur un implant.

### PRÉCAUTIONS

- L'implant est fourni stèrile dans un embaliage scellé. Si l'implant ou l'embaliage paraît endommagé, si la déle 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.
- nestériliser.

  Les implants doivent être manquiés avec des instruments à bout mousse pour ne pas rayer, couper ou entailler le dispositif et ne pas perturbler les performances de l'implant. Le paier poi et les surfixes consiques ne doivent pas entrer en contact avec des surfaces stratérés ou dures.

  Il ne faut pas implanter la tête et la tipe s'il y a un risque d'endonnager les surfaces articulaires, notamment en ces de pose et de dépose répétées.

  La tête de la prothèse est fixés aur la bille de la tige, Avent l'assembley, vérifier que les autoces articulaires sont abéctus et qu'elles ne sont pas contaminées.

### EFFETS INDÉSIRABLES

EFFETS INDESSIRABLES

Las effits inclusivables éventuals qui ont été rapportés avec des prothèses articulaires sont la douteur, le relâchement, la tracture avec luxation ou l'infaction. Des cas de patients présentant des relactions d'allergée au metal autre à un remplacement d'articulation ont été rapportés. L'implantation de matérieux lets que le cohetichrons et/ou le trâne peut entrainer une résction au come étranger adjacente au site de l'implant. L'implantation de of dispositif pour avoir pour conséquence une fésion traumatique des nerfs, des veisseaux sanguins, des tendons ou des tiesus mous.

### PROCÉDURES CHIRURGICALES

PROCEDURES CHIRURGICALES Une proclèture chirugicale concernant l'utilisation de cet implant est disponible commissance de cette procédure est de la responsabilité du chirugien. Il inco-également au chirurgien de se tenir au courant des publications perinentes e consulter des confréres expérimentés au sujet de la procédure à utiliser.

consulter des confireres expérimentés au sujet de la procédure à utiliser.

CONSEILS DONNÉS AU PATIENT (hor aussi Avertissementa)
Avant l'opération chiurigicale, il est nécessaire de fournir à chaque petient
programme pour une chiurigie d'implaint des conseils et des informations sur les
complications aventuelles et les solutions de remplacement, notamment le
sconstruction de tissue mous ou l'artitrodée. Outre l'information resistre eu petient
contenue dans les sections Aventissements et Effets indéserables, le patient dont
recevoir l'information sulvenire : 1) Des éfets indéserables peuvent nécessiter la
réopération, le révision ou la fusion de l'artitoution concernée. 2) il est difficiel
réstimer la durée de vie prévué des composants de remplacement d'artituation,
mais às no sont pas inusables. Ces composants de me senteurer la mobilité ou de
réduire la douteur. Toutefois, en raison des nombreux facteurs biologiques,
mécaniques et physio-chimiques qui affectent ces dispositifs, les composants ne
peuvent pas supporter le même nineau d'activité et les mèmes charges qu'un os sain
pendant une période dismitée.

### STÉRILISATION

STERILISATION

Ce composant a été sitérisé per oxycle d'éthylène ou rayons gamma. L'implant est fourni stèrile dans un emballage scalé. Si l'implant ou l'emballage parait endommagé, si la date de péremption set dépassée ou si la stérilé est mise en cause pour une mison ou une autre, i ne faut pas utiliser l'implant. Ne pas restériliser. Des calibreurs d'essai sont disponibles : is évitent d'ouvrir l'emballage stèrile avant l'implantation de la protible. Il fruit entière l'implant des on emballage stèrile uniquement après la préparation et le dimensionnement correct du site de l'implant.

### GARANTIE LIMITÉE

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

### REPRÉSENTANT EN EUROPE

### **ESPAÑOL**

ral de los EE.U.V. restringe la venta, la distribución y el uso de este ndo que se efectúen solamente por un médico o por orden de un

DESCRIPCION

La pròlesia rifead Recon está compuesta de un vástago de croxeo-cobalto y de una cabeza del mismo material, con un núcleo articulante de polietieno. El vástago del arplente ha aido diseñado para insertarse en el actremo proximal de la diáficia del La cabeza del implante articula con el condio humeral. Esta implante se tatre en varios tamaños, cada uno de los cuales puede aplicarse duamente para la extremidad superior desecha o izculerda. Con el propósito de tar la preparación del hueso, se asumisiente una gaina de prótesia de prueba de distintos tamaños pere cada tipo de implante.

- ASTM F-1537: Alención foriada de cobello-cromo-molibdeno para implantes
- quirúrgicos; ASTM F-1580: Polvo de titario para el revestániento de implantes quirúrgicos; ASTM F-648: Forma fabricada de polvo de polietileno de peso molecular ultrassievado para implantes quirúrgicos.

- INDICACIONES
  El Implante ri-tead Repon ha side diseñado pera la austitución protésios de la epifisis proximal del radio:

  1. Sustitución de la cabaza radial en caso de afecciones degenerativas o posi-traminationes que producen oldor, complación y restricción de la movididad en rivel de la erticulación humano-radial y/o de la articulación radio-cubital proximal, com:
  a. Destrucción articular o subtuación visible a reyos. V.
  b. Falta de respuesta o respuesta inastisfactoria al tratamiento conservador;
  2. Sustitución primaria en caso de fractura de la cabaza radial;
  3. Tratamiento de secuelas sintomáticas post-ressección de la cabaza radial.

- CONTRAINDICACIONES

  1. Condiciones inadecuadas de la piet o del sistema músculo-tendinoso;

  2. Pacientes en edad de crecimiento, con epitisis albertas;

  3. Fractura sistema previs o infección en o artededor de la articulación;

  4. Hipersensibilidad conocida e los materiales utilizados para la fabricación de este

ADVERTENCIAS (Ver tambén el apartado "Información y asesoría del paciente"). La sobrecarga mecánica extrema, la movifided excesiva y la inestabilidad articular pueden conducir a un desgaste excelerado y a un falto eventual por afloramiento, frectura o dislocación del implanto. Deberá explicarsa a los pacientes que el rieser de fallo del dispositivo aumenta el áste as ometido a una sobrecarga mecánica

excesiva.

Los impliantes son dispositivos mecânicos susceptibles de desgeste, fatiga de material o fractura. El sitio de impliantación puede presentar infección, dolor, hinchazón o inflamación, La calidad del hueso y de los tejedos blandos adysection puede ser inselecuación para proporcionar sustentación al impliante , o puede deteriorarse con el tiempo, pudiendo producirsa inestabilidad, deformidad o ambies complicaciones. Los beneficios de la civilgá impliantarios pueden no satisfacer las expectativas del peciante o pueden aminorarse con el tiempo, haciendo necesaria lo cirugia de revisión para sustituir el impliante o para efectuer pronoccimientos alternativos. En la cirugia de impliantes, las intervenciones de revisión no son introcuentes.

### PRECAUCIONES

- EIECAUCIONES

  El impiarte as suministra estéril en un envase intacto. No utilizar el producto si el impiante o el envase están daflados, si la fecha de caducidad se ha sobrepasado, o al por cualquier otra razón la esterilidad se considera dudosa. No reesterilizar el producto.

  Los impiantes deberán manipularse con instrumentos romos para evitar las rayaduras, po corteo o las melladuras, y para no alterer su funcionamiento. Las superficies pulmentatada de sostén o alhusadas no deben entrar en contacto con superficies duras ni abrasivas.
- superficiae duras ni abrasivas. La cabeza y el vistago no deberún implantarse al se sospecha que sus apperticas articulares puedan estar dafladas. Esto incluye el caso de su inserción y desinserción reterendas.

  I cabeza de la protesia se impactada aobre la estera del vietago. Artes del critage, comprobar que las apperficies articulares estén aecas y libres de justancias contientementes.

### REACCIONES ADVERSAS

REACCIONES ADVERSAS

Los posibles efectos destavorables observacios en caso de implantación de articulaciones protásicas incluyen dolor, aficiamiento, fractura, dislocación o infección. Se ha publicado algunos casos de pacientes con reacciones de hipersensibilidad at metal después de la sustitución articular, La implantación de materiales tales como el cobatio-corron y ole ol transio puede trane como el cobatio-corron y ole ol transio puede trane como escuencia una reacción de cuerpo extraño artededor del altío de implantación. Pueden courrie lesiones de los nervios, los vasos sanquiences, los tendones o los tejidos blandos circundantes como consecuencia de la implantación de este dispositivo.

### TECNICA QUIRURGICA

I ECUNICA CUPRURGICA Se aministra una descripción de la técnica quíntigica a aplicar para la implantación del producto. El cirujano bene la responsabilidad de familiarizanse con el procedimiento quírtigipos antes de usar estos productos. El tiene, además, la responsabilidad de mantenere informácio de las publicaciones cionificas relevantes si respecto y de consultar a expertos soeros del procedimiento, antes de la aplicación clinica del profusicio.

clinica del producto.

MFORMACION Y ASESORIA DEL PACIENTE (Ver también "Advertencias").

Antes de la intervención, es indispensable asegurar que todo paciente que haya de someterse a le ciruga de implantación reciba una documentada asesoria scerça de las complicaciones aventuales y sobre les posibles intervenciones attentaries, las cuales pueden incluir procedimientos no implantations, tales como la reconstrucción te telédos blandos o la artóreales. Adventacias "y Resociones advensas", debe proporcionama al paciente la siguiente información: 1) Las resociones advensas pueden hacer necestaria la recoeración, la revisión o eventualmente la fusión de la artículación comprometida, y 2) Si ben la vide útil que cabe esperar de los componentes artículares protestados es dificil de estimar, edito no son trifindos. Entre componentes están hachos de materiales extraños al organismo y se los coloca para restablecer la movificiad o para cartículos y fisico-cuminos que afectura a estos depositivos, no puede esperanse que ellos resostan el mismo nivel de actividad su las sobrecargas meclanicas que el hueso normal sano durante un periodo de tempo rimitado.

### ESTERILIZACION

ESTERILIZACION

Este componente ha sido esterilizado con duido de atlieno o por rayos gamma. El implante se suministra esterilizado y en un envase intacto. No utilizar el producto si el implante o el anvuse están dufiscios, si la fectar de caducidad se ha sobrepasado, o al por outilizar el trapacione de razolo la esteridad se considera dutosa. No revesterilizar el producto. El suministro incluye componentes de prueba para que el civijano na tempa que abre el envase están finata el momento mismo de implanta isa protesa. El implante deberá sacarse de su envase estéril solumente después de que el sidio de implantación haya sido completamente preparado y recién después de haber determinado apropisidamente el lauriaño requerido.

GARANTIA LIMITADA
Avanta Orthopaedics, inc. garantiza que, en el momento de su entrega, este producto
currocie les especificaciones del fabricante y está tizre de de defectos de fabricación,
La presente grantita excluye especificamente los fatiliss que resulten como
consecuencia del mai uso, del abuso o de la manipulación incorrecta del producto,
con posterioridad a su produpción por para del contryardor. Avanta Orthopaedics, inc.
no garantica el resultado del procedimiento quiving co.

RESENTANTE EN LA UE S145 NP Wasalwijk, The Netherlands 31 (0) 416 563754

## Records Processed by CDRH DID on 3/31/2023

Krachtens die federale wetgaving (VS) mag dit medische hulpmiddel uitskutend door of op voorschrift van een arts worden verkocht, gedistribueerd of toegepast.

### BESCHRUVING

BESSLITHILIVING
De riflead Recon prothese bestaat uit een steel van kobaltchroom en een kop van kobaltchroom met een arboulerend itzetstuk van polyettiysen. 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 capitalium. Het implantaat is in verscheidene maten verkrijpbaar, die elk in de rechter- of sinksyhand kannen worden toegepaat. Voor elk type implantaat is en neeks proefpassens verkrijpbaar ter ondensteuring van het gereedmaken van het bot.

- Meteriaat:

  ASTM F-1537 gesmede legering van kobat, chroom en molybdeen voor chiurgesche insplantaten

  ASTM F-1530 titsampoeders voor het coaten van chiurgische implantaten

  ASTM F-648 Un-RAVP (Uitze-High Molecules Weight Polyethylene) vervaardigd in de vorm van een poeder voor chirurgische implantaten.

### INDICATIES

ritiead Recon implantaat dient voor de vervanging van het proximale uiteinde van

- It rhead Recon implantated dent voor de vervanging van het proximate unterdov en redulos: van de radiuskop vanwege degeneratieve of posttraumatische invaliditeit die gepaard gaat met pfin, creptatie en verminderde beweeplijkreid van het radiohumerale envol proximate radio-ulvaler gewricht en tevens: a. Gewrichtsbraak of subkuste die zichtbaar is op een röntgenopname b. Ongeschilicheid voor een conservatieve behandeling Primere vervanging na een frestuur van de radiuskop Symptomatische sequelae na resectie van de radiuskop

### CONTRA-INDICATIES

## Intercement of the second of t WAARSCHUWINGEN (zie ook het onderdeel Informatie over advisering van de

patienti Zwar belastirig, overmatige mobiliteit en articulaire instabiliteit kunnen alternati lederi tot verareide stittage en uttendelijk faten door loratken, breuk of dislocatie van de protiesee. Patienten moet duidelijk worden gemaand dat er een urehoogde kara op delect raten ven de prothese besteat als fatea wordt overbellast. Implemation zijn mechanische bruipmiddeen die kunnen afstijlen, onderworpen zijn aan mastrasiamienheid en kunnen breken. Een implantsteiphaats kan gelrifecteerd, pijntij, gezwellen of ontstoken raken. Het neburge bot on de nasstiggende weke deen kunnen onvoktoende steun geven aan het insplantaat of kunnen in de koop der lijd achteruitgaan, waardoor instabiliteit kan ontstaan of mevorming kan optreden De voordelen van operatieve insplantate kunnen niet overeenkomen met de verwachtingen van de patietisch of het emplantaat kan ne verkoop van tijd achteruitgaan, waardoor revisie let vervanging ven het implantaat of alternatieve ingrepen noodzakeilijk kunnen worden. Revisies van implantaties zijn niet ongebruikelijk.

### VOORZORGSMAATREGELEN

- DORZORGSMAATREGELEN
  Het implantat wordt steriel in een onbeschadigde verpakking geleverd. Als het implantaat of de verpakking beschudigd lijkt of de vervaktatum is verstreken, of as de steritiett om enige reden wordt betwijfakt, dan mag het implantaat wordten gebruikt. Niet oprieuw steritiseren. implantaaten moeten wordten gebruitet voorden gebruitet op de voorkomen diet brassen, sneden of bramen op de prothese ontstaan die het functioneren ervan nachelig kunnen betinkoleen, Geooligist algeroopen/akken in taps tookopende vlakken mogen niet in aanvaking komen met harde of schurende open-vlakken.
- tape bescoprede valueer nogen net in aurant particular texter in the control of schools opportunities.

  3. De kop en steel mogen niet worden gerimplanteerd als de articulerende oppervlakken mogelijk beschadigd zijn; dit is ook het geval bij herhaald aarbrengen en wignemen.

  4. De kop van de prothese wordt op de bel van de steel geïmpacteerd. Controleer, ekvorens de groep samen te stellen, of de articulaire vlakken droog en vrij van verontreinigingen zijn.

### COMPLICATIES

COMPLICATIES:
Potentièle complicaties beschraven met gewrichtsimplantaten zijn onder meer pist, loszaken, breuk, dislocatie of infectle. Er zijn patiënten beschraven met metaalovergevoeligheid na een gewrichtswarvaging, Implantatie van metarielsen als kobalich oon en/of (titaen kunnen een reccie op inchaarneveende voorwerpen naast de implantatieplaats tot gevolg hebben. Er kan letsel van de ommigende zenuwen, bloedvalen, pazen of weite deen optreden als gevolg van implantatie van deze

### CHIRURGISCHE PROCEDURES

Christian in invocation in production of the first send in inclantaat verlerighear. Het vert en en christian in inclantaat verlerigheid ver de christig om, coorsignaad aan gebruik van de oppoducten, vervouwel te zijn net de procedure. Dearmaat valt het onder de veramvoordelijkheid van de christig om vervouwel a zijn met de speviewinde publised en vooraligaand aan gebruik advies te vroeget aan erveren collegae ontrieetii de en vooraligaand aan gebruik advies te vroeget aan erveren collegae ontrieetii de processes ontrieetii de contrieetii de contrieetii de contrieetii de processes ontrieetii de contrieetii de contrieetii de contrieetii de processes ontrieetii de contrieetii de contrieetii de contrieetii de contrieetii de processes ontrieetii de contrieetii de contrieetii de contrieetii de contrieetii de processes ontrieetii de contrieetii de contrieetii de contrieetii de processes ontrieetii de contrieetii de contrieetii de contrieetii de contrieetii de processes ontrieetii de contrieetii de contrieetii de contrieetii de contrieetii de processes ontrieetii de contrieetii de contrieetii de contrieetii de contrieetii de processes ontrieetii de contrieetii de contrieetii de contrieetii de processes ontrieetii de contrieetii de contrieetii de contrieetii de contrieetii de processes de contrieetii de contrieet

### INFORMATIE OVER ADVISERING VAN DE PATIENT (zie ook

INFORMATIE OVER ADVISERING VAN DE PATIÊNT (zie ook Waarschuvengen) het is noodzakelijk om elike patiënt die implantatie zai onderpaan tevoren documentatie en advies te geven betreffende de potentiële complicaties en alternatieven, waarnoder mogelijk het atzien van insplantatie, bijvoorbeeld reconstructie van weke dele of artrodese. Naast de patiëntperelatierde informatie in het onderdeel Waarschuvelingen en het onderdeel Complicaties most de volgende informatie aan de patiënt kenbaer worden gemaakt 1] Comolicaties kunnen een nieuwe ingreep, revisie of hissie van het betreffende gewricht noodzakelijk maken. Hoowel de verwachte levenatuur van de onderdelen van de gewrichtsvervenoging moeilijk is te schatten, is deze eindig. Deze onderdelen zijn gemaakt van inchaarsnierdend matenaale in worden in het hotaarsniepdenacht om, waar moegelijk, de mobiliteit te herstellen of de pijn te verminderen. Als gevolg van de divorse biologische, mechanischte en hysiochemische factoren die mivood hebben of een dergelijke prothese, kan van de onderdelen niet worden verwacht dat ze gedunende onbeperkte tijd de natie van activiteit en de belasting van normaal gezond bot kunnen wererstaan.

### STERILISATIE

STEMBLISARIE: Dit ondereid is gesteriliseerd door middel van ethyleenoxide of garnmastraling. Het implantaat wordt steriel en in een onbeschadigde verpasking geleverd. Als het implantaat of de verpnisking beschadigd jkt of de vervaskund is verstelen, of als de sterilieli om enige reden wordt betwijfeld, dan mag het implantaat niet worden gebruikt. Niet opniseev steriliseern. Er gir proefonderdeine verkrijgbaar, zodat de steriele verpalsking voorafgaand aan de prodiseer-implantatie niet hoeft te worden peopend. Het implantaat neg urstalutend uit de steriele verpalsking worden genomen nadat de implantatieptaats is voorbereid en grondig is opgemeten.

### BEPERKTE GARANTIE

BEPERIKTE GARANTIE.

Avanta Orthopsedica, inc. garandeert dat dit product ten tijde van de levering voldoet aan de spocificaties van de fabrikent en vij is van producteforiene. Deze garante skuit specifiek defecten uit de het gevolg zin van verheerd gebruik; mistruik of verkeerde omgang met het product na ontvangst door de koper. Avanta Orthopsedics, inc. geeft geen garanties omtivent de uitkomst van de chluvigsche

VERTEGENWOORDIGER BINNEN DE EU Schutweg 13a

### ITALIANO

ATTENZIONE

La legge federale (degli Stati Uniti) limita la vendita, la distribuzione e l'uso del 
reseanta dispositivo al personale medico o al caso di presortaione medica.

### DESCRIZIONE

DESCRIZIONE

La presente protesi ri-lesd Recon è costituita de uno stelo e da una testa in lega di cobato-cromo con inserto articolare in poletilene. Lo stelo dell'impianto è stato progettato per l'inserimento nei fusto del radio prossimale. La testa dell'impianto è articola nel capitelo. L'impiento è disponibile in varie misure, clascune delle quali può essere utilizzata per la mano destra o sinistra, linoltre, a ogni tipo viene abbinata una serie di calibratori di prova, che possono fornire un ausilio per la preparazione dell'osso.

- Iterials'.

  Lega ASTM F-1537 di cobatto-cramo-molibdeno per la levorazione piestica di impianti chiurgici.

  Polveri di tranio ASTM F-1580 per il rivestimento di impianti chiurgici.

  Componenti in polvere di polietiera ASTM F-648 ad affissimo peso molecolare per la realizzacione di impianti chiurgici.

- redio:

  1. Sostituzione della testa radiale in seguito a disabilità degenerative o poettraumatiche caratterizzata da dolore, orepitazione o mobilità ridotta dell'articolazione 
  radio-omerale e/o radio-ultran prossimila cost:

  a. distruzione o subbissazione dell'articolazione visibile si raggi x.

  b. resistenza si trattamento conservativo

  5. Sostituzione primaria dopo la frattura della testa radiale

  3. Sequele sintomatiche dopo la reseazione della testa radiale.

- CONTROINDICAZIONI

  1. Apparato cutariao o muscolo-tendineo inteleguato
  2. Pazienti in crescita con epifisi aporte.
  3. Fratura soperta o intigione progressa all'interno o intorno all'erdicolazione
  4. Accentata (persensibilità ai meteriali impegati in questo dispositivo

AVVERTENZE (Si veda anche la Sezione relativa alle Informazioni per la Consuleroz al Paziente) I carichi periocolamente pesanti, la mobilità eccessiva a l'instabilità erisolare possono accelerare l'utura e determinare l'eventuale danno della protesi per allertamento, frattura o dialocazione. Si racconanda di Informare i pazienti sulla maggiore probabilità che si verifichi tale evenienza; se vengono esercitate

silentamento, frettura o dislocazione. Si racconsenda di Informare i pacienti sulla maggiore probabilità che si verifichi tale evenienza, se vengono esercitate soleccitazioni eccessive. Gli impienta sono dispositivi meccarici esposti a usura, sforzo o rottura. Il atto di un mpiento potrebbe essere popito da Infazione, procurare disione, gonfiarati o intermarsi. Lo atto dell'osso adiscontra e del tessulo mole potrebbe risultare sindegiunto a sostenere l'impiento, oppure potrebbe deteriorari nel corso del tempo evidenciando instabilità, deformità o entremathi i problemi. Il benefici della criurgia simplamiologica potrebbero non soddisfrare le aspettative del paziente o deteriorare in corso del tempo, richiedendo un intervento di revisione per sostituire l'impianto o l'esocuzione di procedure silemative. Le operazioni chiurgiche di revisione non sono

- PRECAUZIONI

  1. L'impianto viene foruto staria in confezione integra. Non utilizzarlo se il dispositivo stesso o la confezione sembrano diarrienggiati, se è superata si data di scudenza o in caso di dubbi per qualissia mottro eulla sterita della confezione. Non ristarfitzzare.

  2. Manipoliare gli impianti con sinumenti amussati per evitare graffi, tagli o incistoni che ne comprometterebbero il funzionamento. Le superfici lucidate del cono e del supporto non devono venire a contatto con parti dure o abtrasive.

  3. Non impiantare la testa e lo steto, qualora le superfici di articolazione dovessero presentare danni dovetti anche ai ripetuto attacco e distacco.

  4. La testa della protesi s'incastra sulla stera dello steto. Prima dell'assemblaggio, accertaral che le superfici di articolazione siano asciutte e prive di contaminanti.

IN TECLATIVI

1 potenziali eventi negativi resi noti in merito alle protesi anicolari comprendiona dolore, pertita, sussazione o infezione. Alcuni pazienti hanno riportatto reazioni di joersenabilità ai metalli dopo la sostituzzione dell'articolazzone. L'impianto di materiali come le leghe di cobalito-nome allo i titanzio può determinane runa reszione al corpo estranno in prossamità del alto dell'impianto, in seguito, all'introduzione del praesnite dispositivo possono verificiarsi lesioni ai nervi circostanti, si vissi aanguigni, ai tandini o ai tessuti molti.

PROCEDURE CHIRURGICHE

É disponibile una procedura chirurgica destinata all'uso del presente dispositivo per
imparsto. El responsabilità del chirurgo acquisire tamigiantia con tale procedura prima
i utilizzare questi prodosti. Il chirurgo è attrast lenuto a consocere la documentazione
sull'argomento e a consulturai con colleghi esperti, in mento alla procedura prima di
escarura l'inferioratio.

### INFORMAZIONI PER LA CONSULENZA AL PAZIENTE (Si vedero enche le

PRIVENINAZIONI PER LA CONSULENCA AL PAZIENTE (5 vedano enche le Avverienze).

Pixina di effettuare l'intervento, ogni paziente in lista d'attesa per la chirurgia implantologica deve ricevere una consulenza documentata sulle potenziali complicanze a sulle alternative, che potrebbero comprendere procedure di non-implanto comi la ricossizzione dei tessuti moli o l'artrodesi. Otre alle informazioni specifiche, riportate nelle Avverienze e negli Eventi negativi, si recoronande di comunicare al paziente anche quanto seque. 1) L'aventuale insorgenza di eventi negativi potrebbe inchiedere un secondo intervento, la revisione o la fusione dell'articolazione coliviota. 2) I componenti sostituivi dell'articolazione hanno una durita limitata che, purtopo, rautta di difficile stime. Ess sono realizzati con materiali estranel, che vengono introdotti nel corpo per ripristinare is mobilità o ridure à dolore. Tuttavia, considerando i motti fattori biologici, meccani e fisicochimici legali a questi dispositivi, non si può pertre dal presupposto che siario in grado di sostenere il ivelio di attività e i carichi di un osso normalmente sano per un periodo di tempo l'ilminato.

### STERILIZZAZIONE

SI EMILIAZZAZIONE

Il presente componente è stato sterilizzato con ossido di etilene o raggi gamma.
L'implianto risulta sterile nella confezione integra. Non utilizzanto se il dispositivo
atesso o la confezione sembrano diamenggiati, se i rascorera la diata di acadenza o se
si dobbia della sterifica per quasissali motivo. Non risterifizzane. Sono disponibili del
calibratori di prova per evitare il apertura della confezione sterile prima d'implantare la
protest. Preisvane l'impento dalla confezione sterile poi dopo aver preparato e
comettamente dimensionato è sito dell'implanto.

### GARANZIA LIMITATA

GAPTANICIA LINE CLAIA
Avanta Crithopaedica, inc.; generitisco che il presente prodotto risponde alle specifiche
del fabiricaria e noi escribi presenta d'ieti di vorzazione al momento della consegna. La
representa e noi escribi especificamente i del rifetti risultati momento della consegna. La
o manipolazione societta del prodotto dopo il ricoviniento da perio dell'accusivente.
Avanta Crithopaedics, inc. noi risponde per l'estato della prodotta chirufocca.

RAPPRESENTANTE PER L'UE

5,5

# 

PRODUCT INSERT

AVANTA HEAD RECON IMPLANT
AVANTA HEAD RECON IMPLANTAT
AVANTA HEAD RECON IMPLANTAT
AVANTA HEAD RECON
A IMPLANTE AVANTA HEAD RECON
A IMPLANTA AHEAD RECON IMPLANTANT
AVANTA HEAD RECON IMPLANTANT
A SIMPIANTO AVANTA HEAD RECON

### **ENGLISH**

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

### DESCRIPTION

DESCRIPTION
This friend Recon implicit consists of a cobalt chromium siem and a cobalt chromium head with a colyethylens articulating insert. The stem of the implant is designed to be married into the shart of the proximal radius. The head of the implant articulation when the capitalism. The implient is available in several sizes, each of which can be used in right or left hards. A range of trial sizers for each type of implant is available to aid in bone preparation.

- denais: ASTM F-1537 wrought cobalt chromium molybdenum alky for aurgical implanta ASTM F-1580 trianium powdera for costings of surgical implants ASTM F-848 ultra-high molecular weight polyethylene powder fabricated form for

### INDICATIONS

- IDICATIONS
  lead Rocon krupant is intended for replacement of the proximal end of the radius:
  Replacement of the radial head for degenerative, or poet-traumatic disabilities
  presenting pain, crepitation and decreased motion at the radiohumeral and or
  proximal radio-ulter joint with:

  a. Joint destruction or substaution visible on x-ray
  b. Resistance to conservative treatment
  Frimary replacement after facture of the radial head
  Symptomatic sequetae after radial head resection

### CONTRAINDICATIONS

- WARNINGS (See also the Patient Countering Information Section)

  Stremous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by toosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for devide felicine in excessive demands are made upon it.

  Implants are mechanical devices that can be worn away, fatigued or broken. An implant alter may become infected, painful, swollen or inflamed. The status of the adjacent bone and soft lessur may be inadequate to support the implant, or may deteriorate in their resulting in instability, deformity, or both. The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time, excessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

### .ECAUTIONS

- ECAUTIONS
  The inpain is provided sterile in an undamaged package. If either the implant or the puckage appears damaged, explained date has been exceeded, or if sterility is questioned for any mason, this implant should not be used. Do not resterilize, implants should be handled with blant instruments to avoid excelcting, cutting or nicking the device as a so not to adversably affect the implant performance. Policy beauting and taper excellent most not come in contact with hard or abrasive sur-
- oceaning and tapter statuts from the country oceaning and tapter states. The head and stem should not be implained if the articulating surfaces are possibly damaged, this includes repealed aftaching and detaching. The head of the prosthesis is vaparated on to the bell of the stem. Prior to assembly confern that the articular surfaces are day and the strong contraminant.

### ADVERSE EVENTS

ADVERSE EVENTS
Potential adverse events reported with joint prostheres include pain, loosening, fraction, dislocation or infection. There have been some reports of patients with metal sensitivity reactions following joint repicement, implantation of materials such as cobet chromo and/or littenkim may result in foreign body reaction adjacent to the implant stel, injury to the surrounding nerves, blood vessels, tendons, or soft lissues 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 support 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.

and consult with experienced associates regarding the procedure before use.

PATIENT COUNSELING (INFORMATION (See also Warnings)
Providing each perient scheduled for emplant surgery with documented counseling of potential complications and alternatives, which may include non-implicit procedures such as soft issue reconstruction or attractions, prior to surgery is necessary. In addition to the patient related information contained in the Warnings and Adverse clivents sections, the following information should be conveyed to the patient. 1) Adverse effects may necessariate reoperation, revision, or fusion of the involved joint. 2) While the respected (See 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 pair. 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 cormal beafting bone for an unlimited period of time.

### STERILIZATION

STERILIZATION

This component has been sterifized by ethylene oxide or gamma radiation. The implient is provided sterile in an undamnaged package, if either the kinplant or the package appears damnaged, expiration date has been exceeded, or if sterifity is dussioned for any reason, the implant should not be used. Do not resterifize. This sizer components are available to asoft baving to open the sterile package prior to prosthesis implantation. The implant should be removed from it sterile package only effect the implant sterile has been prepared and properly sized.

### LIMITED WARRANTY

LIMITED WARHANTY
Award Othopaedics, Inc., warants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of definery. This waranty specificatly exclused selects 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 supplied procedure.

# EU REPRESENTATIVE

# Medical Products International Europe, BV Schutweg 134 514S NP Waziwijk. The Netherlands 31 (0) 416 563754

## Records Processed by CDRH DID on 3/31/2023

### RESCHREIBUNG

BESCHREIBUNG
Diese Haad Roon Prothese besteht aus einem Coball-Chrom-Schaft und einem Coball-Chrom-Kopf mit einem Gelenkörsetz aus Polyethylen. Der Schaft des Implantats ist zum Einsetzen in den Schaft des prozimatien Radios bestämmt. Der Kopf des Implantats artisufiert ma dem Humensköptchen. Das Implantat ist in mehreren Größen erhällich, die jeweils für die Inite oder die rechte Hand verwendelt werden können. Zur Erleichterung der Knochenpräparation ist ein Satz Probeimplantate für jeden Implantatiyp erhältlich.

- Cobalt-Chrom-Molybdän-Knetlegierung für chirungische Implantate gemäß ASTM F-1537
- ASTM F-1537
  Titiopulver for Beschichtungen von chrungischen implantation gemäß ASTM F-1580
- ASIM F-1960 Pulvergetertigte Form aus ultrahochmolekulkretti Polyethylen (UHMW-PE) für chirunglache Implantate gernäß ASTM F-646

### ANWENDUNGSGEBIETE

- KWENDUNGSGEBIETE
  si had Agono hiplantal ist zum Ersatz des proximalen Fladiusendes besterrint:
  Ersatz des Radiussköpfichens bei degenerativen oder postiraumatischen
  Behindeungen im Schmerzen, Cemptatio und Bewegungseinschränkung am
  Ratiichnumeral- und/oder proximalen Radiculvangelenk mit:

  8. Radiculgen stemtbarre Geleinkzestbrung oder Subbusution
  b. Resstenz gegenüber konservaltimer Behandlung
  Primiterratzir zeuch Fralkür des Radiusköpfichens
  Symptomatische Folgeerschahrungen nach Radiusköpfichervessektlion

### GEGENANZIEGEN

- COEMANZACIONE In Machaum begriffene Patienten mit offenen Epiphysen Frühere offene Fraktur oder kriektion im Gelenk oder im Umkreis des
- Bekannte Überempfindlichkeit gegenüber den Impianta
- 4. Bekannte Überempfindlichteat gegenüber den Impantarwerkschein
  WARNHINWEISE (Siehe auch Abschnitt, Informationen zur Patientsnberatung")
  Extreme Belastungen, übernäßige Mobilität und Gelenfansstabslähl können zu fützuseigen Verschleiß und eventurietem Versagen der Prothese durch Lockern, Brochen oder Voltagen Inforen. Der Patient sollte über des enfolde Plasitio eines Versagene der Prothises bei Überbenaspruchung anfgeldart werden. Protheses sand mechanischen Produkte, die verscheißens, ermüden oder berchen können. An der Impatriationsstelle Mohrmer Intektionen, Schmerzen, Schweitungen oder Entründungen auftietert. Des umliegende Anzochen- oder Weichteiligewebe kann in einem Zustand selt, der keinen auseischenden Halt des Impatriationstabeit, der Zust verschiederen und dadurch eine Instabblität oder Delicmität oder beides nach sich ziehen. Der Nutzen der Impatriation kann unter Umständen den Ervertrungen des Patienten nicht geschli werden oder mit der Zeit abnehmen, sodass ein Revisconseingriff zim Austaussch der Prothese oder zur Durchführung allematurer Verfahren erforderlich sis, Revisionseingriffe sind bei Profinesen nicht seiten.

- VORSICHTSMABNAHMEN

  1. Die Prothese wird steril in einer unbeschädigten Verbackung geleifart, Sollte entweder die Prothese oder die Verpockung beschädigt, das Verfalldatum überschritten oder die Startität aus rigendenen Grunde zwerfelbert sen, darf die Prothese incht verwindelt werden. Die Prothese nicht verwindelt werden, Die Prothese nicht verwindelt werden. Die Prothese nicht verwindelt werden. Die Prothese nicht werden die Startität verwindelt werden. Die Verfalle verden und Kratzurs Schrifte und Kerben auf die Prothese zu vermieden. Poleefe Geleink- und Korustoberflächen dichten nicht mit herten oder abzasiven Oberflächen in Kontakt
- kommen.

  3. Der Kopf und der Schaft sollten nicht enplantiert werden, wenn die Gelenfdlächen möglichravverse beschädigt sind; dies ist auch bei wiederholten Zusammensetzen und Zertegen der Fall.

  4. Der Kopf der Protinses werd auf die Kuget des Schafts geschlagen. Vor dem Zusammensetzen ist darsuf zu achten, dass die Gelenfollschen trocken und sauber sin.

### NEBENWIRKUNGEN

NEBENWIRKUNGEN
Bekannte mögliche Komplikationen bei Getenkprothesen sind Schmerzen,
Lockerung, Fraktur, Distokation oder Infektionen, Bet einigen Patienten traten
Überempfindlichkeiten gegen Metall nach dem Getenteszatz auf. Die Impalantation
von Materialien viel Cobet-Chrom und/doser Titan kann zu Fremdikhöpernesktionen in
der Umgebung der Impalantationsstelle führen. Darüber hausus können Mertelzungen
oer umgebenden Nerven, Bikrigefälle, Bänder oder Weichtelse auftreiten.

### CHIRURGISCHE VERFAHREN

CHINDRISISCHE VERN ARTHEIN Ein Operationsverlahmer zir Verwendung dieser Prothese int erhällich. Der Chirum muss sich vor der Verwendung dieser Produkte mit dem Operationsverfahren vertraut machen, Außerdem legt es in der Verantvendung des Chirumgen, vor der Verwendung dieser Produkte die relevanten Publikationen zu Rate zu ziehen und sich mit

errahnenen Kollegen über das Operationsverlahren auszulauschen.

INFORMATIONEN ZUR PATERNTENBERATUNG (Sehe auch Warmhisveisie)
Vor der Operation miss jeder Patert schriften über potenstiele Kompikkidionen und
mögliche Abernativen aufgeldert werden. Heizzu können auch Mishaahmen ohne
Proffussen, wie z.B. wiechteilnikonstrudionen noder Arthrodesen zühlen. Zusätzlich zu
den Patanteinstormationen in den Absochntien Warnhrweise und Komolikationen
sollte der Paterst über Folgendes Homielt werdent: 1) Kompikkitätionen können Operation, einem Revisionensyllf oder eine Fusion die bestruffenen Gelenie
enfordenn. 2) Die Labersadsvor der Geienkanstell-Kompikkitätionen können verineren Scholiken vorherzussigen, in jedem Fall aber begreichte Die Komponenten ist nar schwer vorherzussigen, in jedem Fall aber begreichte Die Komponenten bestehen aus
korpportremdem Material und werden in den Korper eingesflanzi, um die
Beweglichteite nöckjuchst wiederierzusstehen und Geffinenzen zu verningem. Aufgrund
zahlreicher biologischer, mechanischer und physiochenischer Faktoren, die auf derstehe seinen gesunden knochen nicht über einen unbegenzten Zakraum standhaften.

STERILISATION
Desse Produkt wurde mit Etnykenoxid oder mit Hille von Gammastrahlen sterikslert, Esse wird sterik in einer unbrachfädigten Verpackung gelletert, Sollte entweder die Prothese oder die Verpackung beschädigt, das Verhalbditum überschritten oder die Sterikität zus isgandeneme fünde zweishalt sein, dar die Prothese nicht verwandet werden. Die Prothese nicht erneut steritielsenen. Um die sterik Verpackung exzit zur Feststellung der richtigen Größe der Prothese vor des implantation dichten zu müssen, stehen Probeimplantate zur Verfügung. Die Prothese darf est dahn aus der sterile Verpackung einzemmen werden, wenn die knipstantaionsstelle ausreichend vorbereitet und die richtige Größe der Prothese ernittett wurde.

### EINGESCHRÄNKTE GEWÄHRLEISTUNG

Avanta Orthopaedics, Inc. gavantient, dass cleases Produkt den Spezifikationen des Herstellens entspicitst und zum Zeitpunkt der Lieferung feit von Herstellungsfehlern ist. Diese Gewährbsichung schiedt erschrücklich Schäden aus, die auf ensachgemäße Behandlung. Misstrauch oder fallsche Verwendung durch den Benutzer zurückzuführen sind. Avanta Orthopaedics, Inc. gibt keine Gewährleistung für einen Erfolg des Chirurgischen Eingriffs.

EU REPRÂSENTANT Medical Products International Euro; Schutweg 13a 5145 NP Waalwijk, Die Niederlande 31 (0) 416 563754

### FRANÇAIS

### DESCRIPTION

Cette prothèse ri-lead Recon consiste en une tige et une tête en cobell-chrome ainsi qu'en un module d'articulation en polyétitylère. La lige de l'implant est prévue pour une lesertion dans le corpe du radius praximat. La tête de l'implant s'articule sur le combyle de l'itunérus. L'implant est deponible en plusieurs tailles, utrésables à la main droite ou gauche. Une etire de caltireurs d'essai est deponible pour chaque type d'implant, en tant qu'assistance à la préparation osseuse.

- infrinka: "Alläge de oobalt-chrome-molybdene façonné pour implants chirungicaux (conforme à la norme ASTM F-1537). Pources de tilane pour envolages d'implants chirungicaux (conformes à la norme ASTM F-1580). Forma de poudre de piùpethylène à poida moliculaire ultra élevis tranée pour implants chirungicaux (conforme à la norme ASTM F-048).

INDICATIONS L'implant rélead Recon est prévu pour le remplacement de l'extremité proximale du

- sius :
  Remplacement de la tête radiale en raison d'incapacités dispénieratives ou post-traumatiques accompagnées de douleur, crépitation et perfe de mouvement de l'anticutation radio-humérate et/ou radio-úthaire proximale avec :
  a. Destruction de l'articutation ou subhustion visible aux rayons x in, Résistance à un traitement ocraenvateur
  Remplacement primare après fancture de la tête radiale
  Séqueles symptomatiques après résection de la tête radiale

- CONTRE-INDICATIONS

  1. Incompetibilité de la peau ou du système muscuto-tendineux

  2. Patients en cours de crolesance et systet des épithyses auvertes

  3. Antécédant de tracture ouverte ou d'infection dans ou autour de l'anticulation

  4. Allergie avérée aux matériaux de ce d'appositif

- \*\*MISSE SIN CARDE (voir sussi le section Conneils donnés au patient)

  \*\*De fostes charges, une mobilité excessive et une instabilité articulaire pouvent accidèrer l'asune du dispositif et entraîner un échec éventuel par relâchement, inactire ou dispositif en cas de adiscitations excessives.

  Les implants sort des dispositif en cas de adiscitations excessives.

  Les implants sort des dispositif en cas de adiscitations excessives.

  Les implants sort des dispositif en carde de l'autorité du l'acque et les peuvent s'user ou s'erbni. Il es peut que l'etat de fois adjacent et des tissus mous ne parmette pas la posse de l'implant pout devant contra, minimant une instabilité, une difforenté du les deux. Il se peut que les avantages de l'implantation ne repondant pas aux attentes du patient ou direituent au lit du temps, necessitant une chrunge de révision et fine de l'acque et l'acque de l'acque de l'acque et d'autorité procèdures. Il n'est pas rare de pratiquer une chrunge de révision aux un implant.

### PRÉCAUTIONS

- EU-cut HONS

  L'implant est fourni stérile dans un emballage soellé. Si l'implant ou l'emballage parah endommagé, si la date de péremption est dépasaée ou la stérilité est mise en cause pour une raison ou une autre, il ne faut pas utiliser l'implant. Ne pers
- restériéser.

  Les implants doivent être manipulés avec des instruments à bout mousse pour ne pas rayer, couper ou entailles le dispositif et ne pas perturber les performances de l'implant. Le paier poi et les surfaces coniques ne doivent pas entrer en contact avec des surfaces abrasives ou dures.

  Il ne faut pas implanter la tête et la tigo s'il y a un risque d'endormager les surfaces articulaires, potamment en cas de pose et de decisie expetiess.

  La ties de la protrèse est fixèe aur la bilé et la tigo, avec les seurfaces articulaires sont aisches et qu'elles ne sont pas contaminées.

### EFFETS INDÉSIRABLES

EFFETS INDESIRABLES
Las effets indéairables éventuels qui ont été rapportés avec des prothèses articulaires
sont doubles, rélachment, fracture, laxation ou infection. Des cas de patients
presentant dos réactions d'alergie au métal suite à un remislacement d'articulaires
ont des apportess. L'emplanations de matériales tes que le coball-direme et/ou le
tilane pout entraîter une réaction au coppe déranger adjacente au atte de l'implant.
L'emplanation de ou dispositif peut aver boux consequence une lésion traumatique
des mets, des verisseaux sanquins, des tendons ou des tiesus mous.

PROCÉDURES CHIRURGICALES
Une procédure chirurgicale concernant l'utilisation de cet implant est disponible, La connassance de cette procédure set de la responsabilité du chirurgient. Il incombe également au chirurgien de set tenir au courant des publications portrantes et de consulter des continues expérimentés au sujet de la procédure à utiliser.

CONSELS DONNÉS AU PATIENT (vor sussi Mises en garde) Avant l'opération chiuripcale, il est nécessaire de fournir à chaque patient devant subri un implant des conseils et des informations sur les complications éventuelles et les solutions de remplacement, notamment le reconstruction de lissus mous ou l'arithnodèse. Quire l'information relative au patient contenue dans les socitions Mises en garde et Effets indéshables, le autient del reconsir l'information suivante : 1) Des effets adélès lables pauvent inécessiter la récopération, le révision ou le fluxion de l'articulation contiernée. 2) Il est difficile d'estimer la utieré de ve prevue des composants de remplacement d'articulation, mais ils ne sort pas trusables. Ces composants sont en effet labriques dans des matériaux étangers su corps humain et implantes en le restituer les mobilés ou de rédute la douésui. Toutelois, en ration des nombreux lacteurs biologiques, miscanques et physie-chimiques qui affectent exe disposaté, les composators en peuvents ne peuvent pas supporter le nême riveau d'activité et les mêmes charges qu'un os sain perdant une période lièmète.

STÉRILISATION

Ce composant a été stéritisé par oxyde d'éthylène ou rayons gamma, L'implaint est forum séries dans un embellage accité. Si l'implaint ou l'emballage paraît endommagé, si la date de pérempion est dépassée ou s' la stérité est mise en ceuse pour une raison ou une autre, i lie feuri pas difficir l'implant. Ne pas raisettisser. Des colabreurs d'essai sont disportibles : le évitent d'ouvre l'emballage stèrie ment l'implantation de la prothèse. It feut enluere l'implant de son emballage stèrie uniquement sprés la présonation et le dimensionnement corract du site de l'implant.

### GARANTIE LIMITÉE

GARANTIE LIMITEE 
Avanta Crhopsedica, Inc., agrantil 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 norometé du produit postérieure à la réception par l'achetour. Avanta 
Orthopsedics, inc. ne garantit pas l'issue de la Cheurgis.

### REPRÉSENTANT POUR L'UE

Medical Products International Schulweg 13a 5145 NP Waatwijk, Pays-Bas 31 (0) 416 563754

### **ESPAÑOL**

DESCRIPCIÓN

La protesta ri-lead Recon está compueeta de un vástago de cobalto-cromo y de una cabeza del mentre material, con una inserción articulante de poleridino. El vistalida del implante ha sodo disendado para insertares en el extremo proximal de la úditista del radio. La cabeza del implante artícula con el capitellum. Este implante se summistra en varios tamaños, cada uno de los cuales puede aplicarse indestintamente para la mano derecha o izquierda. Con el propisido de facilitar la preparación del hueso, se suministra una gama de prótesis de prueba de distintos tamaños para cada tipo de intelledere.

ales: STM F-1537: Aleución forjade de cobalto-cromo-molibdeno para implantes

"ululirgicos; ASTM F-1580: Polvo de titanio pera el revestimiento de implantes quintirgicos; ASTM F-648: Forma fabricada de polvo de polietileno de peso molecular ultreelevado para implantes quintirgicos

INDICACIONES

INDICACIONES

B implame rifead Recon ha sido diseñado para la sustitución proteana so provincia del radio:

1. Sustitución de la cabeza radial en caso de afeccionas degenerátivas o post-traumáticas que producen dolor, crepitación y restricción de la movilidad a nivel de la enticuteicón humero-radial y/o de la articulación radio-cubital proximal, con:

a. Destrucción articular o subhasicatión visible a rayos X;

b. Resistencia at tratamiento conservador;

2. Sustitución primaria en ceso de fractura de la cabeza radial;

3. Tratamiento de socuelas sintomáticas post-resección de la cabeza radial.

THE THE PROPERTY OF THE PROPER

ADVERTENCIAS (véase también la sección Información de asesoramiento para

cientes).

La sobrecarga mocánica extrema, la movilidad excesiva y la inestabilidad articular pueden conducir a un desgasta acalerado y a un fallo eventual por efojamiento, factura o dislocación del implante. Deborá acpticarso a los pacientes que el riesgo de fallo del dispositivo aumonia si dete es conetido a una sobrecarga mocánica.

de laso de disposini estrelaria especiale. Los implantes son dispositivos mecânicos succeptíbles de desgaste, fetiga de material o fractura. El altio de implantación puede presentar infección, dolor, hinohazón o inflamación. La calicad del fueso y de los tejidos bandos adyndentes puede ser inadeciarda para proporcionar austernación al implante, o puede deteriorarse con el tiempo, pudendo producirse inestabilidad, deformidad o ambast comiticaciónses, be beneficios de la ciruja implantariora pueden ne astificacer las expeciativas del paciente o pueden aminorarse con el tiempo, haciendo necesaria la crugia de revelario para surstitu el integrator o para efertual proceedimientos alternativos. Las intervenciones de revisión de implantes no son

PRECAUCIONES

RECHAUCAUTICO

El Implemte de suministra estéril en un envissa intacto. No utilizar el producto si el implemte de l'envisa están dañados, si la fecha de validaz se ha sobrapasado, o si, por cualquier otra razón, se duda de la esterilidad. No reesterilizar el producto.

o si, por cuasquos ente resulta.

Los implantes deberán manipularres con instrumentos romos para evitar las regaduras, los costes o las meladuras, y para no alterar su funcionamiento. Las superficies pulmentadas de aostén o ahusadas no deben entrar en contacto con acuerícies duras ni abrasidas.

La cabeza y el vietago no deberán implantarse si se sospecha que sus superficies articulares puedan estar dahadas. Esto incluye el caso de su inserción y extracción relieradas.

La cabeza de la profesis se impacta sobre la esfera del vistago. Avites del monteja, comerpoder que las superficies articulares esten secas y libres de sustancias contaminantes.

THTOS ADVERSOS

"NTOS ADVERSOS
posibles eventos adversos observados en caso de implantación de
utaciones protésicas incluyen dolor, aflojamiento, hactura, dislocación o
entección. Se han documentado algunos casos de pacientes con reacciones de
imperenciabilidad al metal despues de la sustitución eriticular, La implantación de
materiales tales como el cobalido-cromo y/o el titario puede traer como consecuencia
usa reacción arte un ouerpo extraño alendedor del sitio de implantación. Pueden
producras elaciones de los nervios, los vasos sanguineos, los tendones o los tejidos
blandos circumdantes como consecuencia de la implantación de este dispositivo,

PROCEDIMIENTOS OURÚPGICOS

Se suministra una descripción del procedimiento quivirgico a apicar para la implantación del procedio la fedicar para la implantación del procedio la Editariam timos la responsebilidad de familianteziane con el procedimiento quirulgico sintes de user estos productos. El tene, edornas, si responsabilidad de maintenerse informado de las publicaciones científicas revievantes arrespecto y de consulter a axpertos acerca del procedimiento, antes de la aplicación.

INFORMACIÓN DE ASESORAMIENTO PARA PACIENTES (visase también

INFORMACIÓN DE ASSOCRAMIENTO PARA PACIENTES (vease también a sección Adventerciais) a sección Adventerciais) a la sección Adventerciais) antes de la intervercición, es indispensable asequirarse que todo paciente que haya de asmeterse a la criugia de impotantación recibio uma documentada associa acerca de las complecaciones potenciales y sobre las posibles intervenciones atternativas, las cuales pueder incluir procedimentos sa meglante, tales como la reconstrucción de legidos biandos o la atritodesia. Adventada de la información comiencia en los apartados "Adverterciain" y "Eventos adversos", debe proporcionarse al paciente la signicial información: y las resociones adversos queden hacer reconstrais la represencian, la revisión o eventualmente la fusión de la articulación comprometida. y 2) Si bien la vida dique cabe separer de los comprometes acticulación comprometida. y 2) Si bien la vida de particulación comprometida. La composito de setimar, ésta no es infinita. Estos componentes sestan hechos de materiales extrafos al organismo y se colocen para enstablose la movidad o para reducir al dodo. En todo cara, debido a la gran centistad de factiones biológicos, muclanicos y fisicoquínicos que alectar a estas dispositivos, no puede esperarse que recistan el mismo miel de actividad y las sobrecarpas mecânicas que el huesto normal sano durante un período de tempo ilimitado.

**ESTERILIZACIÓN** 

ESTERILIZACIÓN
Esta componente ha sido estartilizado con oxido de etileno o por rayos gamma.
El implante se suministra esteritizado y en un arvase ratacto, No utilitar el producto
de el imponente o el envise estaña dialisados, si la fecha de velidez se ha sobrapasado,
o si, por qualquier otra razon, se dudid de la esteritidad. No neesteritizar el producto.
Se dispone de componentes de pueba para que el cinigidan on tenga que abrir el
envisas estarti hasta el momento mismo de implantar la professo. El implante deberá
sacarsa de su envisas estidifa documente dessues de que el sixto de implantación haya
sobo completamente proparado y después de haber determinado apropiademente el

GARANTÍA LIMITADA

GARANTIA LIMITADA

Avanta Orthoseatica, he, garaniza que, en el momento de su entrega, este producto 
cumple las especificaciones del fabricante y está libre de defectos de fabricación. La 
presente garanta accityn especificamente los fallos que resulten como 
consecuercia del uso indebido, del abuso o de la manipulación incorrecta del 
producto, con posteriorded a su recepción por parte del comprador, Avanta 
Orthopaedios, Inc. no garantiza el resultado del procedimiento quintingico.

REPRESENTANTE EN LA UE

edical Products International E hutweg 13a 5 NP Waalwijk, Palses Bejos J; 416 563754

### Records Processed by CDRH DID on 3/31/2023

BESCHRIJVING

De tribad Recon prothece bestaat uit een steel van kobaltchvoorn en een kop van kobaltchvoorn met een articulevend inzetstuk van polyetriyfeen. De steel van het kop an het implantaat derin ont ne vorden ingebracht in de schucht van de proximiten and van De kop van het implantaat articuleert met het capitulum. Het emplantaat is verscheidere maten verkrijgbaat, die elk in de rechter- of linkerhand kunnen worden toegepast. Voor ekt type implantaat is een reeks proefonderdelen voor dimensionering verkrijgbaar als hullo bij de botpreparatie.

Materiaat:

ASTM F-1537 gesmede legering van kobalt, chroom en molybuleen voor chrungische implantation:

ASTM F-1580 (tissunpoeders voor het oosten van chkungische implantation:

ASTM F-649 UHMWP sintra-high molecular weight polysthylene) vervaandigd in de vorm van een poeder voor chrungische implantation.

INDICATIES Het rilead D ut Recon implantast dient voor de vervanging van het proximale uiteinde van

radius:
Vervanging van de radiuskop vanwege degeneratieve of postiraumatische anvelliditeit die gepaard gaat mei pijn, orephalie en verminderde beweeglijkheid van het radiohumerale ers/of proximale radio-utiliare gewicht en tevens:
a. Gewichtstrassk of subunatie des zichtstear is op een röntgeropinerne b. Ongeschishieid voor een oorservatieve bohandeling Primare vervanging na een frectuur van de radiuskop
Symptomatische sequelien ne resectie van de radiuskop

CONTRA-INDICATIES

1. Onvoidoende beschikbare huid of spieren/pazen.

2. Patienten in die groei met open epitylwer.

3. Een eerdere open facture of infectie in of rond het gewricht.

4. Bekende overgevoeligheid voor in de prothese gebruikt materiaal.

4. Bisende overgevesignen voor in de prouses gezurun materiae.
WAARSCHUWINGEN (zie oak hat hoofdstak informatie voor patientvoorlichting).
Zware belasting, overmatige mobiliteit en articuleire stabiliteit kunnen altemaal istden tot veranetde eijtuge en usterdelijk fallen door istratien, bruck of dislocatie van de prothese. Britischen moet dukelijk worden gemaakt dat er een verhoogde kans op defect caken ven de prothese bestaat als deze wordt overbekest.
Implantatier zijn mechanische hulpmiddelen die kunnen afatigen, onderwoopen zijn son metlersaalmoeheid en kunnen breken. Een implantatieplaats kon geintscheerd, plylifik, gewolen of ontstoken raken. Het naburge bot en de nasstiggende weise deten kunnen onvoldoende steun geven aan net implantaat of kunnen in de loop det gils achterufiggen, waardoor instabilitet kein ontstaan of miscorming kan optmeden. De voordelen van operalieve implantatie kunnen niet overwesthaanen met de vervachtingen van de patieter of het implantaat kan na verkoop van tijd achtestuigsan, waardoor revisie ter vervanging van het implantaties zijn met ongebruikelik.

VOORZORGSMAATREGELEN

1. Hel implantaat wordt steriel in een onbeschatdigde verpaldving geleverd. Alls het implantaat wordt steriel in een onbeschatdigde verpaldving peleverd. Alls het implantaat of die verpaldving beschatdigd fjilt of die vervalderum is verstreken, of als die sierliefet om enlige reden wordt betwijfolt, die mag het trepkriliaat hel worden gebruikt. Niet opnieuw sterifiseren.

Ernglantaten moeten worden gehantered met stompe instrumenten om te voorkomen dat ienssen, sneden of kenven op die prothese onlistean die het functioneren ervan jasdelig kumen beisvinderde. Georgiste lageruppentaksiven en tans toeligeende vlakken nogen niet in aanraking komen met harde of acturende oppordiektig.

tass toelopende visikion nogen nied in aervaaring komen met nature in achterende opponstekken. Die kop en steel mogen nied worden geimplatineerd als de articulerende oppenstekken mogelik beschadigid zijn; dit is ook het gevel bij hekhaald aarbringen en wegnenen. De kop van de protifese wordt op de bal van de steel geimpacteërd. Controller, alværens die groep samen te stellen, of de articulaire visikken droog en vrij van

Potentiale complications beachreven met gewichtsimplantaten zin onder meer pijn, lostaken, bewich dislosatie of infectie. Er zijn patienten beschreven met metaalovergevoeligheid na een gewichtsvervenging, implantatie van materialen sis choallichroom en/of titaan kunnen een reactie op lichtemervenend voorvervenn neast de implantatieplasts tot gevolg hebben. Er kan letsel van de omringende zenuwen, bijserbatten, pezen of weise delen optreden als gevolg van implantatie van deze pruthese.

CHIRURGISCHE PROCEDURES

CHIRUNGISCHE PROCEDURES

fi se en chiungische procedure voor gebruik van dit implantaat beschildbaar. Het valt
onder de verantwoordelijkheid van de chirung om, vooralgaand aan gebruik van deze
producter, vertouwd te zijn met de procedure. Daarnaast valt het onder de
verantwoordelijkheid van de chirung om vertouwd te zijn met de nakvante publicaties
en voorafgaand aan gebruik advies te vragen aan ervaren collegae ontrent de
procedure.

INFORMATIE VOOR PATIENTVOORLICHTING (zie ook Wäarschuwingeri)
Het Is noodzakelijk one elike patieln die implantatie zei ondergean, tevoren
documentatie en advies te geven betredlende de potentiele oomplaceties anderentenen, waaronde endere dan implantatie lengegen; zoals de reconstructie van
wels delen of arrudese. Naast de patiengwelstende informatie in het onderdiet van
wels delen of arrudese. Naast de patiengwelstende informatie in het onderdiet van
wels delen of arrudese. Naast de patiengwelstende informatie in het onderdiet van
wels delen of arrudese. Naast de patiengwelstende informatie in het onderdiet van
wels delen of arrudese. Naast de patiengwelstende in netwe trigtere versies of tusie van het betrefferd gewicht noodzalelijk, nalson. 2 Hoowel de
verwachte leversdure van de onderdelen van de gewichtsvervanging moelijk is ob schatten, is deze eindig. Deze ondordelen zin gemaald van lichaamsweemd materiaal en worden in het kidwam regetracht om, waar mogelijk de mobiliteit le honstellen of de pin te verminderen. As gewolg van de oldvirste blotogische, mechanische en fysischemische factoren de invloed hebben op een dergelijke mothere, kan van de ondordelen net worden er verwacht det ze gedurzels ontoenberkle tijd de meis van activiteit en de balasting van normaat gezond bot kunnen weerstaar.

STERILISATIE:

Dit anderdoel is gestleriliseerd door middel van eithykeenoxide of gammastraling. Het impaniaat wordt steriel en in een ootbeschadigde verpalking geleverd. Als het emplantaat of de verpalking beschadigd fils of de vervalking steriel en die sterifieln om enige reden wordt betwield, dan mag het implantaat niet worden gebruiks. Niet opnieuw steriliseren. Er zijk proetonderdehen verkrijbaat, zodat de steriels verpalking voorstigaand aan de prothese-implantatie niet hoeft te worden geopreid. Het implantatien genomen nadat de emplantatieptiests is voorbereid en het implantaat is gedimensioneerd.

BEPERKTE GARANTIE

BEPERITE GARANTIE

Availa Orthopadics, inc. garandeert dat dit product ten tijde van de levering volidoet
aan de specificinies van de fabrikant en vrij is van productietouten. Deze garante
skilt specifiek delecten uit die net gevolg zijn van verkeerd gebruik, mistuulik of
verkeerde omgang met het product na ontvangst door de koper. Avanta
Orthopaedick, inc. geeft geen garanties ontrent de uitkomet van de chizungtsche
norreen.

EU-VERTEGENWOORDIGER Medical Products international Europe, 8V Schutweg 13a 5145 NP Waalwijk, Negerland

### ITALIANO

DESCRIZIONE

DESCRIZZONE

La presente protesì ri-lead Riocon è costituita da unu stello e da una testa in loga di 
cobalco-como con inserto articolare in polerifene. Lo stalo dell'impanto è stato 
progettato per l'inserimento nel futto del radio prossmale. La testa dell'impianto al 
articola nel capitello. L'impianto è disponible in vasia misure, ciascura delle quala può 
essere utilizzata per la mano destra o sinistra. Inotre, a ogni tipo vene abbinata una 
sene di calibrationi di prova, che possono fornire un aussira per la preparazione 
relificaso.

Lega ASTM F-1537 di cobalto-cromo-molibdeno per la lavorazione plastica di

Legia ASTM F-1931 in secessiva in secessiva in participation chargosis in secessiva in participation astmitus in policipation in policipation

INDICAZIONI L'impianto i lead Recon è destinato alla sostituzione dell'estremità prosemi

redio.

1. Soutituzione della testa radiale in seguito a disabilità degenerativa o posttraumetiche caratterizzate da dolore, crepitazione o mobilità ridotta,
dell'articolezione radio-omersia e/o radio-ulmare prossimale con:
a. distruzione o subsinazione dell'articolezione visibile ai raggi x
b. resistenza al trattamanto conservativo
2. Soutituzione primaria dopo ia trattura della testa radiale
3. Sequies sintomaliche dopo la resura della testa radiale

CONTROUNDICAZIONI

Apparato cutanea o muscolo-tendineo inadeguato Pazienti in creacita con epitei aperte Frattura aperta o intezione pregressa all'interno o intorno all'articolazione Accertata (persensizità al materiali impiegati in questo depositivo

4. Accertata persensorara ai meterata impegati in questo deposario.
AVERTENZE (Si veda anche la sezione informazioni per la consulerza ai pazienti).
I carichi particolarmente pesanti, la imbalità eccessiva e l'instabilità articolare possono accelerare l'usura e determinare l'eventuale danno della protesi per alentamento, frattura o delocazione. Si raccomenda di vitormara il pazienti sulla meggiore probabilità de si verifichi tale evenienzia, se gli implanti vericono sottopodi a soleofozioni eccessive.
Gli implanti sono dispositivi encosnici espositi a usura, etorzo o rottura, il sito di un impanto potrobbe essere copito da infazione, procurser dotore, gonifiarati o infarminarii. Lo stato dell'osso a di la lessuri molti adiciare il potrobre inultare inultare inultare indedicazioni o sistente e implanto, oppura potrobbe destaforarai nel corso del tempo evidenzando instabilità, deformità o entrambi i problemi. I benefici della chirurgia implantologica potrebbero non soddisfiare le aspettative del paziente o detericarati nel conso del tempo, richiadendo un ritervanto di revisione per sostituira l'implanto o l'esecuzione di procedura alternative. La operazioni chirurgica di revisione non sono infrequenti.

PRECAUZIONI

PRECAUZIONI

1. L'impainto viene tomiso sterile in confezione integra. Non utilizzario se il disponitivo stetaso o la confezione sembrano darmeggiati, se è superale la data di sociativa o se si duntra delle sterillà per qualessal motivo. Non ristorifazzare.

2. Mampokare gli impianti con situmenti simussati per vivaze graffit, tajo i orizosioni che ne comprometterebbero il huzionamento. La superifici lucidate del cono e della supporto non devoro venera a contatto con parifi dere o etaraleve.

3. Non impiantare la testa e lo stelo, qualora le superifici di articolazione dovessero presentare darva divorti amche al ripettori antacco e direttoco.

4. La testa della protessi s'incestra sulla stera dello stelo. Prima dell'assembleggio.

EVENTI AVVERSI

EVENTI AVVERSI I pomerziali eventi avversi resi noti in merito alle protesi articolari comprendono dolore, perdita, lussazione o infezione. Alcuni pazienti hanno riportato reazioni di inpernensibirità e inertali dopo la sostituzione edili articolazione, ci trispiano di come le leghe di cobatio-cromo avo il titanio può determinure una reazione al corpo-estraneo in prossimità del sto dell'impianto, in seguito, all'introduzione del presento dispositivo possono verificaral lesioni al nervi ai vesi sanguigni, al tendini o al tessuti

PROCEDURE CHIRURGICHE
É disponibile una procedura chirurgica destinata all'uso dei presente dispositivo per
impianto, è responsabilità del chirurgo acquisire lamigiarità con tale procedura prima
di utilizzare quella prodotti. Il chirurgo à attenti e travita o conoscere la documentazione
sull'argomento e a consutarsi con colleghi esperti in mento alta procedura prima di
cerca la l'Esterando.

INFORMAZIONI PER LA CONSULENZA AI PAZIENTI (Si vedano anche le

Neverlateza de l'entrare l'intervento, ogni paziente in lista d'intress por la chiargia implantologica deve ricevere une consulenze documentata suite orienziali implantologica deve ricevere une consulenze documentata suite orienziali complicatize e suite afernative, che potrebbero comprendere procedure diverse diffirmipanto come in ricostruzione del tessuiti moli o farrodesi. Oltre ella intormazioni specifiche, riporiate nella Avvertenze e negli Eventi avverati pracomanda di comunicare al pariente satche querto seguer. Il freventuale incorperata di eventi avverati potrebbe richiedere un secondo intervento, la revisione o la fusione del articologicame cominità. 2) i componenti esostituri del articolazione harrori una diusta limitata che, purtroppo, risulta di difficile stima. Esti sono malicizati commandicali estrarele, che vengono introdetti dei compo per riportanue la mobilità o indune il diolore. Iluttavia, considerando i moli tattori biologio, meccanici e ferinodiscini logati a questi disposotivi, non si può partiere dal presuppostati che siano rio gracho di sosteneni il ivello di attività e il carchi di un: osso stano per un periodo di tempo illentatio.

STERILIZZAZIONE

STERRILIZZAZIONE

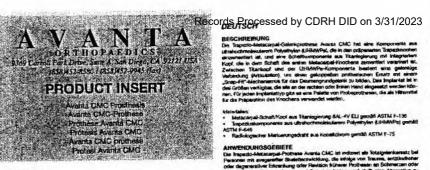
Il presente componente è stato sterilizzato con ossido di ettiene o mogi gamma.

L'impanto risulta sterile nella confezione integre. Non utilizzario se il dispositivo
eseso o la confezione sembrino damoggiati, se è triscoresi si data di sodierza o se
si dubita della sterittà per qualsiasi motivo. Non risterritizzare. Sono disponibili dei
calizzatori di prove per eviture l'apertura della confezione sterile risma di miseritaria: la
protest. Pretevare i impanto dalla confezione sterile sola dopo aver preparato e protesi. Prelevare l'impianto dalla confeziori correttamente dimensionato il sho dell'impian

GARANZIA LIMITATA

GARANZIA LIMITATA
Avanta Orthopeadics, inc., garantisce che il presente prodotto risponde alle specifiche
del fabbricante e non presenta didetti di isvorazione ali momento della correspira. La
presente gazanzia assakda specificamente i difetti insilianti dia usa improprio, albuzio
o manipolazione sonoretta del prodotto dopo il ricevimento da piane dell'acquirente.
Avanta Otthopeadics, inc. non risponde defle festo della prodotto deporta.

RAPPRESENTANTE PER L'UE Medical Products International Europe, BV Schutweg 13a 5145 NP Waalwijk, Paesi Bassi 31 (0) 416 563754



### ENGLISH

ricks this device to sale, distribution and use by or on

DESCRIPTION DESCRIPTION.

The Aversit CAMT. Proposo-instructional pain posteriores consists of an utilizating miscolate vestigit polyatinglere U.H4MMP-in corresponsat which is comerted to the proposed begander, and a listensium alloy she no component with hingain faced which is restricted that the faced instruction of the first instruction. The distruction has defounded with the U.H4MMP-in component to their an amount of constant provided provided profession with the U.H4MMP-in component to their an amount of constant provided prov

SADICATIONS
The Avaria CAC Topodo-material prothesis is indicated for total part replacement in selecting materials and in part replacement in selecting materials materials with pair or instability of the trapazio-materials joint due to travers, infarmationy or degree station disease or medical of provious processes, are an instructive to surprise supervisor in supervisor.

- CONTRAINDICATIONS

  Bone, munculature, lendone, or educant soft Basse contratonised by disease, intection, or prior implantation which carnot provide adequate support or fixation for the prosilents.

  Any address supported infection in or around the thumb york.

  States the inventority.

WARNINGS Ger also the Patient Courteding Information Section)

The denote is for comerced use only.

Streamouse bording, accessive mobility, and writinate instability all may lead to accessivate uses and avertical fallows by loosening, fracture, or dislocation of the denote. Patients should be made aware of the increased potential for device fallows ascessive demands are fraidal upon it.

### PRECAUTIONS

- PRECALTIENS

  The impliest is growthed sharlle in an undamaged package. It either the impliant or the pestage appears demayer, expiration date has been exceeded, or it sharllly is questioned for any nassor, the instant alreaded not be used. Do not instantiate.

  Meticulous preparation of the implant site end not be used. Do not instantiate.

  Meticulous preparation of the implant site end to be used. Do not instantiate to a successful outcome.

  The impliest should be premoved tool.

  The state been prepared and properly stored.

  In the package only after the implant at the last been prepared and properly stored.

  In the package of the package of the package only after the implant at the last been prepared and properly stored.

ADVERSE EVENTS

Advance events in a published series of 50 patients included lootening, transient galaxy curries, cement advance injury to the patient digital nerves and de Overwin't conditions.

Event	Number of events \$1450	
Loasening	5 00,0 %)	
fransient radial neuritie	2 ( 20 %)	
Comers extrusion lejury	1 ( 2.0 %)	
De Quervain's tendinitis	6 (12.0 %)	

- Potential adverse sower's reported with other finger (orit potsithese incluse locationing, insidure dislocation), or infection of the implant, No additional significant adverse events have been reported to nate during the manifering proted of this device. Supply to the summanding previous, blood versells, tendions, or soft insues can occur as a consequence of implanting little device.
   Metal sensitivity resident new been imported believing print explanement.

### CLINICAL RESULTS

CLINICAL RESULTS 
Pleasing on the enthylating patients implanted with the divince were reported, 
Pessionment all performed by arthula, falling of attended atthroughlis, previous 
States, the property of the performed attended a

In a subsequent expanded publication including an additional 21 cases in the series', most of the 50 patients showed a full raige of motion within four weeks of subsequenced and centiment of demonstrate good knippetern results. Full range of service period of the series showed clarical or redougnable evidence of toolsering. No cases of trapast flucture, surface week frequentiation or infection were seen.

SURGICAL PROCEDURES
A manual in subsidiary detailed unique annual procedure for use of tiesse implant devices. It is the mesonability of the surgices to be familiar with the procedure better use of the surgices to be familiar with the procedure better use of these responds in the surgices to be familiar with the procedure better use of these procedure. In addition, if it the responsibility of the surgices to be terminar with relevant publications and consult with experienced insociates regarding the procedure before use.

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

While the expected life of total print regiscement components as difficult to assistant is a first. Trade components are made or knewn marketile which are placed within the body to the no learned recovered or some construction. It is first. Trade components are made or knewn marketile which are placed within the body to the no learned recovered or register, or southern the southern than the components cannot be exceeded to withing the solicity level and leads or commit healthy bore to an unswind precise of time. The recoverable solicity level and leads or commit healthy bore to an unswind precise of time. The recoverable solicity level and leads or committee or committee of the solicity level and Vide at the total point state of the solicity level and Vide at the total point state of the solicity level and Vide at the total point state of the solicity level and the solicity

- BTERILIZATION

  The component has been storilized by ethylene covic or girmin a radiation.

  The implicit is provided storili in an undersigned production. It either the implient or the produce grade is either the implient or the produce grade produced by the produce grade and the product of the storilization of the storilization of the production of the product of the storilization of

### LIMITED WARRANTY

LIMITED WARRANTS "Annual Office of Control of Warrants that this product meets the menufacturer's specifications and is told from manufacturing defects at the time of defectly. This warrants proceedings socialised detects resisting from instead, above or impropose harding of the credict assesspine to receipt by the purchases. Annual Orthopaedics does not variet the outdoors of the sergical procedure.

EU REPRESENTATIVE: Medical Products International Europe, BV Schribberg (3a 5145 NP Vesting). The Netherlands 31-0) 416-963754

(1985 May/199): 161-7 (supp. 9th. Folds pith replacement at the base of the training-prefittingly report, 37: 4 Head Supplicition May 1137-15-51

Die Tragosto-Motacarpal-Gelerisprotresse Aussta CMC hat alse Komponente aus strak-chronisesderen Polyethylen (Lithat/Pell, die in den präperenten Tragostonomen ausstansteit als, und eine Jellerisprotresse und der Verlagen der

- Natividation:

  Netacorpal-Schaft/Mord aus Tilaniegierung 6AL-4V ELI gemäß ASTM F-136

  Tilgebitschorpponente aus ultrahochmolekularen Polyettylen (UHMMPE) gen
  ASTM F-648

  Radiologischer Markerungsdraft aus Koostichsom gemäß ASTM F-75

# Ant/VENDUNGSGEBIETE Die Irspedic-Metzuspiel-Protines Aneria CMC ist indiziert ein Totalgetenkensetz bei Presioner mit ausgesettes Siederberskeitschap, die arfolge von Traxme, entzilschoher oder degementalner Estrantiang der Freistens führere Proditieste als Gebrenzam oder Instalziskist des Trapeson-Alessearpal-Georgeste sieden, und stellt eine Alternative zu Antrodess oder erkonstruktioner Untwigfe dat.

- GEGENANZEIGEN

   Durch Krandrian, terheikinn oder frühere langkentetion engegegriffene Knochen, Martisulatus, Schrene oder angemaande Velichteile, die keine sichere Lintertege oder Füsenung für die Profitses belation hörrent.

   Aktive oder vermudets belation in oder an olem Deumengelenik.

   Unmale sit der Skiedettenfreiddung.

- Vessigners der Institut sein de Germannten von der Verpackung geledert. Ween eine Beschädigung des Implementes oder der Verpackung geledert. Ween eine Versigkeitum überschriftlich des Implementes oder der Verpackung vorzullegen sichent, die Verlackstum überschriftlich oder die Sterfeltet aus legendenem Grand in Fringe gestellt (der des Implementen verden. Nicht restelltetenen. Songtätige Verberschung des Implementatigeres und die Vahlt der zichtigen Größeres Implementatigen sentimen des Erfolgeursschricht der implementation. Des Implementation vorzeitenen der Verberschung im einterentation. Des Implementations vorzeitenen der Verberschung im einterentation. Verberschung der V

IEBENWIRKUNGEN

2u der Neberhaltungen, die von 50 Patierten verößentlicht wurden, gehörten ockening, transfertte Neuntlie des Nemus radellis, Verleitzung der palmaren legemenvan Infolge von Zemententrussion und De-Cuenvain-Tendinitis.

Hebenwirkung	Amenini der Nebemeirkungen (n = 50)
Lockerung	5 (10,0 %)
Transporte Neutis des Nervus reclais	2 ( 4,0 %)
Verletzing chirch Zementextrusion	1 ( 2,0 %)
De-Quervain-Tendinitis	6 (12.0 %)

- Zu den potenziellen Nabenwitkungen, über die bei anderen Fingerspalenchprotinesen berichtet wurde, gestöene Lucksanten des Insparets, Debiskellen der Frachter oder Heldelten des michaltens. Sait der Mantderführung des Gestöne gabt des bisher erlein Berichte über weiters dignifizatie federmeiskungen. Weitersparet in den ungebanden haberen, begräffelten, Betrein oder Weiterstein kommen strötige der Profesionaler werde flower, übersprofesiolischen Betrein oder Weiterstein berichte. Der Verlagen der Verlagen

KLINISCHE ERGERNISSE

Er gab Barchie Glow die Erspheriese bei neumnachvenzig Patenten, denen das Gerte 
impopinionet wurde. Der Ersatz erlogte vergen Arthrida, intregeochlagener versuchter 
Arthrodose, vorhneiger Indiquecklagener Arthrodiestin mit Glassisprotitises oder 
Täcksgenicherster oder Erbedere Arthrodiestin. Des Gerte Arthrodiestin 
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en Rahmen einer späteren größesen Veröffertlichung, die 21 weitere FMs umfasster, erreschtlen die Imeisten der 50 Pasiersten Innerhalb von vier Wechsen nach Natientrichenung den vollen Bewegungsspielaum und zeiglen gufz Europärtespissiens. Die 25 derbeutet innerhalb Posiersten mit Gesterviorschriebung wurde der vollentlandige synstomtes Bewegungsspielaum erreich. Bei fürf Pasiersten zeige sein kirklichen der unfolkspielste hers Locherung des teipharten. Est waren teine Elate von trepte achtraiehur. Die Hälbenverschließ, Fragmenteilen oder kristlich notschrieblen.

CHRURGISCHE VERFAHREN En Handschn mit alere grensen Beschneibung des chrungischen Verlahrens für die Ferstatt deser zujeknistsprofinies ub vertigder. Der Chrung ist dath vereinhvertig-sich vor Anvendung deses Medizingrunduler im dem Verfahren vertrauf zu nesche Der Chrung zu weiterfür dicht verannvollich, die erzeidfägigen Publisations sorgistig zu desen und sicht mit Benätsindagen zu besiten, die Erfahrung in di Anwenzung desen Verfahrens gesammel haben.

INFORMATIONEN ZUR PATIENTENBERATUNG Siehe auch Wurchlinweise, Nober des Patienteninformationes in des Abectudien Warritanweise und Nebenwichungen and des Patienten die nachtolgenden Informationen zu vermittels.

Por enventuement and own represent de nactirospiraten intromissione, au vermittels.

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### STERILISATION

STERLESATION

Dess Konrachenine einzte mit fabylenzsid seier Gammabestrahlung stedisiert.

Des knotartat werd stedi in unnerstehter Versnehung geleitert. Wenn eine Beschleitung des Inndantste oder der Versnehung vorzieliger sohreit, das Versakstum überschneiten oder die Beritfäß aus approderent dirend ein Frage gestellt, dart das knotarte nicht erwendel werden, klotic testerliniseren.

Probeprotitiesen, sind verfüglise, um zu vermeiden, dass die starte Verpackung vor der implantation der Protense geditnet werden mass. Das insplantation der der stellt der der stellte Verpackung und für der Gediten Verpackung vordien verpackung vordien verpackung vordien verpackung der stellte Verpackung antibuternen werden, verm die Emplantation der Protense der stellt verpackung vordienwird und für die Gedot des trejukturation chring übernennen in die implantationer vordienwird.

und hir de Grote des regordans Intralia, unternational des l'Elles SCHITAINTE GEWÄRRLESTUNG Avente Orthopeadois Corporation gewählteintet, dans dieses Medialoproduin de Specifications and sel herteilles sottit und bis de Leberung lesien Ferrialburgstehler aufweist. Diese Gewählsbistung schlieft specialif Febber sins, die auf nicht-neibhrungsgenfällen Gebrauch, Abusse oder unsachgemäßle Hendhabung des Mediarpproduktes nach: Emparig bei dem Kluist zurücksinfärens sind. Annite Dirtsosachos Gerenhernt kann Gewählsbistung des Geschlichtspress sind. Annite Dirtsosachos Gerenhernt kann Gewählsbistung des Geschlichtspress der der Bergargen.

EU-VERTRETER: Madical Products International Europe, BV Schemeng 134 5145 NP Westwist, Die Niederlande 31 (2) 416 563754

Brazz, FM, Estal Josef antimoplasty of the carpointmicarpal Junt of the timeth. CB: Onlines plus 1930; disloyers:— Brazz, RM: Soul Junt medicament of the brazz of the Braziti- presentary report, fir of Henri Gray Junt Julie 1932; Till 1955.

### FRANCAIS

DESCRIPTION

Le protribus pour articulation inspiro-méliosopienne Avanta CNIC est composée d'un matériate à base de polyéthyleine à ultra hayte nause motéculaire (JH-MWPe) (ut et grimente sur le traplez présidatement prépare, et d'un comproseure postérieure et allage de litere enrec sités intégrée qui set éroculair dans le creux du prente métacarpe. Le léte en stame en mitée à la pièce ou UH-MWPe de Sopon à torme un auteur entre entre dans à l'enfoulation hausle du pouce, L'impliers soité en de la main de la pièce de cermes sur la maint donés de la maint de cermes sur la maint donés de la maint de l

- Mentireco:

   Tignéfei médicarpiernes en alliage de étene 6AL-IV ELI ASTM F-136.

   Composant trateiblen en polyéthylane is utilis haute misses ne R.H.A.V.Peli ASTM F-649.

  Cétale de marquage rédiográphique en creome-octael ASTM F-75.

Cibite on monyment
 MINDICATIONS
 La protitible trapistro-métacorpienne Averta CMC set indicpuis pour le remolablement
 ano daire le discription de consideration de la métacorpienne de la maturité
 ano daire le discription de la métacorpienne de la maturité
 ano daire le discription de la métacorpienne set saison d'un relatacorpienne set saison d'un respectation de la maturité de la métacorpienne set saison d'un respectation des la maturité de la change reconstruction.

R à agri d'une solution alternative à l'arthrodées ou à la change reconstruction.

- CONTRE-BIDICATIONS

  La descrioration d'ou, de musclos, de tendons ou de seeus mous voient des à une malatice, un réfaction ou une intoleration arbrieure et empérieure d'obtané un mainteu ou une terroire active de se protières.

  Toute réclore active ou suprochée su mayor ou aux alertoure de l'arbrussion du

- recom exchement.

  PRECALTIONS

  \* Limplant est fourm whete, tant que l'embellage aut intect. En cas de déféncestion apparents de l'implant ou de son exchainge, de dépassament de la date de périmption ou de doute air le élétife du dépositir pour peuiseur retion que ca soit, l'implant no doit pas être utiles. Ne pas re-mainties.

  La preparation mélicolaque de site d'implantation et le choux d'une faits d'implantation pas etre utiles. Ne pas re-mainties.

  L'implant doit être contre de certain de l'implantation et le choux d'une faits d'implantation prépare et conventablement calibris.

  L'implant doit être contre des certainless été innéparention prépare et conventablement calibris.

  L'implant duit être manipulé à l'aide d'instrumente amondes etin d'évrier route grif-fatt, cour, sur ou entaille.

EFFETS INDÉSERABLES

Les ettes indésirables relevés chaz une sons de 50 cations et publiées étaient
colarmente le desembranes. Le névrite pessagare du neut acdal, la técon des nerfs
digitaux palmaires Me. à l'auputéon du ciment et la tenosymovite cavorique
éténosatre du pouce de De Quenciari.

venerosid	Nombro d'occurrences (n = 50)
maserrernert	5 (10,0 %)
levers passagere du nert radial	2 ( 4,0 %)
dision lies à l'expulsion du ciment	1 ( 2.0 %)
engevriouse de De Ouervain	8 (12,0 %)

- Las éventuels effets indéstrables observés evet les autres protivises anfoudaires des décide sont, notatement, le dessenantement, la ruptive, la dissipation de l'implient, Austre autre événement indésirable significant le sée emporté à se par depuis la début, de la période de consentrablement de ce disposité.
  L'arguantation de ce disposité part entraîner des fesions au riveau des nerts, veuesaeux, tecnion ou tilsues entres entretinent.
  Des des de néaction allemptique au métal autre à le substitution anticulaire ont étérestrets.

### RÉSULTATS CLINIQUES

RÉSULTATS CLINIQUES

Les resultats de l'explantation de ce deponitif ont été clisannés chec vingt-seuf potentir. La protettuen a été prétituée en raison d'une artivier, de l'extre d'une protettue à les prétituées en raison d'une artivier, de l'extre d'une artivier, de l'extre de l'extr

À l'occasion d'un sopront puble utéressement, portant sur cete misme série de cas auquests s'aputarent 21 cas succidentatiannel, à est apoaru que le paspan des 50 prévents d'aputarent 21 cas succidentatiannel, à est apoaru que le paspan des 50 prévents d'aputarent 21 cas succidentatiannel, à est apoaru que le paspan des 50 prévents d'aputarent le restat des Rice autures et presentation touris les clus-tests à tong terme. Une marge complète de mouvement asymptomatique de l'articu-lières. Dans carg cas, l'incurrien dévique ou radiographique à fait apparaître un desser-ment de l'implant. Aucur cas de moutre de l'implant, d'usures de surface, de mor-celisement de l'implant. Aucur cas de moutre de l'implant, d'usures de surface, de mor-celisement de l'implant. Aucur cas de moutre de l'implant, d'usures de surface, de mor-celisement de l'implant.

PROCEDURES CHRURGICALES

I evide un marvuel dicement en detail l'intervention chrurgicale à pratiquer pour l'inplantation de ces dispositifs. Le driugne est seul cliergé de se terminariest even l'entervenion avent utésation du ces produits, ainsi que de se terminariest even l'enfocutions sur la sujat et de consulter das collègues expérimentés eyent de procéder à
ces transmittours.

CONSELS DONNÉS AU PATIENT (voir aussi la acction Mines en gerde) Las informations suivantes, en plus de colles contenues dans les sections « Mines en garde « et « Ettels indéstration», dos ent être trantenses au patient ;

garda « di e tenta sociamiquos», colore que transmissione lotais est criticia à évaluer mais n'aix, quoi qu'il en soit, pas étemels. Cer péces sons composes de maistrace en autorità en autorità de la proprieta de l'accisi à fineferent de contre en vue l'estable la modificació de l'accisione de la maistra de l'accisione de la maistra de l'accisione de la maistra de l'accisione de la maistra de la

STÉRILISATION

Ca disposer a des electios à l'acycle d'étiylène ou aux rayons germa.

Ca disposer a des electios à l'acycle d'étiylène ou aux rayons germa.

L'implant est four mistre laur ou son emballage, de l'alpassement de la clar de peremption ou de dont au la sterit de que applique qui de dont au la sterit de que de la clar de peremption ou de dont au la sterit de que d'apparais pour que par la clar de peremption ou de dont au la sterit de la clar de peremption ou de dont au la sterit de la clar de peremption de la clar de la companion de la clar de la clar de la companion de la clar de la companion de la clar de la companion de la clar de la

GARANTIE L'INITÉE

Avanta Delhocardicis Corporation garantit que ce produit répond aux curactéristiques décretes que la tennoant et no présente pas de détaute de fabrication au moment de la hinéaison. Cette garantie subbe aphotifiquement les défauts provoqués per la majorite utilisation excenten e ou la manionation incorrent du produit subbe à la réception par l'acquierest. Aventu Ontropandice n'unifer auxiliare garantie quant au risialatie de l'intérversion chronique des

REPRÉSENTANT POUR L'UE :

acampai lovel of the Yournib, in . Cain Ontrop British RM. Total joint inthroplasty at the corpormeasurable lovel of the framit, in - Clar Carbon enter Helds: 1975-1997.

British TRA: Total court implicationment at the cause of the thumbs - person many report, br.: J. stand. Soc. (Sec.) (40): 235-245-29.

### ESPAÑOL

DESCRIPCIÓN

La protente carra la articulación inspecionnetecupiana Avente CAIC consta de un componente de poderion de pasa molecular ultra alto (LMANYO), que se comenta el trapecio propiamedo, y un componente de valetaço de alaudion poderio con una el trapecio propiamedo, y un componente de valetaço de alaudion poderio poderio con una el trapecio propiamedo, y un componente de UNANYON (common un unamplazo poderio de valeta de la selecta con el componente de UNANYON (common un unamplazo poderio de ejaste estación para la elitoricación de la base del projuct El profestora se presente an tree terrantos, codo uno de los cuales puede taures en la mandi desenta e en la revero coperente. Aven ayunter a propercia el hueso existe una serie de medidores de prusaba para caca tipo de empiame.

Véstago/cabeza metacarpianos de afesción de tétanio 6AL-4V ELL ASTM F-136
 Componente de trapecio de politificano de peso motecular séra sito, ASTM F-648
 Alambra metacador radiográfico de cobalfo-como, ASTM F-75

ROBCACIONES

La pricase insocionnécorpiene Avanta CAIC anté indicade para el restrictur.

La pricase insocionnécorpiene Avanta CAIC anté indicade para el restrictur.

Des pricases de la presentación des motivas, que presente dotor o testabledad en la entación de la presentación de productiva de la presentación de procedimientos o depensatores o existención de procedimientos entrodes el actual para entre testable de la procedimientos anteriores, como atemples de servicios de procedimientos anteriores, como atemples de servicios de la procedimiento del procedimiento del procedimiento de la procedimiento del procedi

- CONTRANDICACIONES

  Compromiso de los busiess, missoalos, terciones o tejido biendo adynomines e cuasa de patologías, inhicotino o implante previo, que no ofesican con una insentiación o fesción adecuadas para la prótesia.

  Esta tefecion addivir o sospecha de infacción en la articulación del pulger o

# ADVERTENCIAS (visue también le sección notre información de asespramiento

ADVESTI Emulsia y mass biname is para que para guidernido.

Esta dispositivo as són para que cervantado,

Esta dispositivo as són para que cervantado,

La carga y la movididad secuevas y la inastabidad articular posidion acelerar el desguste y exertivalmente proviocar el fisicacio del procedimiento, por aflicipamento, inniciar o distolación del dispositivio. Se debe informar a los parientes cos una demanda escesiva sobre el dispositivo puede aumentar las posibilidades de fracaso.

### PRECAUCIONES

- PRECAUCIONES

   El propiente o presente autéril en un envisio entactio. Si di implante o el sinustra están distractos, al la transcurrido a legislación dei validor o a por cualquier montre o el ducia de se o serioridad, si inolarina no obbora validarar, No volver a estrelativa.

   La propiencion minusciose de la cone de emplantación y la elección de un implante del terrado executión auteriorida les protibilidades de favios.

   El implante debe secure de se envise están abo desposido de haber concluido la preparadori de la zone de replantación y de haber determinado el unante o coercio.

   Los implantes debe escrito de servicio de la consideración y de haber determinado el unante o coercio.

   Los implantes debe escrito de servicio de la como de republicación y de haber determinado el unante o coercio.

   Los implantes debe en o minima en el disposibilo.

### EVENTOS ADVERSOS

Los eventos achereos que se ran informado en una sene publicada de 50 pacientes incluyen afoçamiento, neutris racial insectoria, insión por extración del cemento hacia las nervices digitales partirieres y lendiristis de de Ouervain.

Evento	Número de casos (n-50)
Aficjamiento	5 (10,0 %)
Nourtes radial transitoria	2 ( 4,0 %)
Lasion por extrusion del cerrenta	1 ( 2.0 %)
Tendinitat de Quervan	6 (12.0 %)

- Los potenciales eventos adversos que se han documentado con cinas prófesis de articulación de decida inclayen afoliprierios, fractura, dislocación o infección del impátente hatela le fortan os el tem documentado otros eventos adversos significaciones. Como comescancia del insparte de esen dispositivo se puede producer una lesión de los renvicos, valos siarguinos, tendores y tedidos blandos que lo rodest. Se han documentado calos en escacion de sensibilidad al metal como oceaciones del memplazo entre del memplazo en escacion de sensibilidad al metal como oceaciones del memplazo entrouter.

# RESULTADOS CLÍNICOS

RESULTADOS CLÍNICOS

Se presentario inserutados horizados con valintimos pacientes a los cuates se tes explanto el depositivo. Los reemplazos se realizaros a cazas de artitis, tracaso del interio de articoleste, facaso de la empotaria de propulsario de significante presenta acualizado parte de articoleste de producir de producir de producir de particoleste, facaso de la empotariado de la articolação, en vertados pagamentes es habia adionación do torio em opo de movimiento sin dobre est el monento de la publicación son un seguimiento de hapita ? afrejo, Sinte de los pademes no logramo securios mortes de la publicación y comerciarse de la regionación de la cuatro de la publicación y comerciarse del tejado blando, No se discumentamen deste de fractura o infaction del impairito, pero hubo bes capos de eficiamiento en la unión entre el comento y ol huspo.

En una publicación posterior más extense, que motuyó otros visirioreo canos articionales de la seria, la insposia de los 50 pacientes sidanzó un sergo de movemento completo derino de se cualmi seramismo acequada de número los puenos de sutura y continuo demostrarios businos resultados a siago patra. Se alcando un inrego completo de movimiemo assimonitácio en 26 pacientes estecentribidos con trasterior sincular. En cinco paciantes se observaren evidencias circicas o reclogatificas de sitigariando. No se observaren casos de fractura del arquiente, desgaste superficial, leagmentación o infección.

PROCEDIMIENTOS QUIRÚ/RQICOS

Existe un manual pas descrites an defaite el procedimiento quincigno para al uso de estos implantes. Es responsabilidad del conjunto landianzame con el procedimiento avien de user ados paracilicos. Trances en responsabilidad del cercipion landianzame con las pubblicaciones helitarians y consultar con colegas experimentados acomo a pubblicaciones helitarians y consultar con colegas experimentados acomo del procedimientos acomo del estos regilamentos.

# INFORMACIÓN DE ASESORAMIENTO PARA PACIENTES (rease lambien

Advertencias)

Además de la información relativo al paciente que incluyen las secciones 
Advariancias y Evertos Ariversos, se deberá transmitir al paciente la septiente intermación:

Si bien resulta officil estimor la curación prevista de los componentes del necesidato enfolate enfolat, ésta es finits, Estos componentes etidar renflucidos con manamaise enforación cue se colocido deriam del ocupo para la portencial estelucación de la movificada o la reducción del dolor. No destarta, destado a multiplos tercore biológicos, mendienos y sistempentos que artector a eston dispositancia, no est destados colos la componentes ententes en rever del actividad y de carga que resista un que de la componente entente el move del actividad y del carga que resista un que se documentó en cua estudo clanco de esta dispositado ha del 10% en un esquirimiento de trasta 10 años. (Brann Ref., Total joint artirioplasty al the exponentescampel piero di me turno. Calo Critico 1985;190;181-73.
Los efectos adversos pueden requenr una ruerva operación, envisión o la busión de la articulada.

- ESTERILIZACIÓN

  Está componente la sido estinitzado con oxido de etitiena y radiación gamera.

  El trojámile se preserve aprieti en un enverse mactio. Si el implame o el enveze están dehados, si ha traminounido el periodo de valosa o el se duda de si el elevitado por alguna ración, no debe o userse el enplante. No volver e electricido.

  Entron componente a modifiques de prusba para entire tener que altir el envase están del confidencia de prusba para entire tener que altir el envase están del confidencia por producto por confidencia por confidencia del confidencia del su envase están del describación del machante y de que se haya determentedo adecuación entre so tramino.

se hajo diserveramo.

GARIANTÍA LIMITADA

Averia Cirtopaedicis Corporation garantiza que este producto turciple con las especificaciones del fanciante y no oportime delector de tabricación en el montento de un entreja. Este garantiza estable, especificamen las sudericos que sulptim de uso indebido, abuso o mantoulación incomecta del productio una vez recisión por el cominación, abuso o mantoulación incomecta del productio una vez recisión por el cominación, abuso o mantoulación incomecta del productio una vez recisión por el cominación, abuso o mantoulación incomecta del productio una vez recisión por el cominación.

# REPRESENTANTE EN LA UNIÓN EUROPEA:

Medical Products International Eu-Schurweg 13a 5145 NP Washville, Paises Basis 31 IN 416 563754

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Bosson 1947, Inchail John anthroposothy on minimization of the physiological plant (1945 Maga)(195) (61-7).
Brason Ref. Total point needle-convent on the base of the shumb - pre-interiory moon), 3 hand Sing Jame (1962 May)(10) 245-51.

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### BESCHANVING

De Austra CHIC Impostometachanal gewichtbaunderes bestäat uit sen component ver ordanizing missiosidie genefici polymitipiens, IMAMPY, welks and niet voorbereide käpischin wordt gedend, ein sen till sen titariumkegening bestäannde stealcomponent mer gelatingsweide kopt welks in die schadid van die eerste metazepals voording gebracht. Die kterkum kop is door een gewicht veroorden met die component van URBAMPY mit op een kraupft oorbestanier portheitsche verninging van his bestemt olumgsweicht is vormen. Het krinserstaat is vertrigbaar in die maten, die allemaal einzere woorden gebruikt in die notstande proteinsta. Voor olik type implantaat ist een sene proteinsahn verorligbaar als hulp bij het voorbereckien van het too.

- Materialent:

  ASTM F-136 Vitahlom 6AL-4V ELI legering metabarpate stendilup

  ASTM F-646 Inspeciale component: veri ultrahong molecular gewich polystryken LIRAMOPEIchnoreen rediografische markeringsonsad

  ASTM F-75 koltablinkonnen rediografische markeringsonsad

INDICATIES

De Avanta CIAC impatrométicarpais protriées às besterrid voor vervanging van het
concreties gewicht in patifieren met een volgroeid skielet met pijn of anticitatien het
lazoezonnelicarpais gewicht door fraums, inflammatiole of degenantiere eaerdoeringen of toor revisie van serdere lignigen, als afternatiel voor artificées of
reconstructieve onteurgis.

### CONTRA-INDICATIES

Door zielde, inlectie of electere implantatie sangetast bot, muscutanar, occes, of aggend zacht wedset, walke nist genong stess of bevestiging voor de prothese ment before.

Actieve of vermosde infectios in of read hat during switcht.
Omolgroeidhaid van het skelet.

WAARSCHEMINGEN die ook het hoofdstak informatie voor patiektivoorsichting)

Dit instrument is uitskalend voor gelijfind gebruik.

Zwes besieting, overmetigt beweeglijfind en gewechtskespabiliteit burnen altemaal lacke tot vernedios stijzige en uitenodijk izen net testrument hat begeven door
lootenen, breiken of dischalen. Perkleden diemen te worden gewezen ook verhoogde
lazes dat het instrument het begeeft wanneer er in hope given aan worden gesteld.

- I wast dan net restrument net begreeft wennes et ei holge esent aus vorzion gestell.

  \*\*VOORZONESSMAATTEGELE \*\*

  \*\*I het Implentaat werdt stende geleveel in een orzioechadigste versteldeligt, inden olwer net mojelande strived die versookiegt beschedig obt bit is bit in de versookstate strived die voorsiokiegt beschedig obt bit is bit in de versookstate in die versookstate strived voorsie opbruikst. Wet herstrefelseer.

  \*\*E een neuvrieurige voorboerdeing van de kredientsfesplaate en die kouze van de jurkee maat insplantaat vergrofeen de karen op een successen resultaate.

  \*\*Het insplantaat mag gans uit zijn sariele versooksing worden gehaald zinden de spekeldelige beeft.

  \*\*Om ta voorbonnen die 4 en het sestimment worzt geenaut, geassedan of gevand

MOGELLIKE BLIWERKINGEN

• Bijnverkingen in nen bekondigemaalde eerle van 50 patievien omvatteri longsan van het krystentaat, tijdoelijke radiele reuntlij, inteel ean de vingerzoniven in de hend-palm door sekrities van het Neemfodel en De Carevinne teandiese van het Neemfodel en De Carevinne teandiese.

Bijwerking	Austial governo (s = 60)
Losgaan van het implantaat	5 (10,0 %)
Yijdelijka radiale neurius	2 ( 4,0 %)
Letsel door extrusie van het ideefiniddel	1 ( 2.0 %)
De Ouervains tendinitis	6 (12,0 %)

- Mogalijos bijuminisupin die in combinatie met andere vragergewrichtsprotheses zie gemed omretten totgaan, fracturatischafer, of infectie van het implantaal. Gedatussed ein pennde dat die kraitenent op de maid in zijn eigemorteeten kontente bijuminingen gerapporteerd.
   Lensel sen de orritigoweid zereuwent, inhedivistori, pozen of zacht weetsel kan certaden ist geredy van de insplantation van het insplantament om versien signification van het insplantament.
   Metadigerooripiedrissenderie zin gerapporteerd na vervanging van het gewricht.

# KLINISCHE RESULTATEN Er die resultaten van negeren

KLINSCHE RESULTATEN

Et der resultation van negorentvertrig patienten gesapporteerd die het institutional gelingstenteerd hebben gelengeler, kevaraging is uitspecoed voor artists, middled poging bit etropoles, excitee middled elestende of tode gewichtsertropisses, of porturatyleische filterioles, extreme statische gesapper of tode gewichtsertropisses, of porturatyleische filterioles gesapper van programmen, op het gemann van publisste tod. 7 jaar kolonivatig het gewicht is zeine gewichtse werd gestellerien van good bereit van publisste beweigt toereit, in zeine gewichten verdig gestellerien van good bereit van publisste beweigt toereit, in zeine gewichten verdig gestellerien van der gewichten verdig der van der de findste van het zeit werden. It zij geen gewallen gewijdendend van besich of infoliet van het replantaut, maar die gewallen verboorden kodeling van het implemaan op het gewinder de verdig van het implemaan op het gewinder van de verdig van het implemaan op het gewinder de verdig van het implemaan op het gewinder verdig van het indexe verdig van het indexe verdig van de verdig van de verdig van het verdig van het verdig van het verdig van het verdig van de verdig van het verdig van he

CHRIJIRGISCHE PROCEDURES

Er is een hardleiding vashrigbass waarin gedetalleent die chivurgische procedure voor het gebruik van deze insplantatie-instrumenter wordt beschramen. Het is die versartswordelijkheid van die chiving dat in ill verstruwel is net die procedure voorschi hij deze productien gelet gebruiken. Destinaat is het die versartwoordelijkheid van die chrung dat hij voorspland van het gebruiken. Destinaat is het die versartwoordelijkheid van de chrung dat hij voorspland van het gebruiken. Oo de hoogte is van relevants publikelies en did hij bij ervaren oofega is achies inwirn met betreiding tot de procedure.

# INFORMATIE VOOR PATIËNTVOORLICHTING (zie ook Waarschuwingen) Naast die patiërdigerstateerde informatie in die laachtstukseen Waarschuwingen en Bijwerkingen dient de volgende informatie te wurden medegedeeld aan de patiënt:

Nixiavali de varvachte leveradur van componenten votre aan complete powentsterwarging mosals er chatren is, le dize bepreit. Deze componenten zijn gemaalt van versende naterialent, die in het fichanne verden gestalstet voor ringstille herstet van de mobiliert of vermindering van pijn, Varnoegs die vele höldigische, mochanische en hysischemstet bestoen die herband og deze versimenten violenen, kan echter eint van deze componenten werden verwecht dat zij gebrande notspeckte diej bestand zijn legen het achthefisches van die bestamming van nomaal gezond doct, has geraponisente personsiger van bestandsgepen in een kleindere studie van die statumment bedoegs (1945 toj) oft 10 gart potenten, (Siston Pith, Chai port arbeitspetsty at the carponisentaarpai joint of the likunth, Cali Onthop 1965; 195: 151-7;

Door nachtige eilforten kan heroperatie, revisie of fusile van het Ontrefinede pewicktin notig zijn.

# STERILISATIE

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  In the implemental wourt steried getword is sen on-beschudigde verpakking, Indien of well in implement of the first properties of the strain of the s

BEPERKTE GARANTIE

Aronal Orthopaeroes Corporation garandeen dat dit product beantwoords aan de specificaties win de betriefen me op het moment van levering gren pro-Sucsefouner bond. Uitgesicten van deze garante zijn met name gabraken sis gevolg van verkeand gebrief, materiek of een ongeste bedelenig van het product natels het doorde kurde is ontwangen. Awants Orthopaericka geeft geen gerande op het resultaut van de chriungsden procedere.

# EU-VERTEGENWOORDIGER:

Medical Products International | Schuring 13A 5145 NP Washing, Nedward +31 81 416 563754

Brain RNA, Relation's antercapacity or the corporatecorage pivol or the thurst, as rue Cetting and 1965(4)661-161-7
Brain RN, folds pair redescentation to the base of the thumb-protection; report 4- J Hand Surg. Ship) are 1987-706. 745-551

### ITALIANO

# DESCRIZIONE

DESCRIZIONE: La protesi vaspetio-netacampale Auseráa CMC é costituta de un elemento in poleniane ad elémento poso moisocolare (LH-SAMPR) commentato al imposito posperato», e de luce rétole in lego de Stanko con teste hangesia, lumanto mal Assis del graine meticanço. La testa in Nianio si articola con l'elemento in LH-SAMPR remando una sostituzione protesios vivocidas "esup-de" ne l'articolazione bease del policio. L'imposimo è disponible in tre maiere, ciatocina della quali può mesere utilizzate per la meno desta a shistra. Inollar, per ogni soo di imposito de disponible in tre ossere di enallo per la proparatione della posserio assere di mallo per la proparatione della posserio assere di mallo per la proparatione della posserio.

- Asserial:

  Institution motocompain in inga di trismo SAL-4V ELI ASTIM F-196

  Demento transciale in posisiliana ad all'instituo pasco reclaccione 8.194.4VP-a) ASTIM
  F-648

  F-60 marcatore radiografico in crones-constru ASTIM F-75.

BIDICAZIONI

La protes Impecto-metacarpale Avanta CIAC à indicata per la scrittudora tolale del Transcissioni in passierii con incluppo attributiono complete, che accusano debre o instabilità dell'articostanne in seguito a trauma, palcioga, inferentratora o degenerativa oppura revisione di procedura procederti, in alternativa all'artirosesi o alle chierape ricostruttiva.

CONTROINDICAZIONI

Data, miscotatura, tendrel o tessuti molt adiacent alteren de patologie, Mestori o precedenti impianti, che non sono in grado di fornira aupponto o fisseggio adeguaocadanti organe, com tom accessor dell'area (viarressala o circustante l'articolazione del Intezioni in atto o sospette cell'area (viarressala o circustante l'articolazione del I

# AVVERTENZE (5) vada anche le aszigne relativa alle informazioni per la com

si pazionte)

- Quanto presidio è destinuto esclusivamente all'uso cementato,
- Loranto persicolemente pesarut, faccesentu recibilità e l'instabilità stricciare pos-tionosi accelerates l'usus e proviocare eventueli dansi dals protesti per distaccos, institura o lassacione. Si raccomentali di Informeri i pazioni sulla maggiore probabilità che si verificati selle reveninza, se pil impranti vanogino sotioposti a sodiocatorio escossivo.

- PRECALIZIONI

  \* L'implanto risulta starila nella confezione integra. Non utilizzarlo se l'implanto escapio de la confezione ambrevo develogiello, se à trescorsa la data de scaderra o se di obtato della starilla per qualitara notico. Non reineratzarea.

  \* Una propianzione meticolosia del sin entretzarea.

  \* Una propianzione meticolosia del sin di rimplanto a la soluta della manura adequata dell'implanto ambrevato dell'implanto ambrevato dell'implanto ambrevato dell'implanto ambrevato dell'implanto della confezione siante acide dopo amer propianto e correttamente relazione dell'implanto della confezione siante acide dello per propianto e correttamente relazione dell'implanto della confezione siante dell'implanto della confezione siante dell'implanto della confezione siante dell'implanto della confezione siante della confezione siante della confezione della confezione siante della confezione siante della confezione della confezione della confezione della confezione della confezione della confezione siante della confezione della co

EVENTS AVVERSS

— Gil eventi acversi publicati per un campione rappresentativo di 50 bazienti com-pendiono il obtazzo il a revitte radiate transitoria, la lesione per l'estivatione di comen-to di nerdi oggitali palmari i a la tendinitto di de Quarvieri.

Everto	Numero di eventi (n=50)
Distance	6 (10.0 %)
Neurite raciale transitoria	2 ( 40 %)
Lesione per l'estrusione di cemento	1 ( 2.0 %)
Tendirate di de Overvain	6 (12.0 %)

- I potenziali eventi evventi essi noti in relazione ad altre protest par articolazioni talangee comprenduno di distacco, la instituz, la lassazione o interpone dell'implanto, non sono stati mai moti districti effetti avventi rilevanti durante lutto è periodo di com-mercializzazione di questo presidio.

## RISULTATI CLINICI

RISULTATI CLINICI Sono state nen noi institute di verninovo pazzenii a cui è stato impiamitato questio pre-sidori, La sostifuzione è sasta affettituda a cavasa di artine, insoccesso di una ionitara articolesi, prescolore insuccesso dell'articopiatica statale ci in Redatic, appriera articolesi estructure incressi costi-cerettiros. Veritifota pataenti aveverno registrato una buona articopianti insolitore ai momento delle unbidicazione dirico al rami di lodive-uni. Sette pademi non soure insolite i regularigene l'articolerata nomale PRUM; a cousse di un notecche soggitation mazzociare o della constituta se dello scarring odi essoni ombie. Non acono stati richti casi di trattaza o intessone dell'impiame, ma la tre casi si è verificario di disenzo oi norrispondoraza dell'interfacco setto-chimento.

In usa auccessive pubblications esfess, comprendente ulteriori 21 casi della feltispocie<sup>1</sup>. Ils reaggior parte del 50 patrimi las mostatos un'articularità completa entre que comprendente qualità montron della suma e les confruente on prospere bone insultare a lungo termes. Una completa articolarità alertomisca è stata raggiunte de 25 pazzello internentificati con tesespone articolarie. In chique cese si è svelicato a d'oblacco directativa della controla della confruente del confruente della confruente della confruence della montrolationa della confruence della

PROCEDURE CHIRURGICHE
E disponible une procedure chiangles destinate all'uso del presente dispositivo per
replanto. E responsabilità del chirungo acquaire familiante cen tale procedure prima
di statzare questi prodotti. I chiango è altresi tendi e a conosciare il adcommentazione
sudi signimanto e a cossistante con colleghi secretti in mento alla procedure para di
esequire l'interventio.

# INFORMAZIONI PER LA CONSULENZA AL PAZIENTI (SI vadano avone le

(Avvertienze)
Oltre alle informazioni apecifiche, riportale nelle sezioni Avvertienze ed Eventi avversi, si raccomaerca di comunicare si pazienis anche quarto segue;

- an adornmenta of commentar de patromanda de patromanda de la compania de la componenta matrimitario dell'arrisolazione hespero una quanta la ministra che, puntoppo, risosta difficiale da sifinaria. Cucaria comoconerii anno malizzati con matericali estimato, che veragiono insensiti nel corpico per risostati una potreziale mobilità in dichere il dicher. Il ministra, il ministra della componenta della primarippostio che senso di qualco di sodiessere il alvatio di sensivia e il capito di un segonda con sono por imperiodicame il alvatio di sensivia e il capito di un segonda con sono por un pinistro on intempo dimenta, chi prescribeto di della di discono risona di primari di componenta di sensi di differe il prescribo di capito di un segonda di primi di risona con tempo dimenta, chi prescribo di della della di fish in si pendoci di Di arrisi di risona di discono risona di propisso di sensi della della di fish in si pendoci di Di arrisi di risona. Cato di prescribi di pres

- STERRIZZAZIONE

  Il presente implante è siato stettizzato con cestido di estene o raggi gamma.

  L'ergistino (primito è stente se la contezione è inregua. Non utilizzazio se l'implanto stesse o is contesione sentirazio caminagolit, se e transcursa la data di scadoruza o se si cubitat della stentifa per qualissim motivo. Non infondizzano.

  Sono disportibili calizarenti di povue par evitare l'appenda della continuone stenie prima d'implantare la porteata. Persevera l'orgistero di dala contezione steria edio doco ever proparato e convitamente misurato è sito dell'imparato.

VANSANCIA LIMITATA

Avanta Ontopastica Corporation garantisce che il presente prodotto è contorne elle
espocifiche del produttion e che è seante de diffetti di libitorizazione al momento delle
consegna. Le presente gerancia escalate specificamente i diffetti delivareni de uso
inventoria e nei con corretto è ce demandi di manifolizatione del prodotto successivamente
inventoria e nei concretto è ce demandi di manifolizatione del prodotto successivamente
della processiva chiungica.

RAPPRESENTANTE PER L'UE: Medical Products International Ex Schulweg 13a 5145 NP Washvilk, Pazzi Basei 31 (0) 416 563754

Brain FM. Total just antwockerty at the corporateconol joint of the thems. In: Clin Democratings tretter visit in the control of the Whenthe restations patientees in J. Hand Sare (Arrighage) 1982.

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19-0353 Rev. D



### **ENGLISH**

### CAUTION

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

DESCRIPTION
This semt constrained wrist joint prostnesses consists of a cobalt chromium radial component, a cobalt chromium carpal component, two (2) cobalt chromium carpal scrawn, and an UHMWPe carpal ball component. The UHMWPe carpal ball component articulates with the radial and cerpal components. The Proximal aspect of the impaint is designed to be inserted into the shaft of the radius bone and the distal espect is designed to be fartened to the carpal bones of the hard. The device is intended to replace the wrist. The implant is available in several stress in right and left hand configurations. A range of itial sizers for each type of implant is available to ad in bone preparation.

- ASTM F-648 utra-high molecular weight polyethylene powder fabricated form for
- ASTM F-1580 transcurant powders for coatings of surgical implants
  ASTM F-1580 transcurant powders for coatings of surgical implants

INDECATIONS
The Aventa Orthopoodics Wrist implant is intended for replacement of the paintul wrist joint due to rheumatoid arthritis (RA), osteo-arthritis (RA), or traumatic arthritis (RA).

- CONTRAINDICATIONS

   Bone, musculature, tendons, or adjacent bolt tissue compromised by disease, relection, or prior implantation, which cannot provide adequate support or fication for the prosthesis.

   Known sensitivity to materials used in this device
   Sicalistal immulature.

- WARNINGS (See also the Patient Counseling Information Section)

  Stremuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by locenting, facilities, or dislocation of the device. Patients should be made aware of the encreased potential for device failure when excessive demands are made upon it.

  Notification it accordance with the California Sate Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemicalej known to the State of California to cause cancer, and/or birth defects and other reproductive loxicity.

- PRECAUTIONS

  Do not resterface. The implant is provided sterile in an undamaged package. It sher the implant or the package appears damaged, experation date has been loceded, or if sterlink is questioned for any maken, the replant 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 mandled with blant instruments to avoid scratching, cutting or nicking the device.

## ADVERSE EVENTS

ADVERSE EVENTS

Potential adverse events reported with joint prostheses include pain, loosening, fracture, transient racial resurfic, testifnilis, dislocation, or infection. There have been some reports of patients with metal sensitivity reactions following joint replacement implemation of materials such as colast chrome and/or titanium may result in foreign body reaction adjucent to the implant site, fully to the surrounding normes, blood vessels, tendons, or soft listsues can occur as a consequence of implanting this device. Surgical intervention may be required to treat adverse effects. This may involve attractions or amputation of the involved appendage.

# SURGICAL PROCEDURES

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

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

In addition to the patient related information contained in the Wernings 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 unknown period of time. Advence effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

# STERILIZATION

- FRILIZATION

  This component has been sterilized by ethylene oxide or gamma radiation,
  Do not resterilize. The implient is provided sterile in an unclamaged package, it
  either the impliant or the package appears damaged, exprision date has been
  exceeded, or if sterility is guestioned for any mason, the implient should not be
  used.

  This steer components are evaliable to avoid having to open the sterile package
  prior to prostness impliantation. The impliant should be removed from its sterile
  package only after the implient site has been prepared and propony sized.

LIMITED WARRANTY

Availe Orthopaetics hic., warrants that this product meets the manufacturer's specifications and is free from manufacturing detects at the time of delivery. This warranty specifically excludes defects resulting from missies, abuse or improper handling of the product subsequent to recept by the punchaser. Avanta Onthopaedics does not warrant the outcome of the surgical procedum.

# J REPRESENTATIVE Medical Products International Europ Schutweg 13s 5145 NP Waalwek, The Netherlands 31 (0) 416 563754 nal Europe. BV

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### ACHTUNG

atz darf dieses Produkt nur von einem Arzl oder in dessen Auftrag

### BESCHREIBUNG

BESCHREIBUNG
Diese habgefrichte Handgelenkprothese besteht aus einer radialen Komponente aus Cobalt-Chrom, zwei (2) Karpelschrauben aus Cobalt-Chrom und einer Karpalkogekomponente aus uhrabochmoheutaren Polyettynen (uhtikW-PE), De UhtikW-PE-Karpalkogekomponente aus uhrabochmoheutaren Polyettynen (uhtikW-PE), De UhtikW-PE-Karpalkogekomponente artikulert mit der Radial- und der Karpalkomponente. Der proximale Teil des 
implantats ist zum Einsetzen in den Schaft des Paduis bestimmt und der distalte Teil zum Beledigent an den Handwurzelfmochen. Das implantat ist als Handgebnikensatz 
iconzistet. Es ist in mehreren Größen für die rechte und die finke Hand erhältlich. Zur 
Erleichterung der Knocheripräparantion ist ein Satz Probeimplantate für jeden 
implantattyp erhältlich.

- ASTM F-648; Ultrahochmolekulares Polyethylenpulver für chirurgische Implantate ASTM F-1537: Cobalt- Chrom-Molybdän-Knetlegierung für chirurgische
- Implantate ASTM F-1580 Transpulver für Beschichtungen von chirurgischen Implantates

INDEKATIONEN

Das Avanta Ottroppedics Handgelenk-Implentet ist zum Ersetz des schmechaften
Handgelenks bei inbunnatolder Arthritis (PA), Osteoartinhis (DA) oder treumentscher
Anthritis(FA) bestimmt.

### KONTRAINDIKATIONEN

- THE PRINCIPLE OF THE PR
- Gelenks Bei im Wachstum begriffenen Patienten mit offenen Epiphysen, Bekannte Überempfridlichkeit gegenüber den Implantatwerkstoffer

# WARNUNGEN (Siehe auch den Abschnitt Patienteninformationen) Extreme Belastungen, große Mobilität und Gliedmaßeninstabilität können zu frühzeit-

gem Versichleiß und eventuellern Vorsagen der Prothese durch Lockern, Brochen oder Vernatsichen führen. Der Pattent sollte über das arhöhle Flisiko eines Versagens die Prothese bei Überbeanspruchzag aufgekläht verden, Mittelbung gemäß California, Seie Drinking Water und fösst Enforcement Act von 1986 (Proposition 65): Dieses Produit enthält einen chemischen Stoff, der hach Kenntnis des State of California Kroba undroder kongenklab Dielekte oder andere reproduidionsticknikologische Wirkungen henvorruten kenn.

ACHTUNG
Die Prothese wird steril in einer unbeschädigten Verpackung geliefent, Sollte entwecker die Pruhese oder die Verpackung beschädigt, das Verfalkstamm überschrikten oder die Sterilät aus ingendeinem Grunde zwerfeituff sein, sollte die Prothese nicht verwordet werden. Nicht dem Entfereme der sterilen Verpackung die Prothese bis zum Zeitpunkt des knobentation in ein Bad mit steriler Salzbaung legen. Die Prothesen sollten ausschließlich mit sturngfen Instrumenten gefasst werden, im Kratzer, Schrittis und Karban auf der Prothese zu vermeiden. Eins gründliche Verbereitung der Implantationsstelle und die Walth die nortligen Prothesen gefore enthem die Chance eines erlogmichen Ergriffik, zur Erleichteung der Knochsenvorbereitung ist eine große Autwaht von Musterprothesen erhältlich. Die Prothese in der richtigen Größe ent aus der starfein Packung mehren, wenn die Implantationsstelle ausreichend vorbereitet wurde.

### KOMPLIKATIONEN

ROMPLIKATIONEN
Bekannte mögliche Komplikationen mitGalenkprothesen sind Schmerzen, Zementeknischissschädigung, Lookerung, Transierte Redalleneuritis, Tendinitis, Fraktir, Verruschen oder Intektionen, Bei ertigen Pettenten traten Überempfischleiten gegen Metalt nech dem Geleinkentatz zul, Daufüber hinzus können Verletzungen der umgebenden Nerven, Bikrigefläße, Bänder oder der Wechteitel auftreten. Ein chrungscher Eingriff kann zu Behanzbung von unanwänschlien Wirkungen notwendig sein. Dies kann eine Arthrodese oder Ampulation des betroffenen Antangsgebildes bedeuten.

## OPERATIONSVERFAHREN

OPERATIONSVERFAHREN

Eine Operationsameisung zur Verwandung dieser Protitese ist erhältlich. Der Chir hat sich vor der Verwendung dieser Produkts mit den Operationsverfahren vertrauf machen. Daruber hinaus liegt es in der Verantvortung des Chirurgen, und Verwendlichser Produkt die selvenden Publikationen zur Kennens zu nehmen und sich mit dieser Angelegenheit erfahrenen Kollogen auszutausschen.

PATIENTEN INFORMATIONEN (Siehe auch Warnung)
Es steht eine Patiententvoschüte zur Information des Patienten zur Verfügung.
Warnung und Komplikationen sollte der Patient über Folgendes kritommiert werden:
It Komplikationen können teine neue Operation, eine neue Begrationtung oder Fusient des betreffenden Geleinks erfordern. 2) Die Lobensdauer der Geleinksratikkomponenten ist beginzurt, Bre Lobensdauer kasst sich nur schwer voraussagen. Die Komponenten sixt sun körperfrenden Material hergestelt, die in den Körper eingepflanzt werden, um möglichst die Mobblikat wiederheinzustellen und Schmetzen zu verrisigen?. Aufgend zahlreicher biologischer, mechanischer und physiologischer Faktoren, die diese Komponenten beeinflussen, überein die Kumponenten des Askirolitationischau und die Beleintung einen normalen gesunden Knochens nicht über einen unbegrenden Zeitraum ausfraffen.

### STERILISATION

STERILISATION
Dieses Proxisté wurde mit Ethylenoxid oder mithille von Gemmaskrahlen sterilisiert. Est
wird steni in einer unbeschäbigien Verpackung gelertet. Sollte entwader die Prothese
oder die Verpackung beschäbigt sein, das Verfaldature. Überschriften oder die
Sterhildt aus gesubenem Grunde zweifehalt sein, sollte die Prothese nicht verwendiet werden. Nicht eineut sterillaueren. Um die stenie Verpackung nicht nur wegen
der Feststellung der richtugen Größe der Prothese vor der hepterstation öffene zu
müssen, stehen. Größermusfer zur Verfügung. De Prothese ereit aus der stenien
Verpackung erntferen, nachdem die Implantationsstelle ausreichend vorbereitet und
die richtlige Größe der Frothese ermittelt wurde.

# BEGRENZTE GARANTIE

ocumente la Gantann III.
Annato Chrispaedica, Inc., gazanteri, dass delses Produkt den Spezifikationen des
Horstellers eruspicht und zum Zeitpankt der Lieferung keine Herstellungsfehler
aufweist. Desse Gannatie besicht sich nicht auf Schäden, die auf unsachgeschte
Benandung, Missbrauch oder felsche Verwendung des Produkts durch den Benutzer
zuschaftlichen Sein, Ausnitu Orthopaadica gewährleistet nicht den Erfolg des chisurgesiches Engriffe,

### EU REPRÂSENTANT

lional Europe Schutweg 13a 5145 NP Washwijk, The Netherlands 31 (0) 416 563754

# FRANÇAIS

MISE EN GARDE La légistation fédérale (des États-Unis d'Amerique) émet la restri doit être vendu, distribué et utilisé par et sur ordre d'un médeci

DESCRIPTION

Cette profilèse de poignet semi-contrainte se compose d'une pièce radiale cobalchrome, d'une pièce carpierne collès-chrome, de deux (2) vis cerperines cobalchrome et d'une bible carpierne en UH-MWPE s'influde sur les pièces radiale et carpierne.

Le spec provinal de l'implant doit être inseré dans le corps du radias; l'aspect distal doit être fixé sur les os carpiens de la main. Cette profilèse s'utilise en remplacement du pognet, L'implant est disponsible en pàriesurs lailles, dans des configurations
de main droit et main gauche. Une séré de calibreus d'éseat pour charge le préd'implant est disponible, pour aider è la préparation osseuse.

- stériaur: ASTM F-648 : forme de poucére de polyétityéene à poide moléculaire utra élevé traîtée pour implants chirurgicaux ASTM F-1537 : allage de cohait-chrome-molybdéne (açonné pour implants
- chicugicaux

  Poudras de tikane conformes à la norme ASTM F-1580 pour enrobages d'implants chirurgicaux

### INDICATIONS

L'implent de polgnet d'Avente Orthopeadics est prévu pour remplacer l'articulation doubureuse du poignet en cas d'arthrite rhumatoide, d'ostécarthrite ou d'arthrite traumatique.

- CONTRE-INDECATIONS

  Os, munoulature, tendons ou tiesus mous adjacents endomnagés per une maiadia, see infection ou une précédente implemation et incapables d'offrir on support ou une foation adéquats à la prothèse

  Jeunes patients en cours de croissance présentant des épipmyes ouvertes

  Sensibilité connue aux matérieux utiledes dans la prothèse

# MISES EN GARDE (voir aussi la partie relative à l'information et conseils destinés

au patiern).

Contraintes importantes, mobilité excessive et instabilité articulaire peuvent toutes accélerer l'ausre et abouir à uve éventuellement défaillance par détachement, frac-ture ou dislocation de l'appareil, Les patients deiven être conscients du risque poten-tet de la détaillance de l'appareil ai ce demine subit des contraintes excessives. Notification en conformité sivec le California Safe Drinking Water and Tout Enforcement et de 1986 (Proposition 65) ce produit cortient un agent chinique comu dans l'État de Californie pour causer le cancer et/ou des malformations néons-

PRÉCAUTIONS

L'implant est fourni stèrile dens un emballage intect. Si l'implant ou son emballage apparaît endommagé, si la date de péremption est dépassée ou si la stérifié est mes en doute pour une raison queboncque. It sur proscrire l'emplici de cet mostert. Ne pas ne doute pour une raison queboncque. It sur proscrire l'emplici de cet mostert. Ne pas re-sterifiser. Les implants obvert être gardes dans une coldition saine stérile après qu'is ont être ettrés de leur emballage sériles avant implantation. Il convient de manipuler les implants uniquement avec des instrument émoussés pour éviter de seyer, de couper ou d'entailles rapperait Des préparation méticuleuse du sits d'implantation et le choix de la tuille appropriée de l'implant augmentent la canno de soucés de l'implantation. Il avisits une garmes completé de galarits pour ader à la préparation de l'ob. On recommende de ratire l'implant de table appropriée de son emballage stériles existiment après que le elle d'implantation a été préparai et correctement dimensionné.

PITE IS INDESSITABLES

Parmi les effets indésiables potentiels des prothisses on a signalé la douleur, blessure par extrusion de ciment, nivirta radiale passagère, tendinite, le détachement, le frac-ture, la dislocation ou l'infection. On a signalé quelques cas de patients que ont man-festé des réactions de sensibilité au métal après remplacement de l'articulation. La leison des nerés, vasseaux serquins, tendone ou tissus mous anvironnants peut suv-venir suite à l'amplantation de cet appurail. Une intervention charunjicate pout être requise pour tradre les éfets contraires, Elle peut comprendre l'arthrodése ou l'am-putation de l'appendice impliqué.

### PROCEDURES CHIRURGICALES

PROCEDURES CAMPACHALLES
Il estée une produive chiumpicale à suive dans la mise en ceuvre de cette proti-èse.
Il esté de la responsablé du chrungen de ben prendre connisteauce de cette proti-èse.
dure avant d'étaire cès produités. De plus, le chrungien est leur de prendre des connaissances des publications utiles et de consulter des confères experimentés quant à cette procédient avant qu'il utilise ces protifiéses.

# INFORMATION ET CONSEILS DESTINES AU PATIENT (Nois également le

INFORMATION ET CONSEILS DESTINES AU PATIENT (voi également la partie Misse en garde). Une brochure à l'attention du patient, contenunt des conseits, a été réalisée. En plus de l'attention neistrée nu patient, contenunt des conseits, a été réalisée. En plus de l'attention neistrée nu patient, contenunt des les parties Mess en garde et Ellets indexitables, il convent de faire savoir au patient que:

Il Les éfets secondaires peuvent nécessière une nouveille opissation, une correction ou une fusion de l'attenutation concernée. 2) Comme la longevité des componants on emplacement de l'artenutation est difficies e sottines, elle est l'artiérieux de l'organisme anu use de tresturation potentièles de la mobilité ou de le réduction de la douleur. Toutefoie, en racion des nombreux facteurs biologiques, mécaniques et physiconhangues intérients à ces appareils, les componants ne peuvent par résister indéfinment au niveau d'activité et aux contraintes d'un os sain normal.

STERILISATION

Ce composant a été stéritéé à l'oxyde d'éthyténe ou eux rayons garmna, L'implant est bourni stérite dans un embalage intact. Si l'implant ou son embalage apparasent endormagés, si la date de péremption est depassée ou ét le stérité est mise en doute pour une raison quotounque, il laut proscrier l'emploi de cet implant. Ne pas re-etériliser. Il existe des gabarts d'easai pour vous évêter d'ouvre un embalage stérite avait l'innolantation de la prothèse. Il faut retirer l'implant de son embalage stérite avait l'innolantation de la prothèse. Il faut retirer l'implant de son embalage stérite seufement après que le été d'implantation a été préparé et correctement dimensiones.

# GARANTIE LIMITEE

GARANTE LIMITEE
Avanta Orthopadica, Inc., garanti que ce produit satisfait aux spécifications du fabricant et qu'il est dénué de défauts de fabricante au moment de sa braisson. Cette grantie exclue expressément les défauts résultant d'une mauvaise utilisation, d'un de l'usage abusil ou d'une manqueletion ricorrecte du produit après que ce rémire a été réceptionné par l'achéleur. Avanta Orthopaedics décline toure responsabilié quant à l'issue de l'intervention disrugicales.

REPRÉSENTANT EU
Medical Products International Europ
Schulweg 13a
5145 NIP Washvijk, The Netherlands
31 (0) 416 563754

### **ESPAÑOL**

### CHIDADADO

La legislación federal de los Estados Unidos restringe la venta, la distribución y el uso de sete producto, autoritandolos solamente cuando sean efectuados por un médico o por udan de un médico.

### DESCRIPCIÓN

DESCRIPCIÓN

Esta protesta semiconstratida para la articulación de la municoa consta de un componente radial de crumo-cobetto, un componente carpiano de crimo-cobetto, un componente carpiano de crimo-cobetto, un componente carpiano de crimo-cobetto, de componente carpiano de crimo-cobetto, de componente carpiano de produce de pesa cultur utra-esto (AHMAWPe). La setera carpiana de limplatine está diseñada para su on en te distina del midio, mientras que la parte distal está diseñada para su on en los fuescos del carpo. El dispositivo está providero para sustituir la articulación de la markeo. El impleme está disposible en varios temaños, para mano derecha y mano loxidido. Para sudar a la preparación del hueso existe una gama de calibraciones de prueba para cada tipo de impleme.

- Materiales.

  ASTM F-648: forma fabricada con polvo de poletileno de peso molecular ultra-alto para implantes quitiripicos.

  ASTM F-1537: alsación forjada de cobalto-cromo-molibdeno para implantes.
- quirúrgicos ASTM F-1580: polvos de titanio para revestimientos de implantes quirúrgicos

INDICACIONES El implente de Implemte de muñeca de Avanta Orthopsedics está previsto para la eustitución de articulación carpiana dolorosa en caso de artiritis reumatoide, artrosis o artiritis

# CONTRAINDICACIONES

- NNTHAMPOKCALIOVECES

  Hussics, musculatura, tendones o tejidos blandos adyscentes alectados por una enfermedad, una infección o un enplante previo, de manera que no pueden proporcionar un soporte o filación adecuacios pura la prófesis. Sentibilidad conocia la los materiales utilizados en este dispositivo. Pacientes en desarrolo con ejerficos abiertas.

# ADVERTENCIAS (Véase también el Párrafo Informativo sobre Asistencia at

ADVENT ELECTAS y coase umiciar la resista.

Cargas significanas, movifical excessiva y inestabilidad articular pueden conduct a un desgasta acelerado y con el tiempo a faisos causados por solarita, quebraras o dislocarse el dispositivo. Los pacientes deben ser conscientes de la posibilidad a un faiso de un dispositivo armenta ejunitacidamente si se la imponen exigencias ascosivas. Notificación de acuerdo el Acta de Seguridad del agua potable y de aplacación de sustancias tolaces del Estado de California, de 1966 Proposición 65; Tiete producto contieve une sustancia quimicació que de acuerdo a la información del Estado de California reconocidamente causa cancer y/o maifornisciona congenitas, autemás de ejercer civas 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 teobra de exprisción o el por culatura motivo estaten dudas sobre es esterificada, el implante no de obre usas. No lo esterifico muevamente. Antes de la implantación y despues de secar la empolura estérit se deben guardar los implantes immersos en una solución estina estérit. Los implantes son destrumentes con instrumentes con fundades estánt que se raya, conte o mede el dispositivo. Una preparación meticulosa de la zona del implante aumentar a la positividad de un resultande estínción de la medida de contrata del implante aumentar a la positividad de un resultande estínción de la medida del hueso. Se monitende maternar el implante de la medida appropiada en el paquete esterit hiesta que la zone de implantación se heya preparado y calibrado appropiadamento.

### **EVENTOS ADVERSOS**

EVENTOS ADVERSOS

Eventos diversos potenciales registrados con prótesis para la articulación de un dedo del pie inchipen dolor, soltras, Neuritis radial transitoria, tendinátis, lesión por admisión indi comento, fracción, dislocación o infección. Esisten ciertos informes de podentes con resociones sensitivas componentes de metal seguidas de une sustitución de la entrodeción. La infecialización de la este discositivo puede causar sissiones en ""

previos circundamies, vissos sanguiripos, tendones o lejidos tauves. Puede ser sará une intervención quiritiripo para tratar los electos secundarios. Esto puede ar la artrodesis o amputación de la extremidad afectada.

PHYOCEDIMIENTOS QUIRÚRGICOS

Hay deponible un procedimiento quintigico para el uso de este dispositivo de esparacion. Es la responsabilidad del quirófano familiarciarias con el procedimiento antes de utilizar estos producios. Antes de usar dicha dispositivo, el quirófano es, además, responsable de famisarizarias con las publicaciones perfanentes y mantener confacto con asociados experimentados responsable del mantener confacto con asociados experimentados responsable del central del procedimiento.

# INFORMACIÓN SOBRE ASISTENCIA AL PACIENTE (Véase también

Advertenciae) Se suministra una monogratia informativa pera dar consejo y explicación a los pacientes. Ademas de la información relacionada al paciente que se describe en los párratos de Advertencias y Eventos Adversos, se ha de informar al paciente sobre lo

páratios de Advertencias y Eventos excessors, asiguientes:

1) Efectos adversos pueden requerir operación repetida, evisión o fusión de la articulación en cuestión. 2) A pesar de que es dificil estimar la vide supuesta de los componentes sustituitivos de una articulación, esta es finta. Dichos componentes son de materiales avirados al cuerpo para han colocado dentro del cuerpo para la restauración potencial de la moveldad o la resucción de doko. No obstante y debido a numerosos factores biológicos, mecánicos y fisioquímicos que pueden alectar estos depositivos, no a puede esperer de los componentes que resistian por un periodo limitado el nivel de actividad y la carga de los liviesos normales y sanos.

ESTERILIZACIÓN

Este componente ha sido esterázado por axido de efileno o radiación gamma. El implante e entinga esterii en un paquete infacto. Si bien el implante o el paquete auste estar deñado, na caducado la fecha de expisación o si por cualquier motivo esterio dessobre la esteridad, el implante no se dobe usar, No lo esterico nue-vamente, Hay disponible catibaciones de pruesa para evitar que se haya de abrir el paquete estrá previamente a la implantación de la prótesia. El implante sobriamente se ha de sacar de paquete estéri cuando la zona de implantación se ha preparado y catibado seponidamente.

### GARANTÍA LIMITADA

GARANTIA LIMITADA, Avaita Chrispendics, Inc., garantiza que este producto cumple don lis específica-ciones del fabricante y due en el momento de entrerga está. Bire de defectos de fab-ricación. Dicin garantía excivye específicamente defectos ceusados por mál uso, ebuso o manejo impropio del producto poisterior al tecibo del comprador. Aventa Orthopsectos no garantiza el resultado de un procedimento quintigios.

# REPRESENTANTE EU

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

# Records Processed by CDRH DID on 3/31/2023

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

### BESCHRUVING

BESCHRIJVING
Data politique/chiprothese met berperkte bewegingsvrijheid beslaat uit een kobaltchroom radiusded, een kobalt-chroom carpaal deel, twee (2) carpale achroeven van
kobalt-chroom en een carpaal kopdeel van UHBMVPe. Het carpale kopdeel van
het knijbalt-chroom en een carpaal keel, het carpale deel. Het provinniale gedeelte van
het knijbartaat is omworpen om te worden ingebracht in de schacht van de radius den
het distale gedeelte om te worden bevestigel aan de carpale botten van de hand. De
profitiese dient ter vervenging van de pols, Het implantaal is verleigbaar in verschrijkene mater en in rechter en laker handooringvardias. Er is een reeks proepteasers
voor elk type implantaat verlerigbaar als hulb bij het gemedmaken van het bot.

- sterialen:
  ASTM F-648: Een vomt van UHIWVPs (Utva High Molecular Weight Polyethylene)
  op poedsrbasis voor chirugische implantaten
  ASTM F-1537: gesmedie legering van kobalt-chroom en molybdeen voor chirursinche inseleste.
- gische implantaten ASTM F-1580 tägampoeders voor deklagen op chirurgische implantaten

INDICATIES

Het Avanta unthopedische polsamplantast dent voor de vervanging van een pirilijk
polsgewiicht als gevolg van reumatokide artinta (RA), osteoertritis (CA) of traumatische
artints (RA).

- CONTRA-INDICATIES
  Bot, spier, poes of andere weize delan atwijkingen veroorzaalid door ontstekingen of voorgaande gewitchts vervangende prothesten die sein goede plaatsing en of hechting van het implantat in de wag staar:
  Bekende overgevoeligheid voor materialen die in dit product worden gelattakt.
  Patienten in de groei met open epitysen

# WAARSCHI MINGEN (Zie ook hat gedeelte over informatie over count

WAARSCHLIWINGERN (Zie ook niet gedeele die nichmatie over coolinaering vair die patient). Sterke belasting, overmatige mobilitäri en erricutave initabilitiet kunnen elle inkten fot versneide sängige en utteindelijk talen door losiating, frachus of dislocatie van het mplannaat. Patienten moeten bewust gemaakt worden van de verhoogde kens op heten van het implantaat als hier overmatige veel van gewergd wordt. Verkalning in overeensternning met de Caltornia Safe Dhinking Water eind Toule Enforcement Act van 1956 (Proposition SS). Die product bevat een chemische stort, wearvan bij de Staat California bekend is dat deze kanker en/ort geboortederlacten en andere reproducti-etosochekt veroorzaakt.

### VOORZORGSMAATREGELEN

VOORZORGSMAATREGELEN Het innbantaat wordt sterlel geleverú in een onbeschadigde verpalking. Als het implantaat of de verpalking beschadigdi liken le zijn, als de uiterale getzurksdatum is overscheeden of als om de een of andere reden twijtel beslaat over de sterliteit, mag het implantaat niet gebruikt worden. Niet oppleuw sterflaaren, Voor het implantaeren moeten implantarien in sterlele zoutoplossing ondergedompeld beiven nadat zij uit de sterliteit verpelsing gehantit zir. Voor implantatien mogen uitsutend stompe instrumenten gebruikt worden, om krassen, strijden of krasikeen van het implantaat en de kauze van de uitset maat implantaat verhogen de kans op een suocesvol muutkaat. Een volledig assordinent in sverkingflobat in ondersteuring van de botvoorbeelding. Geadviseerd wordt om het implantaat met de juiste maat pas uit de sterlele verpalking le haben nadat de plaeta van het implantaat is voorbereid en de juste maat heeft.

### BUWERKINGEN

BLIWERKINGEN
De mogelijke bijwerkingen die gemeld zijn bij het gebruik van vinger gewrichtsprothe pin, lostating, letset door cementextrusie, transliciee radiale neuritist, stendinitist, fractiuur, disboaste en intectie. Er is ook een aantal meldingen van patienten die na gewichtsprotraging overgrovelig bleken te die voor metaat. Letsel aan de heife omringende zersuwen, bloodwaten, pezen en zachte weeftsel kannen optreden als gevolg van het troepussen van dit inngartaat. Compicaties kunnen chrungssche kiterversitie noodzakelijk maken. Dit kan artrodese of amputelle van de betrokken ledemaat

CHIRURGISCHE PROCEDURES

Een chiningsche procedure voor het gebruik van dit implentaat is beschilkbaar. Het is de verantwoordelijkheid van de cheurg om op de hoogte te zijn van de procedure voordet hij deze producter gebruikt. Het is ook zijn verantwoordelijkheid om op de hoogte te zijn van relevante publication en envaren collega's te raidojlegen over de procedure voordat hij deze verircht.

PATIÊNTROPRIMATIE (Zie ook Waarschuwingen)
Er is een patientenbrodzure verkrijgbaar voor gebruik bij het counseien van de potient. Naast de riformatie die betrenking heeft op de patient zoels deze is opgenomen onder Waarschuwingen en Bjaveningen moet de volgereid sindernatie aan de politient worden moegdebeld:
1) Bjavenkingen kunnen heroporatie, revisie of fusie van het betrokken gewricht noodzeleijk maken. 2) De verwachte bevensduur van gewrichtsvervangingscommenten is moelijk te schatten, meer is endig, Doze componenten zijn vervaardiigd van lichaarnvereende materialen de in het schazen worden geplaatst voor potentieel herstel van mobilient of voor potentieel prevenste van motiente de verwachtie de in het schazen worden geplaatst voor potentieel herstel van mobilient of voor potentieel prevenstelning. Door de vele bioksjischen, mechanische en fysiochemische factoren die deze implantatien beinvloeden, isan echter niet verwacht worden dat deze componenten voor ordepstadie igt bestand zijn legen het activitetsniveau en de bekissingen van normaal gezond bot.

STERILISATIE

Deze component is gesterikseerni met ethylesnoxide of gammastraten. Het implantaat
vordt steriel geleverd in een ontbeschadigde verpalding. Als het implantaat of de verpalding beschadigd (siven te zin, als de uiterste gebruiksdritums is oversichselden of als
om de een of andere nichen hvijel bestaat over de sterifielt, mag het implantaat niet
gebruikt worden. Meid opnieuw sterifisseren.
Proeficorsponenter zijn versiegbaar om te voorkomen dat de steriele verpalding wöch
het implantom van de prothese geopend moet worden. Het implantaat mat de juiste
maat mag pae uit de steriele verpalding gehabst worden nadat de plaats van het
implantaat is voorbereid en de juiste maat heeft.

### BEPERKTE GARANTIE

DEPERKTE GARRANTIE

Avanta Orthodaedica, Inc. garandeert dat dit product voldoet aan de aspocificaties
van de tabrikant en ten tijde van de tevening vilj is van fatoridagegebreken. Deze
garantie skilt uitdrukkelijk getreken uit die het gevolg zijn van verheerd gebruik, misbruik of onjuste behandelig van het product na ontivangst door de kopies. Avanta
Orthopaedica geeft geen gerantie op het resultaat van de chisugische ingreep.

# EU AFGEVAARDIGDE

Schutweg 13a 5145 NP Waalwijk, The Netherlands 31 (0) 416 563754

# ITALIANO

### ATTENZIONE

ATTERAZIONE: La legge federale (Stati Unità) limita la vendita, la distribuzione e l'uso di ques positivo el soli medici o previa prescrizione degli stessi.

### DESCRIZIONE

DESCRIZIONE

Outsita protest semi vincolata dell'articolazione del polico è costituita da un componente radiale in cromo-cobalto, un cumponente carpaie in cromo-cobalto, due (2) vin
curpati in cromo-cobalto e un componente a stere corpaie in UR-BAVPPe, quest'ultimo
articolato con i componenti radiale o carpaie. L'aspetto prossimale dell'impianto è
progettato per assere inserto nel corpo dell'osso radiale, mentre l'aspetto prossimale
prevede l'inserimento nello cesa carpati della mano. il dispositivo è correspito per
sositiure il godo. L'impianto è disponitive in numerose misure in configurazioni per si
unano destra e shieltar. Per opinitaro d'impianto è disponitiva in un vasta gamma di calbiratori di prove, che rappresentano un valido availlo nella preparazione dell'osso.

derlas: ASTM F-648 componente articolare a stera in polentilene a peso molecolare ultra-elevato (JHMWPs) ASTM F-1537 lega lavorata in molitodeno-cromo-cobalto per implanti chiungici ASTM F-1580 titanto allo stato commercialmente puno (CPTI)

### INDICAZIONI

L'impianto del polso Avanta Orthopsedics è previsto per la sostituzione del polso dolorante a causa di antrie reumatoide (RA), di osteoprinie (DA) o di antrie traumatica.

### CONTROUNDICAZIONI

- ONTHOUNDICAZIONI.

  Ossa, muscoletura, terdini o tessuti molli adiacenti compromessi da malattie, krizioni o presedenti implanti che non torriscono il supporto o il fissaggio adeguato per la profesi Accertata aeraibitàti nei confronti dei maseriali utilizzati nei presente d'espositivo Pazienti in creocita con epitisi aperta.

# AVVERTENZE (si rimanda al paragrafo relativo alle informazioni per la Consule

al Paziente)

I carchi estenuanti, una mobilità eccessiva e l'instabilità articolere costituiscomo fat-tori in grado di accelerare l'usure e l'eventuale danno del dispositivo attraverso un processo di alteritamento, institue o disbocazione. I pazienti devono essere sivvertiti del fatto che il rischio di danni al dispositivo su unerori e nesso di utilizzo poso moda-ato dello stesso. Notifica ai sensi della Legge d'Applicazione in materia di Prodotti l'ossici e Anqua Potabilis Sicruria dello Stato della California del 1986 (Dichiarazione 65): Questo prodotto conitene una sostanza chimica() nota alto Stato della California come cancerogena e/o in grado di provocare materimazioni congenite e diversa toesicità a hvello riproduttivo.

tossocia a rivesto riprocurvo.

PRECAUZIONI

La protesi viene fomita in condizioni sterili, all'interno di une confezione integra.

Evitare di procediere all'unitizzo della protesi mei casi in cui si consisti un danno alla

stessa o alla constance, oppure in caso di superamento fieta data di scadenza o di

diubi di qualitaria natura sull'ettettiva condizione di sterilità. Non ripetere la sterilizazione, Dopo la immozione diffirmolutori sterili e prima dell'intervento in imparito,

in protesi devono essere conservate in una soluzione sullina sterile. Le protesi vianno

maneggaine eschariamente con l'ausitio di strumenti semusati, per evitare di graffieri
le. Una preparazione accurata del sito di impianto ed una cometta scelta delle dimen
soni della protesi alumentaria ole probabilità di successo dell'intervento. Una garrana

completa di dispositivi di prova è disponibile per la predisposizione dimensionale dell'insoso, Si consiglia di estime la protesi delle gliuste d'immassioni data sua confesione

sterile sottanto dopo aver predisposito e dimensionato adeguatamente il silo di innofento.

### EVENTI NEGATIVI

EVENTI NEGATIVI

Alcuni potenziali eventi negativi riportati in seguito all'impianto di protesi dell'alluce incubciono dolore, allentamento, neurite radishi transitoria, tendente, issone per estrusione del oemento, frattura, dislocazione o referione. Sono stati riportati dei casi di accenti che hamino manifiattivo delle reazioni di sensibilità al ai metali in seguito alla sossituzione dell'articolazione. In seguito alla impianto di questo dispositivo. Si possione verificine dei damia e nervi, vasi sassigni, fuendi e tessisti mole stutta inell'anne occossitate al sito di impianto. Può rendersi mocessario un intervento chirurgico per contrastare eventuale infetti Indesiderati, che pussono includere artrodesi o emputazione degli arriessi colimosti.

### PROCEDURA CHIRURGICA

PHOCEDIMA CHIMMOGICA.

El disponible us protocolo di procedura chirurgica per l'impiego di questa protesi. El responsabilità del cinturgo acquiatre tamiliantà con tate protocollo prine di procedere affutilizzo di cuesti prodotti. Le tiesse chirurgo ha la responsabilità di acquisire conceccenta delle procedere pubblicazioni del autore e di committarai con collegio esperii in relazione alla procedura, prima di desiguere l'inferenza della procedera prima di desiguere l'inferenza della procedura, prima di desiguere l'inferenza della procedura prima di prima di procedura prima di pri

# INFORMAZIONI PER LA CONSULENZA AL PAZIENTE (si rimanda alle

INFORMAZIONI PER LA CONSULENZA AL PAZIENT E şir mendia ale Avvertenze!
E' disponibile una brockure che riporta importanti consigli per al paziente. Oltre alle informazioni per il puzionte riportate al peragrafi "Avvertenze" e "Eventi negativi", è indisponiabile fornire al paziente la seguenti informazioni:
I) eventuale insorpenza di eventi negatif uno rendere necessario un secondo inter-vento chicurgico, una eventione o la fusione dell'articolazione in questione; 2) La dum-tate dei componenti sostitutivi dell'articolazione è difficiale da prevedere me, in ogni coso, avià un formite. Questi componenti sono realizzati in materiali non fisiologici e collocati all'interno dell'organismo per il potenziale inpretino della mobilità o per diduzione del dobre. Connostante, per via dei diversi lattoti di ratura biologica, meccanica e fisico-chimica che sinherizano questi dispositivi, non ci si suo espettare che i componenti siano reasienti, per un tempo alimatora, al vivolto di tribità e alle sol-lectazzoni da canco al quali sono sottoposte le normali cissa sane.

# STERILIZZAZIONE

STERILIZZAZIONE

Questo articolo è stalo atenizzato con cesdo di etilone o con radiazioni gamma, La protesi è fornità in condizioni sterili all'isterno di una confezione integra. Evitare di procedere all'utizzzo dolla protesi nei casi in cui si constati un danno alta stessa o alla confezione, opurue in caso di suppramento fella data di scaderaza o di cubbi di qualsiasi nelura sull'etilettiva condizione di storittà. Non ripotere la sterilizzazione. Del dispositivi di prova sono disponibili per evitere che al dobbta apprie a confezione sterile prima dell'ettettivo impianto della protesi. La protesi va estratta dalla sua confezione sterile soltanto dopo aver predisposto e dinversionatio adeguatamente il stio di impianto.

# GARANZIA LIMITATA

GARANZÍA LIMITATÁ Avanta Critropaedics, inc. garamisos che questo prodotto soddisfa le specificha della casai produttivo e e non presenta difetti di produzione al momento della consegna. Questa garanzia esculare lespresamente qualissis difetto derivante da tilizzo entato, abuso o maneggiamento improprio del prodotto avvenuti accossivamente all'anno dello stesso presso il recapito dell'acquirente. Avanta Critropaedics non garantisce l'estat possitivo della procedura chinorica.

# RAPPRESENTANTE EU

Medical Products International Europ Schutweg 13a 5145 NP Waalwijk, The Netherlands 31 (D) 416 563754





### **ENGLISH**

ed States) law restricts this device to sale, distribution and use by or on

### DESCRIPTION

DESCHIPTION

The Aventa Carpal Fusion Piete is designed for fusion of the cerpal bones of the hand including, capitate, harnate, tunete, and triquetum. The fusion piete is a low profile single piece construct designed to fit over the dorsal aspect of the carpal bones in the hand. The piete has spirelia holes or exist that accommodate screws for fixation. The fusion piete and screws are fabricated from implantable grade stainless steel.

Materials:
Stainless Steel ASTM F-138 or ASTM F-139

### INDICATIONS

NHOICATIONS
The Avanta Carpail Fusion Plate is designed for histori of the carpail bones of the hand including: capitate, braite, harnate, and triquistrum. The fusion plate is intended for use in patients suffering from pain and/or loss of function due to osteoarthrist, sost-travainate arthrists, factures; revasion of failed partial wrist fusions; carpal instability, or rheumatoid arthrists. The fusion plate is used in conjunction with screws that fix the plate of the capital control of the teard.

### CONTRAINDICATIONS

- Active or latest infection Osteoporousis, result/cient quantity or quality of bone/soft tissue Material sensitivity If suspected perform tests prior to surgery
- Sepsie
  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

- ction)
  This device is intended for the uses described in this insert only.
  Control patient selection, education and counseling by the surgeon and rehabilitation care provider is important.
  Stremuous beging, excessive mobility, may lead to falkine of the device. Patients should be made aware of the increased potential for device faikine 8 excessive demands are made upon it.
  Device breakage or damage can occur when the implant is subjected to increased leading associated with delayed union, nonunion, or incomplete heating.
- ing. Improper insertion of the device during implantation can increase the possibility

- improper intention of the device during implantation can increase the possibility of loosening and migration.

  A poor result may be obtained if the inscrue 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 lumber spine. Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). This product contains a chemically isower to the state of California to cause cancer, and/or birth defects and other reproductive toxicity.

## PRECAUTIONS

- RECAUTIONS

  An implant should never be reused. Previous stresses may have created imperfactions which may lead to device failure.

  The implant is provided sterile in an unidermaged package. If either the implant or the package appears damaged, explain or date has been exceeded, or if sterilly is questioned for any reason, the implant should not be used. This is a single use texted to not standed for re-use. Re-standation is not recommended for the implant.

  Meticulous preparation of the implant site and proper implant positioning increase the potential for a successful outcome.

  The stratic products should be removed from its starile package only after it is determined that the implant will be used on the potent.

- DVERSE EVENTS
  Advence events published in the Inerature should be reviewed prior to using this device.

  Metal sensitivity reactions have been reported following metal implantation, injury to surrounding nervee, blood wassels, tandons, or soft tissue.

  Additional possible adverse events may include fracture of the bone, intection, peirs and soft insue initiation.

# SURGICAL PROCEDURES

SUFFIGURE PROJUCTURES

A manual is variable describing the detailed surgical procedure for use of this det
is the responsibility of the surgion to be familiar with the procedure before us
these products, in addition, it is the responsibility of the surgion to be familiar
reterant publications and consult with experienced associates regarding the pro-

# PATIENT COUNSELING INFORMATION (See also Warnings and Adverse

vents Section! a addition to the patient related information contained in the Warnings and Adverse vents sections, the following information should be conveyed to the patient: While the expected file of this device is difficult to estimate, it is rink. These components are made of foreign materials, which are pixed 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 uninvited pointed of time.

# STERILIZATION

- EFISILATION
  This product is sterifized by ethylene oxide (EOI gas or gamma radiation).
  The incident is provided sterifis in an undamaged package. If either the implant or the peckage appears damaged, expiration date has been exceeded, or if sterifly is quastioned for any reason, the implant should not be used. This is a single use

## LIMITED WARRANTY

LIMITED WARRANT IT

Awarta Orthopaedics Corporation warrants that this product meets the manufactuser's specifications and is free from manufacturing defects at the time of delivery. This
warranty specificatly excludes defects resulting from misuse, abuse or improper handing of the product subsequent to recept by the purchaser. Availa Orthopa "as not warrant the outcome of the surgical procedure."

# EU REPRESENTATIVE

# Records Processed by CDRH DID on 3/31/2023

### BESCHREIBUNG

BESCHREIBUNG
Die Platta zur karpaien Fusion von Aventa dent zur operativen Versteltung der
Karpaknochen der Hend, einschließlich Capitatum, Hamatum, Lunetum und
frqueturun. Die Fusionsplatte ist eine eintreiße Pläderigneif-Konstruktion, die üben
dem dorsallen Bereich der Karpalenochen in der Hand eingesect wird. Die Platte hat
nunde Lücher oder Schitze für die Schrauben zur Festerung. Fusionsplatte und
Schrauben sind aus rostfreem Stahl mit fenghantatqueitlich herpstelet.

Werkstoffe:

Rostfreier Staht ASTM F-138 oder ASTM F-139

### ANWENDUNGSGEBIETE

De Platte zur korpalen Fusion von Avanta dient zur operativen Versteltung der Karpallenochen der Hand, einschließlich Capitatum, Hamatinn, Lunatum und Tingustrum. Die Fusionsplatte werd bei Patisanten singewendet, die auf Grund von Osteoarinkte, poettraumstlicher Arthritis, Frakturen, Revision am Handgelenk bei ausgobliebbenen Teillusionen, karpaler Instabilität oder ehermatioider Arthritis an Schmeizen undroder Fundionsverkust leiden. Die Arwendung der Fusionsplatte erfolgt in Verbindung mit Schrauben, die die Platte an den Karpalknochen der Hand florenn.

- GEGENANZEIGEN

  Aktive oder latente Infektion:
  Deteoporate, unzureichende Mange oder Qualität des Knochens/Welchgewebes
  Empfractionen gegenüber dem Matental wenn ein dienbezüglicher Verdacht
  bestaht, sind vor dem chlungischen Engritt antsprachende Teste durchzuführen
- Sepsis
  Patienten mit mentalen oder neurologischen Erknenkungen, die nicht gewilt oder nicht fählig ahd, die postoperativen Behandlungsanweisungen zu befolgen

# WARNHIWEISE (Siehe auch die Abschnitte Informationen zur Patientenberatung

- ARNHWEISE (Siehe auch die Abschnitte Informationen zur Patientenberatung 
  wie Neberweitkungen)
  Dieses Medizinprodukt al nur Kir den in dieser Packungsbeikige beschriebenen 
  Newendungsweich bestimmt.
  Sorgfäßige Patientenauswehl, Edukation sowie Beratung durch den Chirurgen 
  und den Leistungsanbeiter für Pehabstitation sind besonders wichtig. 
  Starke Befestung und übermäßige Mobilität können zum Ausfall des 
  Medizinproduktes (Emplantaversagen) führen. Die Petienten sind darauf 
  hirzuweisen, dass sich das Ausfallrichko des Medizinproduktes bei übermäßiger 
  Beenepurchnig erhört. 
  Brucht oder Beschärigung des Medizinproduktes weiten eintreiten, wernt das 
  implantat bei verzögente Frishtunteitung, Pseudarhinne oder unvollständiger 
  Heitung einer erhörten Belantung ausgesetzt wird. 
  Unsachgemäßige Insention des Medizinproduktes während der Implantation kann 
  dass Lockerungs- oder Migrationieristiko des Implantatis erhöhen. 
  Ein schliechtes Ergebnis kann erzücht werden, wenn die Fraktur nicht korrekt eingerichtet oder das Medizinproduid nicht ordungsgemäß assammengesetzt wird. 
  Es kann erforderlich sen, dieses inplantat zu ertfernen. 
  Warnhrivmeis: Deses Medizingungt fist nicht zur Verschrizubtung oder Fizierung an 
  posterioren: Elementen (Pedikal) der Vallawirbel-, Brustwirbel- oder 
  Lendenwebstatie zugeltasson.

  Mittellung gemäß dem Gesetz für sauberes Tirriowsser und zur Bekämpfung faux 
  sischer Stoffe des Bundesstates Kalltörnien (California Safe Drinking Water and 
  look Erriorcement Act] von 1986 Proposition 65: Dieses Produkt erthält eine 
  Chernikalier-könneisien, von der/denne dem Bundesstatust von Kalltornen bekannt ist, dass sie Krabs und/oder Gebuntsschäden und/oder andere 
  Reporduktionstokalist erzeugt/erzeugen.

# VORSICHTSMASSNAHMEN FÜR DIE ANWENDUNG

- DRSICHTSMASSNAHMEN FÜR DIE ANWENDUNG

  Das Implantat dart nie wiederverwendet werden. Durch frühere
  Beanspruchungen können Störungen und Defekte eristanden sein, die zum
  Ausfalt des Medizingroduktes führen können.
  Das Implantat wed steril in unversehrtet Verpackung geliefert. Wenn eine
  Beschädigung des Implantates oder der Verpackung vozulegen scheint, das
  verätligfatum überschriften oder der Steritikt aus signedienem Grund in Frage
  gestellt et, dard das implantat nicht verwendet werden. Bei diesem inrighertat hein
  det iss sich um ein Medizingrodukt für ehmeligen Gebausch; es ist nicht zur
  Wiederverwondung bestimmt. Die Restorilisation des Implantates wird nicht emptohlen.
- icoren.
  Scorglattige Vorbereitung der Implantationsstelle und korrekte Positionierung des Implantates erführen die Erfolgeaussichten der Implantation.
  Das sterille Produkt ist erst aus seiner sterillen Verpackang zu entnehmen, wenn entschleiden ist, dass das Implantat bei dem Patienten eingesetzt wird.

- Die in der Lieratur veröffentlichten Nebenwerkungen sind vor Anwendung dieses Medicianproduktes zu besichten. Empfindlichkeitsreaktionen auf Metall wurden nach Metaffenplantation gemeidet. Verletzung der umgebenden Nerven, Bürgefäße, Sehnen oder Weichteile. As werden Nobewerkungen können Knochenfraktunen, Infektionen, Schmarzen und Weichteilerhaten auftraten.

CHIPURGISCHE VERFAHREN
Ein Handtsoch mit einer genzeuen Beschreibung des chirungischen Vertaltrens zur Anvendung dieses Medizinscholles ist werfügbar. Der Chirung ist defür veranftwortlich, sich vor Anvendung dieses Medizinsproduktien dient Vertaltren unerhalt zu machen. Der Chirung ist weiterbin dafür verantwortlich, die einschlägigen Publikabenn sorgfähig zu issen und erfahrene Mitartsetor über das Verfahren vor der Anvendung zu konzullerens.

# INFORMATIONEN ZUR PATIENTENBERATUNG (Siehe auch die Abschnitte

INFORMATIONEN ZUR PATTENTENBERATUNG (siehe auch die Abschnitte Warnhinweise sowie Neberwirkungen) Neten der Petientenunformationen in den Abschnitten Warnhinweise und Nebenwirkungen sind dem Patienten die nechtologenden informationen zu vermittetz:

Die erwarters ("ebensdauer dieses Medizingrodulikes ist zwar schwer zu bestimmen, aber sin ist beginnzt. Die Bestandteile sind aus Fremdstoffen gefertigt, die zur Ersichterung des Heilungsprozosess in den Körper amplemtent werden. Auf Grund einer Veltzalls blodgscher, mechanischer und hypkielksich-fremstofter Fastoren, die diese Medizingrodulike beeinfriichtigen, kann jedoch nicht erwarden. Auf dass diese Bestandteile auf unbegrenzle Zindauer derzeitlich Abnintatisstufe und Belastung wie der normale gesunde Knochen standhaften,

## STERILISATION

- Dieses Produkt wird durch Ethylenoxid (EO)-Gas oder Gammabestrahlung sterit-
- Das Implantat wird sterl in unverseinter Verpacisung geliefert. Wenn das Implat oder die Verpacisung beschädigt zu sein scheinen, das Vertallistem überschrift oder die Verpacisung beschädigt zu sein scheinen, das Vertallistem überschrift oder die Sterlist aus grendeltem Gund in Trage geneffe ist, darf des Implate nicht verwendet werden. Dies ist ein Medizinprodukt für ehrmäligen Gebrauch

EINGESCHRÄNKTE GARANTIE

Avanta Orthopaedics Corporation gewishribistet, dass diesas Produkt die Spazifikationen des Herstellins artikelt und bei der Lielerung keine Herstellinsgefehlste sufweilst, Ausgeschlossen von dieser Garantie sind spazielt Ferlier, die auf nücht-beniermungsgemäßen Gebrauch, Answers oder unsachgemäße Handhabung des Medichproduktes nach Engang bei dem Klurfer zurückzuführen sind, Für das Ergebnis des chrungisichen Verfahrens überminnt Avanta Orthopaedics keine Garantie.

# EU-VERTRETER

# FRANÇAIS

AFRICATIVE SAFE.

La plaquie de fusion carpienne Avante a été conçue pour la fusion des os du carpe, inclusal : grand ois, os crochu, semi-làvasire et pyramidal. La plaque de fusion est composée d'une unique pièce à profit bas, qui a été compa pour recouvrir la face domais des os du carpe. La plaque el des trous aphériques ou des fentes par où passent les vis de fixation. La plaque de fusion et les vis sont fabriqués en acier recoyclable de quelle médicale implantable.

Acier inoxydable ASTM F-138 ou ASTM F-136

### INDICATIONS

INDICATIONS

La pieque de tusion cerpienne Aventa a été conçue pour la tusion des os du carpo, incluant : grand-os, os crochu, semi-lunaire et pyremidat. La pieque de fusion est prévue pour être utilisée sur les patients confrant de doublers et/ou d'une porte functionnelle due à l'oridoanthrie, l'arthrite post-less-matique, les frachers, la révision chrungicale postérieurs à l'achoc d'une futice partielle du poignet, l'estabilité carpisens pur l'arthrie réventaire sur l'arthrie de post-less sur partielle du poignet, l'estabilité carpisens pur l'arthrie réventaire. La pléque de fution s'utilité conformement avec des vis

### CONTRE-INDICATIONS

- Intercion active où lateres.

  Catécoporose, quantiée ou qualife insufficante d'os/de lossu poseux:

  Allengie su metierles en câs de suspicion d'allengie, taire des sesse avant le cràrurgie

  Sepois.

  Patients qui, du fait de leur étet mental ou neurologique, e'ont pas le volonté sufficients qui du capitales de autive les treinuctions relatives eux soins positieurs ou seux soins positieurs.

AVERTISSEMENTS (Voir aussi les sections Conseils donnés au patient et Effets

- derables)

  Co disposité sal uniquement prévu pour les utilisations décrites dans cel encart.

  La sélection rigoureuse des patients, l'information et les conseils donnés au patient par le chirusgien et le prestateure de soins de réhabilitation sont impor-

- patient par le chinagien et le prestatere de sons de réhabilitation sont impor-tants.

  De lostes charges et une mobilité aucessive pauvent entraîver l'échec du dis-positi. Il teut informar le patient de l'augmentation du risque d'échec du disposi-tien can de solicotations excessives.

  Une rupture ou un dommage du dispositi pout se produire si l'implant est soumis à une augmentation de charge associes à un retant de consolidation, une pasudarthrose ou une guietison recompléte.

  L'insertion incorrecte du dispositi pout autre de consolidation, une pasudarthrose ou une guietison recompléte.

  L'insertion incorrecte du dispositi pout n'implantation peut augmenter la pos-sibilité de résichement et de migration.

  La résultat obteun peut être invastissant en cas de réduction de fracture incor-recte ou d'assemblage incorrect du dispositif.

  I peut être nécessaire d'explantar le dispositif.

  Avantissement : Ce dispositif n'a pas reçu d'approbation pour l'attachement par vis où la fibation aux éléments positifeirais (pédicules) de la colonne vertébrale foenicale, thoracique ou lombaire).

  Notification conformer à le Proposition 65 de Californie (California Safe Drinking Water and Toxic Enforcement Act, acte exécutoire de la protection de l'eau polable contre les produits louques, approuve en 1865; or produt contient un orgen chimique connu dans l'État de Californie pour causer le causer et/ou des mistornations récretations.

- PRÉCAUTIONS

  Il no faut jamais réutifiser un implant. Les tensions précédentes peuvent avoir crée des imperfections réquart d'entrainer l'éches du dispositif.

  L'implant est fourni stréet dans un emballage accèle. Si l'implant ou l'emballage paraît endommage, si la dale de péremption est depassée ou si la stéritifé est mise en cause pour telle ou telle raison, ne faut pou tiliser l'implant. C'est un dispositif à usage unique qui n'est pas prévu pour la réutifisation, il n'est pas recommandé de resteriore l'implant.

  \*\*Une préparation méticuleuse du sêt de l'implant et un positionnement correct augmentent le potented de réussite.

  Les produits stéries ne doivent être anjevés de leur emballage stérile que si la décision d'implantation a été prise.

# EFFETS INDÉSIRABLES

- oles publiés dans la intérature doivent être revus avent l'utilisa-
- factions d'allergie au métal ont été rapportées suite à l'implantation du dis-
- Lésion traumatique des nerts, vaisseaux sunguins, lendons ou du tissu mou envi-
- romaints.
  Les éventuels effets indésirables supplémentaires sont notair osseuse, infection, douleur et infaction des tissus mous.

PROCÉDURES CHIRURGICALES
Un maruel est disponible ; il décrit en détail la procédure chirurgicale permettant d'utiliser l'amplant. Le connaissance de cette procédure est de la responsabilité du chirurgien. Il incombe épalement su chirurgien de se tentra u courant des publications pertinentas et de consulter des confières expérimentes au sujet de la procédure à

CONSEILS DONNES AU PATIENT (Voir aussi les sections Avertis

Effets indideisables)

Outree l'information relative au petient qui sel contenue dana les sections 
Avertissements et Effets indiesirables, le patient doit recevuir l'information suivante :

Il est déficie d'estimer le duné de vie prévue de ce dispositif, mais effe n'est par 
illimitée. Ces composants sont en effet fabriques dans des matériatis d'arangers au corps humain et implantée afin de sactiste le processus de guérain. Toutefois, en reson des nombreux facteurs biologiques, mécaniques et physio-chrinques qui affecteur ces dispositists, les composants ne pervient pas supporte le méme inheau d'activité et les mêmes charges qu'un os axin pendant une période litmine.

- STÉRILISATION

   Ce composant est stérifisé par oxyde d'éthyéne ou rayons gemma.

   L'implant est fourni stérile dans un emballage scelé. Si l'implant ou l'emballage paraît endommage, si la date de pérention est dépassée ou si la stérilité est mise en cause pour une raison ou une autre, il ne taut pas utièser l'implant. C'est un dispositif à usage unique.

# GARANTIE LIMITÉE

GARANTIE LIMITEE
Avanta Orthopaedic Cepration parantit que de produit est conforma aux spécifi-cations du fabricarti et qu'il est livrit sans défaut de fabrication. Cette garantie exclui spécifiquement les défauts résultant d'une utilisation incorrecte ou abustive, ou d'une manipulation incorrecte du produit postenoure à la réception par l'acheteur. Avanta Orthopaedics ne garantit pas Fissue de la chaugile.

REPRÉSENTANT EN EUROPE : Medical Products International Europe, BV Schutweg 13a 5115 NP Waatwijk, Pays-Bas 31 (2) 416 563754

### **ESPAÑOL**

### DESCRIPCIÓN

DESCRIPCION
La placa pera fusión carpiana. Avanta está diseñada para la fusión de los huesos carpianos de la mano, que incluyen el hueso grande del carpo, el hueso grandoso, el semikurar y el premotal. La placa para fusión es una construcción de un sob componente, de pertil bajó, disendada para encajar sobre la cara dorsal de los huesos cerpianos de la mano. La placa tiene zanuas u ordicios esténicos donde se alcian los tomillos de figición. La placa tiene ranuas u ordicios esténicos donde se alcian los tomillos de figición. La placa pera fusión y los tomillos están fabricados en acero inoxidable apric para implentes.

ero inoxidable ASTM F-136 o ASTM F-138

### CACIONES

.CACIONES

La placa pera fusión carpiana Avanta está diseñada para la tusión de los hisesos carpiamos de la mario, que incluyen el hueso grande del carpo, el hueso gendrioso, el semitinar y el prantidal. La placa para haión está prevista para sumpleu en parientes que presenten dolor o pédide funcional debisos a antreais, arirles postraumélica, fracturais, inveltón de fusionas parciales falládas de la artículación carplana, inestabilidad carplana o artitis reumaticida. La placa para fusión emplea en combinación con territios destinados a figara a los huesos carplanos de la mano.

### CONTRAINDICACIONES

- Infrección activa o latente Ostaoporopsis; carátidad o calidad insuficiente del hueso o los telidos blandos Hipersensibilidad al material: en caso de sospecha debe realizarse una prueba
- es de la cirugía
- Pacientes con trastomos mentales o neurológicos que no estén dispuestos a securit las instrucciones para los culclados posoperatorios o no sean capaces de

ADVERTENCIAS (Véanse lambién los apartados "Información para el paciente" y

- ectos adversios"). Este producto está previsto exclusivamente para los usos descritos en el pre-
- Este inociucto está previsto exclusivamente para los usos descritos en el pre-sente prosporto.

  Es emportante une selección cudadadas de los pacientes, así como una apropi-cia información y adesoramiento por parie del ciuígano y el responsable de la reinabilitación.

  Los estutoros infensos o la movilidad excesiva pueden provocar el fracaso del dispositivo. Debe informante a los pacientes de que las prohabilitades de fraca-co del dispositivo numerian a se acontra a una carga accedera.

  El dispositivo puede tramperse o dafarare si el implante se somete a un estuerco accione esconipieta.

  La del considera del consideración difieráda, una seudostravos o una conso-ciacione esconipieta.

- idación incombeta.

  La inserción madecuisda del dispositivo durante la imperición puede aumentar la posiciódiad de su aflojamiento y migración.

  Puede obtenense un resultado insatisfactorio si la fractura no se reduca correctamente o el dispositivo no se monta conscitamente.

  Puede ser necesaria una explantación del dispositivo.

  Advenencia: seste producto no está autorizado pivo.

  Advenencia: seste producto no está autorizado asu dijección o unión mediante turrillos a los elementos posteriores (podiciulos) de la columna cervical, dorsal o autori.
- territario. Se los unidos de acuerdo con lo establocido en la California Sale Drinking Water Notificació inforcement Act de 1986 [Ley sobre Segunded del Agua Potable y Agentes Toxicos del estado de California, conocida también como Proposición 65). Este producto contiene uno o más productos quimosó de los que el estado de California abbe que provocan cáncer o difectios congánitos y otros efectos de toxicidad reproductiva.

### PRECAUCIONES

- RECAUCIONES Nunca debe reutizarse un explante, Los esfuezos anteriores pueden haber provocado imperfecciones que podrán llevar a un finacaso del dispositivo. El implante se suministra estéré en un envase intacto. Si el implante o el envase aparecen dañados, ha transcuarido la fecha de caducidad, o existe alguna duda sobre la estetilidad, el implante no dobe unificario. Se intalo de no poducto desecchable no prevento para su reutilización. No se recomienda reestieritizar el
- imblante.

  La preparación meticulosa de la zona de implantación y la colocación comecta
  lei implante aumentan las posibilidades de éxito,
  s productios estériles solo deben axtracrao de su envase estéril una vez que se
  dermine que el implante va a utilizarse en al paciente.

### EFECTOS ADVERSOS

- ECTOS ADVEHSOS

  Antes de utilizar este dispositivo deben estudiarse los efectos advensos descritos en la tireatura.

  Se han descrito reacciones de hipersensibilidad a los metales tras la implantación.
- de materiales metálicos. Existe posibilidad de lesionar los nervios, vasos sanguineos, tendones o tejidos
- biendos circurdantes. Entre otros posibles efectos adversos figuran tracturas óseas, infección, dolor e inflación de los tejidos blandos.

TÉCNICAS QUIRÚRGICAS

Existe un marqual dende se describe detalladamente la técnica quirúrgica pera si uso de este dispositivo. Es responsabilidad del chujano famillarizarse con la focrica antese utálzar estos productos. También es responsabilidad del chujano esta amiliatizado con las publicaciones meivanes y consultar sobre la técnica con colegas experimentados antes del empleo de estos productos.

INFORMACIÓN PARA EL PACIENTE (Véanse también los apartados

INFURMACIUM PANA EL PACIENTE (veanse tambien los apartados "Adventencias" y "Efectos adversos") Además de la información relecionada con los pacientes que figura en los apartados "Adventencias" y "Efectos adversos", debe transmitirse al paciente la siguiente infor-

solor:

Si ben resulte dificil estimar la expectativa de vida de este dispositivo, ésta no eslirmitada. Los componentes estan fabricados con materiales ajences el organismoque se introducen en el mismo para lacilitar el proceso de consolidación desa.

Se embargo, debido a los numerosos factores biológicos, meclánicos y fisioquímicos que afectan a estos dispositivos, no el posible esperar que los componentes meistras durante un periodo limitado el nivel de sictividad y los estueszos a los que está sometido un hueso normal sano.

- ESTERLIZACIÓN

  Este producto está esteritizado por óxido de elleno o radiación gamma.

  El emplante se suministra estáril en un envase intacto. Si el emplante o el envase aparecen danados, ha transcurido la teora de ocatucidad, o caide alguna desobre la esteridad el emplante o debe ulturarse. Este producto es de un solo

### GARANTÍA LIMITADA

GARANTIA LIMITADA

Aventa Orthopaedics Corporation garantiza que este producto comple las especificacionas del fubricante y no presenta defectos de tabricación en el momento de su
entrega. Este garantila excluye especificamente los defectos denvados del uso incornecto, abuso o manejo hadecuado del producto texto su necepción por el comprador,
Avanta Orthopaedica no garantiza el resultado de la operación quivurgica.

REPRESENTANTE EN LA UE:

# Records Processed by CDRH DID on 3/31/2023

BESCHRUVING De Aventa carpele fu HESCHRIAVING
De Aventa carpele fusieplaat is criticorpen voor fusie van de carpele botten van de hand vagaronder: caostatum, hervaltum, binatum en tricuetrum. De fusieplaat is een constructie uit éen taluk met een geringe bouwboogte, ontworpen om over het dor-sale deel van de carpele botten in de hand te posten. De plaat heeft einersche geten of sleuven die plaats beiden aan schreueren voor fuutile. De fusieplaat en activoeven zin germaald van kmyteriebschaar roestwij staat.

Materialen:
Roestvrij steal ASTM F-138 of ASTM F-139

# INDICATIES

DICATIES
De Avante carpale tueleplant is ontworpen voor flusie van de carpaire botten van de hand waaronder capitatum, turatum, aerastum en triquetrum. De buseplaat is bedoekt voor gebruik in petilenten die fijden aan pijn en/of konctiewerinst verbeste steoeutrist, postitratumatische artists, sacturen, correctie van miskufati partiéle polititusies, carpaie sustabaltiet of resumatokie artists. De flusieplaat wordt gebruik in combinatie ennt actroeven die de plaat aan de ostpale botten van de hand

### CONTRA-INDICATIES

- Actieve of latente infectin Ostooporose, onvoldoende kwantiteit of kwaliteit van bol/zacht weefsel Materiaalgevoeligheid voer bijf vendenking hiervan voor de chirungische ingresp
- sepsis. Patiënten met mentale of neurologische afwijkingen die instructies voor postop-eratiove zurg niet willen of kunnen opvolgen.

# WAARSCHUWINGEN (Zie ook de peragrafen Informatie voor patläntadvisering en

- /AARSCHUWINGEN (Zie ook de persgrafen Informatie voor patliintadvaering en logerijke complicaties) uitfalikend bedoeld voor gebruik zoals beschreven in deze bijlage. Een zorgvuldige patlienteeldele, voordcriining en advisering door de chrung en de verderer van revaldatiezzen ja belangrijk. Zvariv britasting, overmatige motiliteit, han entoe leiden dat het toestel het begeet. Petiterien dienen ersop te worden geattendeerd dat er een verhoogde kans bestaat dat het toestel het begeet wanneer er te veel van woord gerengrijk. Warmeer net imparinati wordt beogeet wanneer er te veel van woord gerengrijk. Warmeer net imparinatie wordt beolgesteld aan een verhoogde belastig. Nan het toestel kappt gaan of beschadigd staken, gepeard gaand met vertraagd aanseen; greeien of onvolkelige genezigig. Ondust intrengen van het toestel bijdens de imparinatie kan de kans op loegaar, en migratie vergreten, en secht nesultaat kan worden behaatst winneer de fractuur net goed wordt gezet of het toestel het goed wordt genomiserd. De secht nesultaat kan de goed wordt genomiserd. De secht nesultaat ken de de de goed gehaard voor aanhechting of fuatte met behalds van achroenen aan de achterelementen (podicusé) van de cervicale, thomcale of britsele wervelskolon.
  Notificatie conform de wet van de Armenkaanse deelstaat Calforniii inzaler veilig drinkwaier en torsloch product/erweinsche productieren waarun in de stake Calforniii inzaler veilig drinkwaier en torsloch product/erweinsche productieren waarun in de stake Calforniii inzaler veilig drinkwaier en torsloch product/erweinsche productieren waarun in de stake Calforniii inzaler veilig drinkwaier en torsloch product/erweinsche productieren waarun in de stake Calforniii inzaler veilig drinkwaier en torsloch product/erweinsche productieren waarun in de stake Calforniii inzaler veilig drinkwaier en torsloch product/erweinsche productieren waarun in de stake Calforniii inzaler veilig drinkwaier en torsloch product/erweinsche productieren waarun in de stake Calforniii inzaler veilig drinkwaier

### VOORZORGSMAATREGELEN

- DORZORGSMAATREGELEN Een implantat mag nooit worden hergebruikt. Eordere belastingen kunnen gebreken hebben veroorzaald die ertoe kunnen teiden dat het toestel het begeet. Het enplantaat word steriel gelevrend in een onbeschedigde verpakting. Indien het implantaat of de verpakking beechadigd biljkt te zijn, de vervalziatum is ver-lopen, of om weller enden dan ook wordt getwijflukt aan de steriliest, dient het mindantaal niet te worden gebruikt. Dit is een bestel voor eenmalig gebruik niet bedoeld voor hergebruikt. Dit soen bestel voor eenmalig gebruik en het bedoeld voor hergebruik. Henterifsatie wordt niet aanbevolen voor het
- implantaal.

  Een nauwkeurige voorbereiding van de implantarieplaats en een juiste positionering van het implantaal vergroten de kans op een successvol essuttaat.

  De steriele producten mogen uas úid de sterede verpakking worden gehaeld zodra vasislaart dat het implantaat zal worden gebruikt op de petient,

- MOGELIJKE COMPLICATIES

  Complicates die in de literatuur bekend zijn gemaakt, dienen te worden bestudeerd voordat dit toestel wordt getrukk.
  Metzalgevoelignektrasuicie zijn gemeid na metsalimplantatie.
  Verwonding van ommigende zenuwen, bloedvatien, pezen of zacht weefsel, Mogelijke bijkomende ommigende is kunnen bottractuik, infectie, pijn en vritatie van zacht weefsel omvatten.

CHRURGISCHE PROCEDURES

Er is een handleiding verkrijgbaar, waarin in detail de chrurgische procedure voor het gebruik van dit toestell wordt beschreven. Het is de eigen verantwoordelijkheid van de chrung om voord gebruik van dare procudent op de hoogie te zijn ven de procedure. Daarnaast is het de verantwoordelijkheid van de chrung om voor gebruik op de hoogie te zijn van nekwarte publicaties en het advles in te winnen van erveren collega's met betrekking tot de procedure.

INFORMATIE VOOR PATIÊNTADVISERING (Zie ook de paragrafen Waarschuwingen en Mogelijke complicaties)
Naast de patientrifformatie in de paragrafen Waarschuwingen en Mogelijke complicaties dient de volgende informatie aan de patiënt te worden verstruit:

\* Hoavel de verwachte leverschur van dit toestal moeilijk in te schatten is, 'n dizze beperk!. Deze componienten zijn gemaalt van vreenude materialen, die in het lichaam worden geplaatst om het gerezingsproces te bevorderst. Vanwege de vele beloogische, mechanische en fysiochenische factoren die deze toestellen belindecelen, kan echter niet van de componenten worden verwacht dat ze voor onbeperket trijd bestand zijn tegen het activiteitsniveeu en de belasting van nov-maal gezond bot,

### STERILISATIE

- STERILISATIE

   Dit product wordt gesterliseerd door ettlyleenoxide (EO) gas of gommastraling,
   Het implamaat wordt sterel geleverd in een onbeschadigde verpakking,
   indier het implamaat of de verpakking beschadigd bijst te zijn, de vervaktetum is verkopen, of om verbe reden dan ook wordt gestelfield aan de sterlifelt, dient het implantaat niet te worden gebruikt. Dit is een toestel voor eenmalig gebruikt.

Avanta Othogasdics Corporation garandeert dat dit product up het moment van levering voldoni aan de specificaties van de fabrikant en vrij is van fabricagelouten. Met namn uitgesicher van daze garantie zijn deketten die een genotig zijn van verkoerd gebruik, misbruik of een onjuiste behandeling van het product na montvangstrenning door de kopes. Avanta Othopaedics bredt geen garantie op het resultaat van de phinungische procedure.

# VERTEGENWOORDIGER IN DE EU:

Schutweg 13a 5145 NP Washwijk, The Netherlands

### ITAI IANO

### DESCRIZIONE

DESCRIZIONE

Le Placca per fusione carpelle Aventa è progettata per la fusione delle cesa carpai,
comprendent capitato, uncinato, lunato e piramidale. La clasce per fusione è una
struttura a besso profilo in un unico pezzo, du adentare suda facosa dorsale delle cesa
carpai. La placce à dotatat di fori aferici o asole per la viti de usare per la fissuzione.

La placce per fusione e le relative viti sono in accialo inossidabile di qualità per
remienti.

Material:
Accieto inox ASTM F-138 o ASTM F-139

### INDICATION!

DICAZIONI

La Piscos per fusione carpete Avanta è progettata per la fusione delle ossa carpis, comprendenti captato, uncinato, tunato a pramindes. L'implego della piscos per fusione à destinato a pazienti con dobri e/o pentida funzionale diovuti a ossevante, artite post-fraumettica, fratture, revisione di fusioni perzital del polso non rusosta, assabilità carpale o artitre revensione. La placcia per fusione à de sissani el associazione con viti oficia il resamo sulle osse compili.

# CONTROUNDICAZIONI

- Infezione in atto o laterate
  Ostooporodi, tessuito osaso/molle insufficiente per quantità o qualità
  personalellità ul materiale in caso di sospetta iconsenalibilità, eseguiro test prima
  delli interventi

AVVERTENZE (vedere anche le sezioni informazioni per la consulenza ai pazienti el Efforti indesiciaretti.)

• 8 presidio è destinato unicemente all'uso describito.

- Effetti indesidenti). à presidio è destinato unicamente all'uso descritto nel presente logilo (Bustrativo, E amportante che il chirurgo e l'équipe di riabilitazione provvedono a selezionare attentamente in paisenti, efficiare le consignati.

  Un eccesso di carico o di mobilità possono comportare il talimento del presidio. I pazienti devono essere a viventti del maggiore potenziale di falimento del pre-sidio e sottioposto a sollocitazioni eccessivo. a presidio più emperio il maneme danneggisto se l'empiritato viene assoggettato a carichi crisscardi in essociazione con ritardo ol unione, menosta unione o gue-rionese incompete.

- a carichi crescenti in associazione con ritardo o unione, mencara unione o qua-rigione sicompleta.
  L'insorimento non corretto del presidio durante d'impianto può aumentare la pos-abilità di distance o spostamento dello alesso.
  Si può ottonero un risudato insoddistalorine se la frattura non viene ridotta cor-rettamente o li presidio non è conertamenta essembliato.
  In tall cesì potrebbe rendersi incossigario l'aepianto del presidio.
  Avvarienza importante: il presente presidio non è approveto per l'attacco o tis-autione con vui degli alementi posteriori (podurocoli) delle vertabre carvicali,
- loraciche o jombar.

  Notifica in conformàti con la Lagge del 1886 dello Stafri della California unia sciunezza dell'acous polibale e suda sostanzo consciente (chiarazzone 65° Cuesto prodotto conflores uno o più sostanze chimiche note alto Stato della California come possibili cause di cancro aro difetti neonatali e di altri effetti tossici sull'at-tività riproduttiva.

# PRECAUZIONI

- IECAUZIONI
  Un impiarto non deve mai essere rutilizzato. La sofectazioni subre in precedenza possono aver dato origine ad imperfezioni che determinembore il fallimento del presidio.
  L'impuarto formito è starile se in confezione ritagra. Non utilizzare l'impiarto se lo stesso o in confezione appaiono disminggisti, en la data di ecadenza è stata superata o se per qualisiasi motivo si è indotti a dubhare deta sus sterilità. Il stata superata o se per qualisiasi motivo si è indotti a dubhare deta sus sterilità, si stata superata o se per qualisiasi motivo si è indotti a dubhare deta sus sterilità, si stata superata o se per qualisiasi motivo si è indotti a dubhare deta sus sterilità, si stata superata o se per qualisiasi motivosi dell'imparato dell'impiarito dell'impiarito se un corretto posizionamento dell'impiarito si sesso aumentano le probabilità di estito positivo dell'intervento. I prodotti sieriti devono essera prelevati data confezione sterite solo dopo aver accertato fuso effettivo dell'impianto sul pitziente.

### EVENTI INDESIDERATI

- i di usare il presidio, eseguire una ricerca degli eventi indesiderati pubblicati
- dalla interatura. Sono stati riferiti casi di reszioni di sensibilizzazione ai metalli in seguito
- es resperato. Leskonii deli nervi, vasi sanguigni, tendini o lessuti molti circostarvii. Altri possibili etietti indesideratii fratture ossee, infezioni, dolore e infazione dei

PROCEDURE CHIRURGICHE
È disponibile un manuale che descrive nei dettagli la procedura chinurgica da apoicare a questo presidio. E responsabilità del chrurgo acquisire familiarità con la procedura prime dell'uso di questi prodotti. È notire responsabilità del chrurgo arche
acquisire familiarità con le pubblicazioni elative e consultarsi con colleghi asperti in
mento dala procedura prima dell'uso.

# INFORMAZIONI PER LA CONSULENZA AI PAZIENTI (vedera anche le

INFORMAZIONI PER LA CONSULENZA AI PAZIENTI (vedere anche le aszoni Avverieze de Effetti indesiderati).
Otre ette intornazioni relative al paziente conferente nelle sezioni Avverienze et Effetti indesiderati, devono essere trassresse al paziente le seguenti informazioni:

La durata prevista di questo presidio, eebbene sia difficile da valutare, è comunque lemitata nel tempo. Si senta natati di elementi composi da materiati estarane all'organismo, inseriti per facilitare el processo di guargione. A causa del molti fattori biologio, meccanici, e fisiochimici che influiscono su questi dispositivi, non si può trittava penzare che essi possano nesistere per un periodo di tempo illimitato a sivelli di attività e carico uguali a quelli del normale osso sano.

# STERILIZZAZIONE

- DIEMILIZZAZIONE

  I prodotto à steritizzato in cestido di etilene (ETG) o ai reggi gamma.

  L'impanto tormito è sterile so in confezione integra. Non utilizzate l'impianto so lo stosso o la confezione appaiono devineggiati, se la della di scadenza è stata auperata o ao per qualsiasi motivo al è instorti e dubitare delle sua steritità. Il presistio è monouso.

# GARANZIA LIMITATA

GARANZIA LIMITATA

La Availe Chriopendos Corporation garantisos che il presente prodotto è conforme
alle specifiche del produttore e che e seente da difetti di fabbricazione all momento
della consegnu. La presente garanzia esobate specificamente i ciesti derivanti da uso
improprio o non corretto o da errori di manipolazione del prodotto successivamente
al recommento das parte dell'acquiente. La Avanta Critiopaedica non garantisce Testo della procedura chirurgica.

AGENTE PER L'UE: mational Europe, BV Medical Products International I Schutweg 13a 5145 NP Waalwijk, Paesi Bessi 31 (0) 416 563754

19-0389 rev A

55

# PRODUCT INSERT

Avanta CMC Prosthesis

DESCRIPTION
The Averta CAIC Teapartic-instacceptal joint prosthesis consists of an ultra-high Inolecular weight; polythesis (A-RAMPie) component which is contented to the prepared sequesters, and a Barrian alloy size component with integral head which is traverted into the what of the after endeautery. In the Barrians and articulates with the U-RAMPie component to form a way-fit constrained prosthetic replacement for the basel faunt joint. The implant is examilate in the was been, each of which can be used in digit or left hends. A range of tiest stress for each type of implent is available to sid in borne prepared to.

- ASTM F-136 Trianium 6AL-4V ELI alloy metacarpal şteruhead
   ASTM F-648 utra-high molecular weight polyethylene (UHANNPe) tra
   ASTM F-75 cobalt chromium radiographic marker wire

INDICATIONS: The Aurola CMC Trapazio-metacarpal prominesis is indicated for lotal joint replace-ment in allestedly mature patients with pain or instability of the trapazio-metacarpal joint due to trauma, inflammatory or department or desease or resistant of previous pro-cedures, was instantable to attribute in or instruction surgery.

- CONTRAINDICATIONS

   Bone, musculature, sendone, or educant soft liseus compromised by disease, interior, or prior terpientation which cannot provide adequate support or fisation by the prosthesis.
- Any active or suspected infection in or around the thumb joint. Skeletal immeturity

WARNINGS Gas also the Pertant Courseing Intermetion Section;

This device is for commented use only

Streamous banding, sectional modelly, and articular instability all may lead to
Societation uses and evertual feature by loosening, fracture, or diskostion of the
device. Pudents should be made even of the increased potential for device feature it
excessive determeds are made upon it.

- PRECAUTIONS

  The implant is provided startle in an undamaged package. If either the implant or the package supposed demaged, explanation date has been exceeded, or if startlery is questioned for any research, the implant all end escention of the proper startlery is replant all end escention of the proper retain simplant is exceeded to the proper retain simplant increases the potential for a successful outcome.

  The implant should be sentended from the shartle package only after the implant after has been prepared and properly startly.

  Implants should be handled with blunk instruments to avoid scratching, outling or nicking the device.

### ADVERSE EVENTS

e events in a published series of 50 patients included loosening, transent tie, cament extrusion injury to the palmar digital nerves and de Quervein's

Ewent	Humber of events (n=50)
Loosening	5 (10.0 %)
framient radial reuritis	2 ( 4.0 %)
coment extrusion injury	1 ( 20%)
de Quervain's tendinitie	6 (12.0 %)

- Potential abrease sentin reported with other larger lart procedures include box soling, Section dislocation, or infection of the sentient. No additional significant senties, and the senties of the senties of the senties of the senties of the senties.
   highly to the surrounding nerves, blood vessels, tendons, or self listues can occur as a corresponding of the senties. The senties of the senties of the senties of the Metal senties of the senties.

In a subsection expanded publication including an additional 21 cases in the sense install of the 50 patients showed a full range of vectors within four weeks of submission of the sense in the sense i

# SURGICAL PROCEDURES

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 finise. These components are made of loveling metalists which are placed within the body for the potential restoration of mobility or education of pan. However, due to the many biological, mechanical and optical-ending factors which infect these devices, the components cannot be expected to efficiated the activity level and looks of normal healthy borns for an understood period of term. The reported size of looks of normal healthy borns for an understood period of term. The reported size of looks of normal healthy borns for an understood period of term. The reported size of looks of normal healthy borns for an understood period of term. The reported size of looks of 10 years of 10 ye

- STERILIZATION

  This component has been steelezed by ethylene oxids or generial redistion.

  The implant is provided steele in an uncorreaged package. If either the implant or the package spaces demaped, exploration other has been acceeded, or it strettly in questioned for any reason. The implant of toold not be used. Do not restrictly.

  That sight components are available to such thaving to open this either package prior to positiones implantation. The implant should be removed from it is stelle package only after this implant set has been propried and properly stoop.

Eige only extra Chropescics Corporation weren'ts that this product meets the manufacture or a specification and at time from manufacturing delects at the time of delever. This warranty specifically excludes delects insulting from missas, abuse or improper fam-ding of the product advesourch to receipt by the purchaser. Avairás Orthopasdics does not werrant the cascome of the surgical procedure.

# EU REPRESENTATIVE: Medical Products International Europe, 6V

Medical Products International Caroli Schutweg 13a 5145 NP Washinja, The Notherlands 31 Ett 416 563754

\* Brean RM. Style jorn arthroplesty of the corporatic appel cert of the shumb. In: Can Onthous (MS) May(1/0): 861-7.

Brean RM. Style Style molecularies at the base of the shumo—preferency report, bt. J franciscopy (MS)

Die Tispachi-Admissung de Cheinfordinste Annete CMC test den Komponente aus derendschnoteist deren Polyeitspes ge-BRMFMI, die nicht songberenden Frogendundens einzemestest leit, und eine Sichetformporrerte son Titterleigerung mit Integrietsten Korpt, die in dem Sichet dies einem Metacarpst-Knockwere zemenfellen vermitzet die Zwischen Titterkopf und der UHMMFM-Komponente besteht eine gelenhöge Werbrichung (Frühlsdeten), um einen geloppeteien profiteillischen Ernatz mit errem "Siesp-Fit"-Heichseiteruns Bir des Deurmergrundgeleient zu bilden. Des Inspiration sie niese fürden werderingen die sein der sechlisten oder Heine Heine deregoeckt werden höhnen. Für placks implicitations die einschliste der Heine Heine deregoeckt werden höhnen. Für placks implicitations die einschliste der Heine Heine deregoeckt werden höhnen. Für placks implicitations der sechlisten oder Heine Heine deregoeckt werden höhnen. Für placks implicitations der sechlisten oder Heine Heine deregoeckt werden höhnen.

- kleanskein:

   Metaczarpa-Scheft/Kopf e.u. Tilanlegierung 6AL-4V ELI gemäß ASTM F 135

   Trapackuskomponente sus utrathochmolekuterem Polyetinyten (LHMWPe) gemäß
  ASTM F-648

   Raciskojdecher Maskierungsdraht sus Kobaltchorm gemäß ASTM F75

ANWENDONGGERIETE
Die Trapazio-Metacarpai-Protriese Avens CMC let inditident die Totalgelentansatz bei 
Praconar nit ausgerettes Bielektentwicklang, die Indige von Trauma, entzienflichte 
der despieratione Esterakung des Breinlon früherer Protriesen an Schmerzen oder 
stratabilität des Trapapo-Makacarpai-Gelenkes leiden, und stellt eine Alternative zu 
Anthropides der entschaftunker Citurapia dar:

GEGENANZEIGEN

- Durch Krankhalt, Infektion oder träners Implantation angegegtflere Knochen, Mosthalate, Seitere oder angestande Wabitiales, Gie tellne sichere Untertage oder Fasimung für die Profitees bisten södnen.

- Abbre oder vermische frießende in oder an dem Daumangelenk

- Unnelle in der Slesietlanthefokung.

ARRHININESSE (siehe such Absolvatt "Informationen zur Petienhenberatung")
Dieses Gestil at nur zur zernertierten Arwandung bestimmt.
Basins Belassung, Sannanläge Mobilität und Gelesskestabilität können alle zu
sechezungstam Verschleiß und werterbalen Versangen darch Lockerung, Fraktur oder
solchandson der Prothess (Dreits. Die Paldersten sind auf des erhörter Potentials des mangeme der Prothess (Dreits. Die Paldersten sind auf des erhörter Potentials des mangemes der Prothess (Dreits. Die Paldersten sind auf des erhörter Potentials des

Vernogenis der Protriete bei libernitätigke telessichig nitschreiben.

VPORSICHTEMARNAHAMEN ERFÜR DES VERWEIBENDUNG.

Das Impliciteit wird stadt in unversierter Verprachung geliefest. Wenn eine Beschädigung eine verpfanstese oder der Verprachung vorzuligen achwert, dies Verladischund überschreiben oder die Steinfälls aus sepredierenen Grund in Frage gewisset, sit der das meigentet nicht verwenndet werden. Nicht resterfallseren.

Songliktige Vorbereining des Impliantatiegers und die Wahrl der richtigen Größe des Impliantatieger vorbereiter und Kritigensweichen der impliantationer. Des Impliantaties er vorbereiter und für die Größe des Impliantationer vorbereiter und für die Größe des Impliantationer vorbereiter und für die Größe des Impliantationer und verwenden, um Kratzer, Schreibe oder Komban auf dem Greßt zu werwenden, um Kratzer, Schreibe oder Komban auf dem Greßt zu werwenden, um

NEBENWIRKUNGEN « Zu der, Nebenwirkungen, die von 50 Pellenten veröffentlicht wurden, gehörten "schanung, transierte Neutrits des Nennus radiales, Verfetzung der palmaren Engenmerven infeldje von Zemardestrusion und De-Quervein-Terdialte.

Nebenwirkung	Anzeki der Nebenwirkungen in e Sil
Lockening	5 (10,0 %)
Transiente Neuritry des Nervus ractisfis	2 ( 4,0 %)
Verletzung durch Zementextrusion	1 ( 2.0 %)
De-Quervain-Tendinille	6 (12.0 %)

berichtet.

KLINISCHE ERGEBNISSE
Eig glo Berichte über die Ergebnisse bei neurundrwanzig Patienten, deren das Gerätimplantient wurde 2 Der Duszt erforgte wegen Arthrite, Meilgeschlagener wertweisen.

Antrodese, nochneigne felligsechlagener Antrodesiek mit Stentigneithans oder

Totolgeienbersatz oder fünderer Antrodes der Gelenha auch LahmungZewundzwenig Patienten hatten zum Zeitgunkt der Veröffentlichung

Geschnichtesunderungen bei zu 7 Jahrej einen zeinbedmistehenden schrenzchein

Bewegungspreiserum erfolk, in sebeen Fällen wurde wegen sägnführten

Musikaltysbaltande, Weichtelwerschungen oder Antrodesteine heb nommeter

Bewegungspreiserum erfolk, erschlich Eig gab kande Bedichte über Frinktundet

bei bestehende Antrodesien.

Bedie Bestehen zu der Bestehen der Bestehen der Frinktundet

zeiner Knochen-Geratz (hiefelber)

im Rahmen eine spälaren globene Nedferdichung, die 21 weitere Fäße umbeste 1, erreichten die meisten der 50 Patienten innerhalb von vier Wochen Rach Nahlerdhemung den vollen Bewegungsspäraum und zeigten gute bangzeitengebnisse. Bei 26 osteostertlinischen Patienten mit Gelerkerverschleibung wurde der vollständige synspiontries Bewegungsspäraum arreicht. Bei für Patienten bei sein binnen ohner deregebnische here Locherung des angatenste zu weren keine Päße von implementantette. Oberhältscharverschleib, Fragmentation oder pfeston kentrelation.

CHIRURAISCHE VERFANREN
Ein Hamblouch mit einer genauen Beschreibung des chirungsbehen Verlateren für der
Einsatz dieses Implantationstress ein verfügbar. Der Chaung ist dafür verenrenntlicht
sach vor Anwendung dieses Medicitoproduktis mit dem Verlateren verfand, zu machen
ber Chaung ist weistenht delfür verenrendrisch, die einschlägigen Fühldebohre
songfärtig as seen und auch mit Benchländigen zu bereiten, die Erfehnung in die
Anwendung dieses Verfahren gesemment haben.

(NFORMATIONEN ZUR PATIENTENBERATUNG (Siehe auch Warnhimmeise) Neber den Patientenfolormationen in den Abschriften Warnhimmeise und Nebenwirkungen sind den Patienten die nachfolgenden informationen zu wermitteln:

# STERILISATION

- STERILISATION

  Dies komponente wurde mit Ethylencsid oder Gammabestreihkrig steritierent.
  Dies Implantat wird sterit in unversehrter Werpschung gelöstert. Weren eine Beschledigung dass Implantatis oder der Versackung vorndangen abheilt, das Versändstatum überschritten oder der Versackung vorndangen abheilt, das Versändstatum überschritten oder des Steritätt aus gegrendehem Flund eine die einge gesellt ist, darf dass inngesenten eines Steritieren, Probeptrofesenson, de gewanntes Steritier des Wertschung vor des Implantations der Prothese geoffnied werden musta. Dies stoplantat darf auf aus der sterien Verpackung einhommen werden, wenn das implantationger vorbereitet und SV die Größe des Implantatis richtig dimensionlief lät.

EINGESCHRÄNNTE GEWÄHRLEISTUNG.
Anwate Orthopsedica Corporation gewährleistelt, dass dieses Medzinprodukt die Spezificationen des Hersteises erfüllt und bei der Leiterung keine Hersteises erfüllt und bei der Leiterung keine Hersteilungsfelbte enfrest. Diese Gewährleitung abriefelt spezifie Feiler aus, die auf hichfosteilungsgemäßen. Debausch, Abseus oder unsachgemäße Handhelung des Medzinproduktes osch Enging Die dem Kahre zurückgluhmer sied. Avsalle Orthopsedics übernennt keine Gewährleistung für das Resultat der chinnigischen Methods.

EU-VERTRETER: Medical Products international Europe, BV Schutweg 13a 5145 NP Wastewijk, The Netherlands 31 (D) 416 563754

Braun, 164. Total joint arthrophathy at the corporationship total of the thurse. Clin Distinct (MS:rsts): 7 Braun, 194. Solar pore replacement at the base of the dound - preliminary report fit. J. Handley (g. Handley or J. 1975): 243–51.

### FRANCAIS

La profibble pour wisculation traptico-métacarplaine Avanta CMC, est composés d'un matiéria à base de pulgétifyation à utres teurse remaie motiousiers (\$40,400°FE) qui est circenté sur le traptice présidébiernem préparé, ail d'un composent possibleur annéabage de litter seve tête entrèpes qui est circenté du les receives métacarps. La tiére est tienne est mété à le pièce en UH-Réviffe de façon à lormer un nobestuit intrabulamentes despié à l'estrousiero bases de pouce. Entreplant selés en trois talles, soutes utilisables sur le main gauche comme sur le main doite. Une gamme de celéfraires ésaits est proposée pour chaque type d'implent selés né controluer à le préparation de l'ou.

- Components:

  Townstern missespierone en alliage de trans 6AL-4V BJI ASTM F 136

  Townstern trapidon en polyethylene à utre insute messe moleculaire (MRMW-PE) ASTM F-648

  Calcia de mempuage exclorgraphique an observe-outset ASTM F75

INDICATIONS MDICATIONS

La postificia et sizultari establizari primaria cui con establizaria con la emplanament settocame total chez les postente dont le développement caseaux est arrivé à maturité et présentate i net dicultur du une instabilité au n'eves un fire totalisation inspéra-mitacampianne en maiori d'un traumatione, d'une matérie intermentaire ou dégénérative, ou en cas de encouvelement d'implentations intrédiseues. Il s'agit d'une solution allementaire à l'arthrodese ou à le crimingre reconstructrice.

CONTRE-INDECATIONS

La délationation d'os, de nuedes, de landons ou de Basus mous votains dus à une malatis, une infection ou une simplementon amérieure et amplichent d'obtenir un mainten ou une fisation satisfaisants de la prothèse . Turule historico active ou semplement eu un eur stendoure de l'articulation du

MISES EN GARDE (Vor également le partie intituée » informations à porter à l'el-teration du patient «).

Co d'appoint est à utiliser un'apprenent deurs le cache d'une application cimentée.

Las charges imposertes, les movements accessits et l'enfabilité étituaisés sont leux autocopilités de provique le leux entrement, le noture ou se discretion du discretion du discretion du discretion du discretif «) de l'expertis de l'expertis de désalance. Les patients doivert étre avents qu'il existe un risque acons de désalance du clappatif en ses de solici-tations accessitses.

PRÉCAUTIONS

\* L'Implient det fount intérile, lant que l'embatilique est intact. En cas de déférioration appareuris de l'implient ou de son embatilique, de dépassement de la date de premiption ou de doute sur les stellés du depositif pour qualque raison que ce soit. Implient moi doit pas d'évaluet, les pass residiants.

La projection hébitalise de l'enterise de l'implient ont chois d'implient adolputé apparent médicalises au series de l'implient de chois de l'implient de l'

ÉVÊNEMENTS RIDÉSIRABLES

Las ávidements indestrates retents clear une aérie de 50 patients (et publiés)
dissert potemente de desserrance. La révets passagère du neif redat, la téstion des
neirs digitaux painnaires liés à l'asputation du climent et la fénosprovité chronique
sténicants du pouce de la Charvathin.

Événement	Hombre d'occurrences (n = 50)
Densiderament	5 (10,0 %)
Névrite passagére du nert radial	2 (4,0 %)
Léske: Hée à l'expulsion du ciment	1 (2,0 %)
Térrosynovite de De Quervain	5 (12.0 %)

- Les éventuals effets indésirables observés avec les aures profitéses articulaires des foigts sorts, notamment, le dessemment, le rupture, le dislocation ou l'infection de l'imparet, buun autre événement indésirable significatif à été supporté à ce jour depuis le début de la périon de continencessation de ce déposité.

  L'implantation de ce disposité paul entraîne des léalons au riveau des nerts, vassaux, levelors ou titules autres des léalons au riveau des nerts, vassaux, levelors ou titules autres autres des léalons au riveau des nerts, vassaux, levelors ou titules de l'économies de l'autres des léalons au proposités.

  Des ces de réaction affertiques eu métal suite à la substitution anticulaire ont éte réservé.

refered.

RESULTATS CLINIQUES

Les reluctes de l'implemitation de ce dispositif cet été observée chez virigi-raid

laignetta L. la substitution à été pratiquée en raison d'une étimite, l'échec d'une
attrocidée préalable, l'échec de l'utilisation d'un implant en Sélezitio ou d'une artinoplante attrocidée préalable, l'échec de l'utilisation de l'une artinoplante attrocidée préalable, l'et l'est de l'utilisation de l'une artinoplante attrocides totes, ou enzoue d'une artinoplante attrocide totes, ou enzoue d'une artinoplante de l'estable de l'estable de l'avent de l'une qu'et le satisfaient de ce mouvements. Deurs sept cas, le jeu de l'articulation de l'une anout et de comparatione. Aucun ces de raption d'une des le l'articulation de l'industriation de l'une mout et de comparatione. Aucun ces de raptions d'une des l'articulation de l'une control de l'une l'articulation de l'une l'une mout et de comparatione. Aucun ces de raptions d'une de l'une de la fonction comentius.

A l'occasion of lun rapport pubble tilidrisserment, portent sur cette même série de cet auxquet s'apolitainnt 21 can supplémentainent, il set appear que le plupart des 50 publiches étaisent en messure de faire pour perhibiernel leur articulation ders les curés publiches étaisent ou messure de faire pour perhibiernel leur articulation ders les curés se long seme Line mange complété de mouvement asymptomatique de l'articu-lation e été obterue chaz 26 petents artitriques atteints de déréglements articu-lents. Ders clinic que, fuvarame chicique ou raidorgéphique set la propiete un desair-mentent de l'implent. Auctin cas de raptire de l'implant, d'usure de surface, de moi-caliernel soit d'infection n'il été s'aféré.

INTERVENTIONS CHIRUPGICALES

I active on marciel décharant en détail l'intervention chirupticate à pratiquar pour l'implination de ces dispositifs. Le drivagien est seul charge de se ternitaires ever l'intervention avvint utilisation de ces produits, ainsi due de se tent su courset des publications au le sujet et de consulter des codégués expérimentés avant de procéder à ces interventions.

# INFORMATIONS À PORTER À L'ATTENTION DES PATIENTS (vor également les Mises en gards). Les informations auxientes, en plus de celles curêtenaire dans les parties - Mises en gards - et . évalements brofésables », doivent étre transmess su patient.

gacta - et - ceveranterats increaseas -, convent eur transmess an jorden 
La durée de vir des pécies de substitution entroviaire India et afficile à 4-visuer
mais n'est, quoi quit an eot, pas éternés. Ces pécies sont composes de météliaix
étanges à l'orpinisme et placés à l'inférier de cu démès en vivus de étable la mobile
à du membre do ce étable à localeur Capacitation en vivus de étable la mobile
à du membre de con étable à localeur Capacitation en vivus de étable la mobile
de la lactification de la composition de la compos

# STÉRILISATION

STERILISATION

Ce disposibil a été stántisé à l'oxyde d'éthyléne ou aux reyons gémma.

L'implant ast fourni stérile tent que son enthallage est intect. En cas de délénoration appearent ce l'implant ou de son enthallage est intect. En cas de délénoration appearent ce l'implant ou de son enthallage, de dépassement de la data de
prinsiption ou de doute sur le sériété du déposité pour quelque reson que ce sor.

Propietre ne doit per alle misleis l'est par entertitéries.

Des places de calèmage fest sont reses à votte disposition aim de vous éntire
d'avoir à ouver l'ambélage séries event l'implant dont de la constète. L'implant doit
des sont or eur entretalige séries event l'implant dont de la constète. L'implant doit
de sont de l'implantation préparé
et conventiblement calémé.

# GARANTIE LIMITÉE

vernonni (E. Liffill E.
Averse Chroquestica Corposation garantit que ce produit répond aux caractéristiques décrates par la staturant et ne présente pas de délarité de libritation eu moment de la terrason. Cette garante escale appelluie par la latination et moment de la terrason. Cette garante escale appelluie par la maioculation moment de que poduit suite à se réception per l'acquisers. Averse Céttroperoice n'othe aucune garantie quant aux résultais de l'intervention chiurgicale.

# Medical Products international Schutweg 13ar 5145 NP Washvijk, Pays-Bas Tel. +31 (0) 416 563/54

Torsun RM. Note part anthropiasty at the corporationapsi part of the thirmb, to "Can Critical (see 1969; 196) 191-191.

Brean RM. Rold part replacement at the base of the thirmb - preferency report. In: 3 Hand Surg Unit Inner 1960; 7(3): 2-5-51

La précest para la articulación trasecto-metacaptana Avanta CMC consta de un compromerá de potentieno de pero motecular ultra año (AHAMYPA), que se ceremeta el trajecto preparado, y un compromente de viertago de alequido de attanto con una cabrar, virtegar que sa trensta destreto der eje de primar metacepo. La cobeza de titudo y se atrocata con el componente de UHMWPA formando un reemplazo potástico de ajutar sexacio para la articulación de la bares del project. El presente para la articulación de la bares del project. El presente para la recurso para la articulación de la bares del project. El presente se presente para la calcular puede usarse an la mano derecha o en la mante topoletad. Para syudes a propues el frueso acidide una serie de mediciones de prueza para cada tipo de implante.

- arerfales.
  Vástapo/cubeze melacarplavos de aleación de téanio SAL-4V ELI, ASTM F136.
  Componente de Impecto de polenteno de peso moleculas utim alto, ASTM F-648.
  Alambre marcador radiográfico de oromo-cobalto, ASTM F75

INDICACIONES

La potienta frepacio-meriacarplana Avanta CMC está indicada para el reemplazo
atricular total en pacientes con estructura desa madora, que sienten dolor o inestaplicad en la articulación trapacto-mesocrapiana delado a trasmetismo, entremediades infamadosas o degererativas o envisión del procidimientos articores,
como atternativa a la articolesa o ciculgie enconfauctoria.

- CONTRAINDIGACIONES

  Comprenies de la trupide reconstructive.

  Comprenies de los huesce, músculos, tendonas o leido blando adyscentes e cause de patriolytica, infeccado o Implanta previo, que no permitan contax con un spuryo o flusión adecuados para la prófesio.

  Totas tendon activo a osopeche de infección activo en la articulación del pulgar o aisolación de la inferio.

  \*\*amadiuse\*\* o dese.

  \*

# ADVERTENCIAS (véase tembién la sección sobre información de asesoramiento

re proclemité. Este dispositivo se also para uso cementado.

La cargo y la movilació escolaise y la inestabilidad estocale pueden scelerar el apparet y encuentamente proceso el finaciano del procedimiento debido a que se esta ablosir, fracturar o debocar el dispositivo. Se dobe estimane a los pacientes que el entena debido, fracturar o debocar el dispositivo. Se dobe estimane a los pacientes que de demanda economia sobre el dispositivo puede amunentar las posibilidades de tenanda economia.

- PRECAUCIONES

  Bi implemte se presenta estéril en un envase intacto. Si el implante o al envase esteri diseñano, e las tarraccurado al periodo de validad o al se dude de su anterididad por alguna razión, no debe usaren el implante. No volver a esteritiza.

  Una preparacción minuclose de lugar de contocación del implante y la elección de un reglaris de transfo adecuado aumentan les posibilidades de obtener un resulta-
- Une problemation into un implementation les gonzentrames de sations.
   El impleme de termanio adecuado auritentan les gonzentrames de sations.
   El impleme debe extreense de su enviase antéré sólo después de que se haya preparado el lugar de colocación del implemente y de que se baya determinado adecuadonnels es terrado.
   Los implemes deben manaquierse con instrumentos san puntir para evitar reyeduras, contres o miseces en el dispositivo.
- EVENTOS ADVERSOS

EVENTOS ADVERSOS

Los eventos adversos que se han informado en una serie publicada de 50 pacientes locuyen, aflojeniento, neurets rabal transitoria, lexión por estrusión del cemento hacia los nervios digitates palmares y tendivitis de de Quervairo,

Evento	Número de casos (n=50)
Aflojemiento	5 (10.0%)
Neuritis racial transitoria	2 (4.0%)
Lesion por extrusion del cemento	1 (2.0%)
Tendinitis de de Quervain	6 (12 0%)

- Los potencisies mentos advantos que se lan internado con otras prótesis de articulación de dedos incluyen sifopmiento, fractura, dislocación o efección del enplanta. No se han informado chos exerticos advantas espiribilidades hasta la fecha durans el persolo de connecticiación de este dispositivo as puede producir una lexión de las previos, vesos sespojamos, tendores y sejicios bisandos que ha redi-sonal de las previos, vesos sespojamos, tendores y sejicios fisionios que ha redi-piso afociale.

PIEDULTADOS CLÍNICOS Se triormatori los assistados obtenidos con 29 pacientas a los cuales se les implan-tos disposables. Los reemplatos se malizaron a causa de artiris, fraceso del infer-to de artiriosable, fraceso de la artiroplatata con profeser de Sistento o articular total pre-vie o amplitosis ficrosa posperambica de la articulación. En 22 parceiras as habita atlamado un bioen reago de movimiento un dotor al momento de las publicación (con un segumento de hasta 7 años.) Siete de los pracierais de los publicación (con un segumento de hasta 7 años.) Siete de los pundentes de los publicación (con un segumento profeseros del las portes de la momento de la publicación (con un segumento profeseros del las policitos de la momento de la profesion de enfección del profeseros del las plos blandos.

En una publicación posterior más extensa, que encluyó otros 21 casos de la seriel, la mayoria de los 50 pacientes eleutros un rengo de movimiento competo dentiro de las ocustos sensureas posteriores a la entitada de los puntos de sutura y continuo demostrando buenos resultados a largo pistos. Se eleutrado un respon comistelo de movimiento aestronatios de 25 pacientes deteorativos con trasforme deficiale. En acros pacientes de observeron vederionias cinicana o radiográficars de efigienterios. No se observeron casos de factura del impliente, despaste superficial, fregmentecion o infacción.

PROCEDIMIENTOS QUIRÚRGICOS

Existe on namual que describe en detade el pocademiento quirunjos para el uso de extra entrante. En responsabilidad del circupino familiarizanse con el procedimiento antes de usar estos productos. Asternat, es negonsabilidad del circipano tamiliarturarse con las guildicaciones pertinentes y consultar con colegas experimentados socreza del procedimiento artes de usar estos implemente.

# INFORMACIÓN DE ASESORAMIENTO PARA EL PACIENTE (VAINSE ENTI-

INPOPUNIQUAÇÃO DE ASESPRANTENTO PARAS DE PACITATE EN INSTITUTA DE INST

Si ben resulta cifici estima ta duración prevista de los componentes del reemplaco arroclate rotal, ésta es finita. Estos componentes están realizados con materiales estatado que se colocion derino del cuerpo para la potencial terraturación del emovisidad o la realización y descoucierios que alectar a estodo e nuntiples factores biologícos, mediencios y descoucierios que alectar a estonación y la componente testam el revel se activación y la componente que se informo en la componente del componente del 10% en la esperamente de nasta o la eficia del 10% en la esperamente de nasta o la eficia del 10% en la esperamente del nasta del 10% en la esperamente que se nasta del 10% en la componente del 10% en la componente

- ESTERILIZACIÓN

  Esta componente ha sido esteritizado con dividad de efiliento y rediscilon garmes.

  El impliente se presente estérir en un envises tritacto. Si el impliente o el envises están distracto, si le ta transcurado el certado de vallecto o el se duda de su esteridad por alguna macin, no dicito suserir el el impliente No obreta esteridad.

  Estates componentes mediciones de pruesta bese avidar ferrer con altra el envise de deserva de la consecuencia del properto de la consecuencia del properto de el esta entre de colocación del impliente y de que se la laya generando el la speri de colocación del impliente y de que se laya desterminado activación del consecuencia.

# GARANTÍA RUMITADA

GARANTIA RJIMITADA
Averale Orthopaedica Corporation generalize que este producto cumple con les
especificaciones del facilicarie y no conferer defectos de fabricación al momento de
sus entrega. Este general exclusive específicamente los defectos que suignir de mais
uso, situacio o manipulación incorección de producto una vez recibido pel compación Aventa fortificación o concesso del producto una vez recibido pel domipación Aventa fortificación de concesso del producto una vez recibido pelo conpación Aventa fortificación o generaliza en resultación del procedimiento currilegido.

# REPRESENTANTE EN LA UNIÓN EUROPEA

Breun RW. Total cont individuality at the component condition of the Brunto Can Christop (1985) May 1995 (65-7).

Brown RM, Total cont includement at the base of the thumb - pretrumeny record. J Mand Sury Many 1992 May 107-745.

NEDEFILARISMO

BESCHRAMING

De Averla CANC hapadometacarpsis gewrichtsprotheae berlaat uit een component van uitsiatoog moleculair gewicht polyectryken (hinkliff); webb een hat voorberlide bepastum wordt gelind, en een uit een titsianulingering bestaande steeloomponent met geintegnearde kop webe in de schackt van de eente metacapsiale wordt gebrackt. De staken hop le door een gewindt wittonden met de component van UHMWP om zo een eraperts constaland protestische verwerging van het basterlumgwercht is eonne. Het eingelaatel is vertingbese in den maten, de selfensal kunnen werden gebruikt in de rachter- of felserhand. Voor sik type implantaat ei een seele proefensetan vertrigigeer ein in maten, de selfensal kunnen werden gebruikt in de rachter- of felserhand. Voor sik type implantaat ein een seele proefensetan vertrigigeer ein hulp bij het voorbereiden van het bot.

- Materialen

  ASTM F 136 tisntum 6AL-AV ELI legering metacerpale sine/hop

  ASTM F-648 trapeziale component van ultrahoog moteculair gewicht poly-ethyleen (JA-6MH)

  ASTM FS tobalischromen racitografische merkeringsdrawd

De Avesta CMC laspedometacurpale prothese is bestend voor vervanging van het complete permicht in patienten met een volgroudd skeet met pijn of trefshilfent in het tappedometacapsie gewricht door trauma, enterminators of degeneratieve son-domingen of voor revisie van sentere trynspen, als alternatief voor antrodese of reconstructieve chisungie.

- CONTRA-INDICATIES

  Door zelds, infectie of serciere implentatio sangetast bot, musculatium, pezen, of ornitigand zacht weeted, weller niet genoeg steun of bevertiging voor de prothese kunen biolem.
- nnen bieden. Actieve af vermoede infecties in of sond het divingewricht. Onvolgroeidheid van hat skelet.

WARSCHWINIGEN (zie ook het hoofdstuk informatie voor patientvoorlichting)

Dit trattument is uitslutierd voor paljing gebruik.

Paties beleisting, voormisigs beversoglijkheid in geweistliche stabilitiet kunnen alemaal leiden tot kommelde sijfinge en uitersdelijk kan het terprunent het begeven door
toestaan, beplan of diestakte. Platierter deeren is voorde sjeetzen op de verhooglet
kans daa hat termunent het begevent anomer en is hoge stem aan voorden paaleld.

Karre dat het hattrument not begeent annoer et te noge essen kan reccion pessett.

VOORZONGSMAATREGEEL wordt sterkel geleven in een probeschedigde verpaleking. Indien retwe het inspiratiaat wordt sterkel geleven in een probeschedigde keptaleking. Indien retwe het kreivertaat ofveel de verpansking beanchedigd blijkt te gin, de verveldstab mit overschieden, of om welke reden dan ook son de sterifleet wordt getwejfeld, mag het inplanteat rejek wordte gebruikt. In het herstefeken.

Einn nauwkanzige voorbereiding van de inplantesleplaats en de keuza van de juste smed breijneats vergorden de kanze op een soosbevord resulteit.

Het mojennaat mag pas uit zijn steries verpaleking worden gehaald zoder de engulantesleplaats is voorbereid en de juste steriedigen heeft.

Om te voorbruiken die ein het instrument wordt gebruikt, geaneden of geleidt mojeen might elleine in self dinnige kanzumenten voordt gebruikt, geaneden of geleidt

MOGELLKE BLIWERKINGEN

Bijvektrigen is een bekandigenaakte serie ven 50 patierten onweiten loegsam van het ingelataat, sjolelijke racitale ventiën, letael aan de vingerzemwen in de hardpelm door aktrusie een het Nederladdel en De Overveins terdinitet.

Bijwerking	santal gevelen (n = 50)
longson van het implentaat	5 (10,0%)
tijdelijke radiele neuritin	2 (4,0%)
letsel door extrusie van het kieeknikkiel	1 (2,0%)
De Querrana tendinitis	6 (12,0%)

- Mogasjie betwestingen die in combreste met andere vingergewichtsprotheses zijn gewoid omvetten lospaan, factuurdslockste, of erfectie van het implantant Gesturende de profice dat dit lastrument op de mand is zijn er gewen vertiers signifi-cante betwestingen gewapporteerd.
  Latsal aan de oerdiggend zeruwen, bloedvaten, pezen of zacht weertel kan optracien als gevolg van de ingsterfalle van het instrument
  Motasjegoverlijneitswacties zijn gewapporteerd na ververliging van het gewricht.

Melangeromymentements are one-protection with entire the first instrument SE zim meutitaten van hagenenhening publishen geagoordeerd die het instrument gemiptenkered habben gekreperd. Verworiging is uitgevoerd voor aktrist, metante proging tot artrodesse, eerdere melaktie selestische art totals gewichtsautropissise, or postpesarjstische formza anktylose van het gewicht. Op het moment van publicate bevergerp bewich in zeuen gewichen verd geen normals beweigingsbehalt verletze, bevergerp bewich in zeuen gewichen verd geen normals beweigingsbehalt verletze, zorts weetstel. Er zim geen gewishen gewichtend van brouk of hindels van het englantzalt, desse dies gewishen verdoorden kinsterfung van het Implantzaal op het gewichts.

CHIRURGISCHE PROCEDURES

Er is een herchiefding verkrijtgoser waarin gedefalleerd de chirurgische procedure voor her gebruik van des kreigkreifde natuumenten wordt beschreven. Het is de weard-woorstelighteid van de chirurg dat hij vertreuwel is met de grooedure voorstel it 6 deze production gang gebruiken. Dearmeast is held er waarstevoordelijkeld van de chirurg dat hij voorstjosend san het gebruik op de hoogte is van retervante publicaties en dat hij be envans collegia schreis krivent im de botteking int de productiest.

INFORMATIE VOOR PATIËNTVOORLICHTING (zie ook Wearnschunkrigen) Naum die patiëntgereisteerde knormatie in die hoofdstykken Waarschunkrigen en Sywerkingen dient de volgende informatie te worden medegedeerd aan die patiënt

A compare used de volgénde informatie le worden medejédésed aan de parlaint.

Notavel de vennestrie levensduur van componenten voor aan committee gewordtraversniging moeijfile se schaffan is, et des bepardt. Dats componenten zegensaalt van vesende malerialen, die in het lichaam worden geplaatst voor mogelijk hemstel van de mobiliert de vermindering van hijn, farmyeig de verei blotogeken, macharische en fysiochservische factoren die invitied op deze instrumenten schefnen, kan echter eelt van deze oorgenersten sowiem erwerde last zij gedurende onbegende is gibt bestalen zijn tegen hat achteristerviseu en de beleesting van normaal genom bot i Het gemspondersde proendetage van bestalenge van en stelleder sowie van dit wirtunkent bedoneg 10% bij de 10 in eeu de judicitiegen in en al neitsicher sowie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedoneg 10% bij de 10 in een de Componitie van dit wirtunkent bedone 10 in een de Componitie van dit wirtunkent bedone 100 in een de Componitie van dit wirtunkent bedone 100 in een de Componitie van dit wirtunkent bedone 100 in een de Componitie van dit wirtunkent bedone 100 in een de Componitie van dit wirtunkent bedone 100 in een de Componitie van dit wirtunkent bedone 100 in een de Componitie van dit wirtunkent bedone 100 in een de Componitie van dit wirtunkent bedone 100 in een de Componitie van dit wirtunkent bedone 100 in een d

- Dies components unter alleist gelevend in een onbeschadigde verpalking. Belain sowei hat ingivernaat oberd die verpalking beschadigd bijde te zijn die vervestablien is overalte ingivernaat oberd die verpalking beschadigd bijde te zijn die vervestablien is overalterenen of oor welke neden des noor oken op seel verpalentaat niet vorden gebruikt. Niet hendereliseren. Proximizationsprongerenten zijn ververligbaar om he voorkompen old die sterijde verpalendig v\u00f3ord die implantate van die protinse moet worden geopend. Het implantaat mag pas uit zijn startele verpalking worden gehandt zodra de implantaat voordenziel en die juzie strivetingen fielen.

BEPERKTE GARANTIE

Avanta Orthopsacics Corporation garandeert det dit product benniverorit aan de 
spochicaties vird on biblikant en op het moment van fevering geen productieforden 
bevat. Usgesichen van deze generate zijn net neme gebreien mit gevolg van verbeidgestruit, machte de ean onglate bedeiming van het product netet het door de koper 
is ontvergen. Avanta Orthopsesics geeft geen gerante op het resultatel van de 
chrungsiche procedue.

# EU-VERTEGENWOORDIGER: Medical Products International Europe BV Schutweg 13A

### DESCRIZIONE

DESCRIZIONE

La protest transactiventescarpale Avenia CMC à contiliste de un elemento in polecilene del attituerno pero molecotien (Beharthigh camentate di transactive preparato, e de 
uno stelo in larga di transactivo non felemento in URANTPE formanzacio, e la 
transactivi in transactivi articola con l'elemento in URANTPE formanzacio una acattinazione 
professica venociate "anap-le" per l'articolazione baselo del polica. L'Implanto a 
disposibile in les misure, dissociano delle qual pode sessere utilizzata per la manza della 
o striata. Inottre, per ogni ligo di Implanto il disponibile in une serie di calibratori di 
prove, che posenno essere d'auticipo per la preparatori dell'import.

INDICAZIONI
Le protest impactio-metacarpais Avanta CRAC è indicata per la sostituzione totale dell' l'articolacione in puestio del vivo e l'articolacione in puestio del articolati dell'articolacione in puestione della residentia dell'articolacione in puestione della residentia della residentia

CONTRICINDICAZIONI

Ossa, muscostara, kindrir o tessuti molli adhecerili attensti de patrologie, infectioni o precedenti argestiti, che non sono in grado di fomire supporto o flessiggio adequato per la porticat.

Infectioni il in stito o acopette neti ense inferessata o circostarine l'articolazione del

- AVVENTENZE (S) veda anche la sazione relativa sile informazioni per la Consentuta di Pazienta) .

  Cusato presioni è desilinato asciusivamente all'uso cerrentato. .

  (cacidir particodeministo esclusivamente all'uso cerrentato. .

  (cacidir particodeministo pesenti, l'accessive mobilità e l'instabilità minolare pos-siono accessivere l'usure a provocare eventual denni alsa protesa per distacco, finditura o assazione. Si raccomanda di informare i pazienti suba ineggiore probabilità che si vertichi laba eventenza, ao vingino esecchia e societte disconere edificializzato.

- PRECAUZIONI

  L'Impianto viene tomico sterite in confesione intégra. Non utilizzato se l'Impianto sterite inconfesione intégra. Non utilizzato se l'Impianto estesso di so confesione sembreno desnesogiati, se è supereta la dista de socializza o in caso di dubbli per Qualistale motivo puls sentità delle confesione. Non rétentizzate.

  Una prospraccione institucione del sito d'impianto e la social della misura soliquista dell'impianto sumereteno le probabilità di eatro positivo dell'impianto e la social della misura soliquisto e convettamente misurato il sito dell'impianto.

  Mazinobiere gli impianti con eferumenti amussati per evitare che subiscano gretti, taggi o incisioni.

EVENTI AVVERSI

Gi eventi avversi pubblicati per un carroxione rappresentativo di 50 pincienti com-prendiono di distaco, la rivutife radiale transitoria, la lesione dell'estrusione di cemen-to ai nevol digitati patimari e la tencirote di de Quarvaini 1.

Evento	Numero di eventi (ne:50)
Distacco	5 (10%)
Neurte radiale transitoria	2 (4%)
Lesione dell'estrusione di cemento	1 (2%)
Tendhite di de Quervain	8 (12%)

- I potenziale eventi erverali resi noti in relazione ad aftre protesi per eritoriozioni fishanges comprendono il delaziono, in trettare, la kaseazione o integione dell'impianto. Non sono siste in min ofioli delazioni dell'ali avveni riferegiri dicamite lutti di periodici di commercializzazione id questio presidio.

  In seguito di dimentimento di questio impianto prossono verificami lesioni si nervi carcostanti, si vesi sengiaggi, al lendari dal fessari modi.

  Sono tatti in su casal di depresendibità si mesti di quoi la sostituzione dell'artico-
- Sono

RISULTATI CLINICI

Sono stati real noti i risultati di ventinove pazienti a cui è sisto impiantato questo preside). La sottiutore è statia elettrosta a causa di artria, insuccesso di una terrista atrocissi, prepodente insuccesso dell'artripitatica, tosse o in Sisazic, oppue archical articolesi, prepodente insuccesso dell'artripitatica, tosse o in Sisazic, oppue archical articolesi insuccesso dell'artripitatica, tosse o in Sisazic, oppue archical articolesi insuccesso regionico una buore astrocistati archical regiona regionale pazienti della controli di discoverupi. Setta pazienti non sono risusciti in regionipperi l'articolatati archical PCMI in costa di un notinote equilibrio muscolare o qualico controllaria archical profice di carriori del territori cancio di ristruta o infesicone dell'impianto, ma in tre casi gi è verificato il distacco in correspondanza dell'interfaccas osso-cerrento.

in una successive pubblicazione estesa, comprendeme uteriori 21 casi della fet-tiopacia I, la maggior carie del 80 parziera ha mostrato un'atticolarità comprista entro quattro estitimano della rimuzione odela entrina e ha contributo si montrera buorri della-tati a sungo termina. Una completa articolarità avistoriarità a sista raggiunta de 25 puerdio detecutività con l'userzione articolare. In cinque cesi al è avvitazta è distat-co dimostrato cinicamente o raciograficamente. Non sono stato ossavato casi di trat-tura dell'impetto, suna su perfectiose, finamentaticolore o infessione.

has del imperio; vene acquire de la PROCEDURE CHIRURGICHE

È disponible une prosedura chirurgica destinata all'uso del presente disponibili en 
imperio. E magorinatifiat del chirurgi acquires familiarità con tale procedura primi 
di tilibizza questi prodotti. Il chirurgi e alimente favolti a comoscine a focumentazione 
una finanziami a a consultarial con collegità esperiil in mento alla procedura primi o
uni encomento a a consultarial con collegità esperiil in mento alla procedura primi o

# INFORMAZIONI PER LA CONSULENZA AI PAZIENTE (SI vedano anche le

Other alle informazioni specifiche, riportate nella sozione Avverienze a Eventi anversi, al raccomenda di comunicare al paziente anche quanto segue:

- a raccommission to continuous en passione learnou una durata ámitata che, purticipo, resita difficie de strinere. Questi componenti sono realizzati com materiale saturane, che vergono insentire compo per reprintamen una potateziate modella o ricuma il diciene. Tuttativa, comasteriano, il numerosi fattori budogici, meccannoi e fascichimio leagle è questi disposibilità, non a puo questi de disposibilità poli o questi disposibilità, non a puo questi de disposibilità della preside di l'emposi bilinitato, La poresentuale di case di disaccomificate in una subsolication elegatori politicativa di stata della 10% en un periodo di 10 anni di follow-up. Sizuani RAL. Totali parti antiropiassi en timo accominato della disconi finata di controli di case di controli della con

- STERILIZZAZIONE

  8 presente impanto è stato steritzzato con osolio di etilene o reggi germa.

  L'implanto restate stante nelle confessione reteign. Non utilizzario se l'implanto
  stesso o le confessione ambrano daminegiale, se è trascorsa le deta di scadenza o se
  il dubita cese serittà per cualitati motivo. Non reteritizzario si deta di scadenza o se
  il dubita cese serittà per cualitati motivo. Non reteritizzario.

  Sono disponsibil calestatori di prova pie evitare l'impetture delle contexione stedie
  pring d'implantare la protesti. Previewer l'implanto calta confessione sterile solo 0000

  aver creparato e correttemente misurato il sito dell'implanto.

# GARANZIA LIMITATA

GARANZIA LIMITATA A Aventa Orthopsecios Comportion garantisce che il presente prodotto risponde alla spocificia del produttore o mon presenta difetti di lavorazione ai momento della con-segnia. La presenta giaranzia esclude spocificiamente i clienti resistianti da uso intro-prio, abusso o manipolisizioni accorretta del prodotto dospo à neavimento da parta del-fracquiente. Avinta Orthopsecior con risponde per l'estro della procedura d'aveniga-

# RAPPRESENTANTE PER L'UE: Medical Products International Europe, 8V Schulweg (3a 5145 NP Wankelk, Paesi Bassi) 31 (t) 416 S63754

Theur PM. Total yout entropeasity at the corporatect pail you of the 3-cmb maggin (9655) 95; 161-7 Serpul PM. Total your explanement at the base of the thumb - relations prefers Serpul PM/maggin 1962 my at the corporatecorpal poet of the thumb in: On Orthop

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19-0353 Rev C

Blazari RM. Total sum anthroplasty at the carponenticarpal port of the thursto. In Clin Circhop time 1903/1951, 161-7.

Blazari RM. Sobalerini replacement at the base of the drambu-presentally report, fir. J. Heint Surg. (Mor) pres 1903/1901. 215-5-51.

# DO NOT REMOVE THIS ROUTE SLIP!!!!

K-93-1588

OKDYS H-35/PA

4/16/93

PJW

LETTER DATE | LOGIN DATE | DUE DATE FROM: 03/29/93 | 03/31/93 | 06/29/93 SUTTER COFPORA' ION ATTN: LOUISE M FOCHT | CONTROL # TYPE OF DOCUMENT: 9425 CHESAPEAK: DRIVE K931588 510 (k) SAN DIEGO, CA 92123 PHONE NO: 619-569-8148 ESTABLISHMENT NO: 2028601 SHORT NAME: STTER CONT. CONF.: ? TO: STATUS : R ODE/DMC REV PANEL : OR PAN/PROD CODE(S): OR/ / SUBJECT: SUTTER PROXIMAL INTERPHALANGEAL JOINT RQST INFO DATE: / / INFO DUE DATE:
DATE: / / DATE: DECISION: DATE: DECISION DATE: / / DATE: DATE: MAR | 0 1994 DATE: DATE:



# Memorandum

Date 3-15 94 Mark Wright , Clerk-Typist, (CDRH, ODE, DMC) HFZ-401 From Subject Premarket Notification Number(s) K931588[Al Tο 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 % Panel:

Attachment

Re: Device Name Dated: Received:

Dear	: :
We have re the 510(k) referenced it does no design, cor referenced responsibil its labelin effectivene you have su	viewed the information dated  notification (K) previously submitted for the device above. Based solely on the information that you have provided, appear that you have significantly changed or modified the appearathed of manufacture, or intended use of the device above (see 21 CFR 807.81(a)(3)). It is, however, your ag could significantly affect the device's safety or ass and thus require submission of a new 510(k). The information
Contact	any questions regarding the contents of this letter, please

Í

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

ク



9425 CHESAPEAKE DRIVE SAN DIEGO, CA 92123 TFL. (800) 854-2216 FAX (619) 279-8249

March 8, 1994

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

- Gamma Sterilization
- Cobalt 60
- Minimum dose 25 kGy, Maximum dose
- Sterility Assurance Level 10E-6
- Sterilization Validation according to AAMI Method 1. Routine audit is performed using AAMI Method 3B.
- 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:

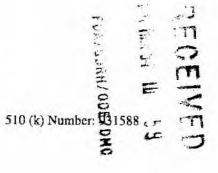
# Sterilization:

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 hours5. Aeration cycle 18 hours

# STEAM STERILIZATION METHOD

1.	Cycle	Standard Gravity
2.	Temperature	250°F (121°C)
3.	Exposure time	35-40 min.

Cycle Prevacuum
 Temperature 270°F (132°C)
 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  $250^{\circ}$  F ( $121^{\circ}$  C) for 35-40 min, or prevacuum sterilization at  $270^{\circ}$  F ( $132^{\circ}$  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

Director of Regulatory Affairs

Touis M Fort

619-569-8148x 2213





DEPARTMENT OF HEALTH & HUMAN SERVICES

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

k812691 - Silicone Implants Re:

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.

Page 2 - Mr. Mike Simpson

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

Sincerely yours,

Headen S Direcce Heather S. Rosecrans

Director, Premarket Notification Section

Program Operations Staff

Office of Device Evaluation

Center for Devices and

Radiological Health

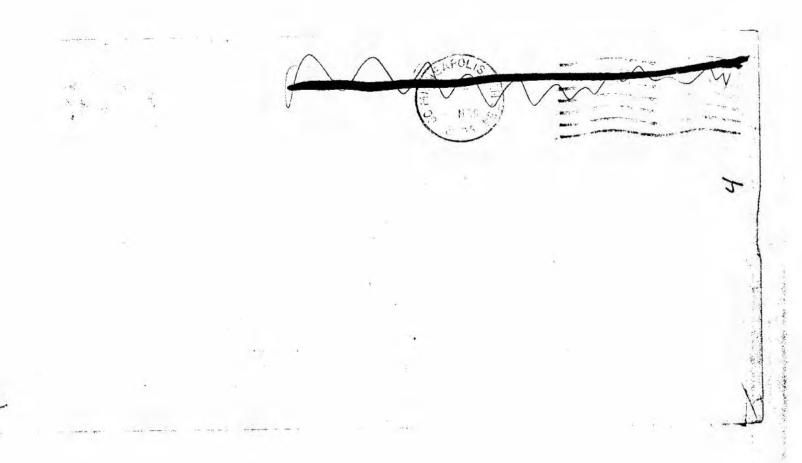
cc: Don Guthner
Vice President
Musculoskeletal Clinical Regulatory Advisers, LLC
505 Park Avenue, 14<sup>th</sup> Floor
New York, NY 10022

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 102/:47





MAR | 0 |994

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

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

# Page 2 - Ms. Louise M. Focht

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,

Paul R. Beninger, M.D.

Director

Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

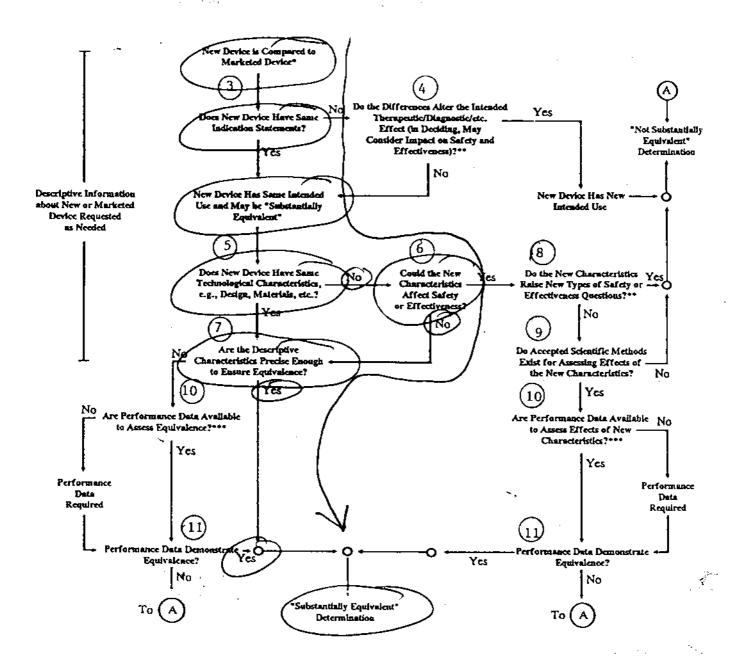




# Memorandum

Date	Mal M	mille			
From	REVIEWER(S) - NAME(S)	V. W. Carrier			
Subject	510(k) NOTIFICATION	3/588			
То	THE RECORD				
	It is my recommendation that the subject 510(	(k) Notification:			
	(A) Is substantially equivalent to ma	arketed devices.			
	(B) Requires premarket approval. NOT equivalent to marketed devices.	f substantially			
	(C) Requires more data.				
	(D) Other (e.g., exempt by regulation duplicate, etc.)	n, not a device,			
Additional Comments:					
	Is this device subject to Postmarket Surveillance? Yes 🔲 No 🔀				
This 510(k) contains: (check appropriate box(es))		x(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		d effectiveness information			
		mmary for class III devices			
	The submitter requests under 21 CFR 807.95:*	Predicate Product Code w/panel and class:			
	No Confidentiality	KYJ Class			
	Confidentiality for 90 days	Additional Product Code(s) w/Panel (optional):			
	Continued Confidentiality exceeding 90 days				
	REVIEW: Daniel S. Melleway () (BRANCH CHIEF)	BRANCH CODE (DATE)			
	FINAL REVIEW: (DIVISION DIRECTOR)	3/13/94 (DATE)			

# 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.



REVI	EWER: MXM	DIVISION/E	BRANCH: 7	GRD/GRDB	
TRAD	DE NAME: SUTTEN PIP	JT. COMMON N	IAME: CONST	RAINED FINGER , POLYM	161
PROD	OUCT TO WHICH COMPARED:	K802342	K870	200, Premonomen Finger	巧
	(510(k) NUMBER IF KNOWN)	5wwson	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	?	×	- IF YES GO TO 5	
4	DO DIFFERENCES ALTER THE OR RAISE NEW ISSUES OF SA EFFECTIVENESS?			- IF YES STOP -NE	
		_	Н		
5.	SAME TECHNOLOGICAL CHARAC	TERISTICS?	×	- IF YES GO TO 7	
6.	COULD THE NEW CHARACTERIS SAFETY OR EFFECTIVENESS?	TICS AFFECT		- IF YES GO TO 8	
7.	DESCRIPTIVE CHARACTERISTIENOUGH?	CS PRECISE	×	IF NO GO TO 10 - IF YES STOP -SE	)
8)	NEW TYPES OF SAFETY OR EF QUESTIONS?	FECTIVENESS		IF YES STOP NE	
9.	ACCEPTED SCIENTIFIC METHO	DS EXIST?		IF NO STOP NE	
10.	PERFORMANCE DATA AVAILABI	E? [		- IF NO REQUEST DATA	
(11)	DATA DEMONSTRATE EQUIVALE	INCE? .			

11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

MEMO RECORD

3/10/94 mnm

FROM: M.N. MELKERSON, Engineer

Center/Office: CDRH/ODE Division/Branch: DGRD/ORDB

TO: File

Document Number: K931588

Proximal InterPhalangeal (PIP) Joint Prosthesis, Common Name:

Finger & Toe

Sutter, Proximal Interphalangeal Joint Prosthesis Trade Name: 21 CFR 888.3230, Finger Jt. Polymer Classifications: 1)

Constrained Prosthesis

Class: II

Product Codes: KYJ: Finger Products To Which Compared:

Preamendments Dow Corning Wright (Wright Medical), Swanson Silastic 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



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 ( ), 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".

- 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 crosssectional 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:

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



4

time necessary to dissipate the absorbed sterilant. Sponsor should supply the following: Temperature (in  $^{\circ}$  C and F), humidity, gas concentration; exposure time, and aeration cycle.

<u>RESPONSE</u>: 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

Physico 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

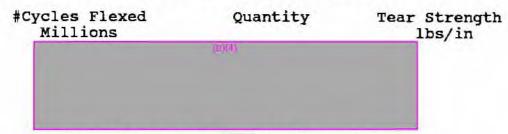
Systemic Injection No toxicity noted systemically: non-toxic Type B, Intracutaneous:: Saline, EtOH, Oil, and PEG

No toxicity noted intracutaneously

Implantation test USP XX 7 Day impla

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):



Dow Corning Wright | lbs/in - literature

Abrasion testing, Abrasion wheel method:

Abrasion rate: ( inch/hour)

PEHT series

Dow HP silastic >>> | 1000

5

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 resterilization 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 /// Disc: Mark025, File: MK931588.





03/08/94

9425 CHESAPEAKE DRIVE SAN DIEGO, CA 92123 TEL (600) 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

- Camma Sterilization
- Cobalt 60
- Minimum dose 25 kGy, Maximum dose
- Sterility Assurance Level 10E-6
- Sterilization Validation according to AAMI Method 1. Routine audit is performed using AAMI Method 3B.
- 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:

17:29

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 othylene 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

Standard Gravity

# STEAM STERILIZATION METHOD

Cycle

2. 3.	Temperature Exposure time	250°F (121°C) 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:

1.

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



03/08/94 17:30



gravity sterilization at 250° F(I21°~C) for 35-40 min, or prevacuum sterilization at 270° F(I32°~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

Director of Regulatory Affairs

619-569-8148x 2213

OTHOPEDIC

510(k) SUBMISSION

CHECKLIST

x 931588

Based on the draft Orthopedic 510(k) Guidance Document, the information checked in the "NO" column ismissing and must be addressed before the review can begin.

MANUFACTURER IDENTIFICATION	Additional Information Required
- PENTITORI (UN	٥
DEVICE IDENTIFICATION	
PROPOSED REGULATORY CLASS.	
INTENDED USE	۵
DEVICE DESCRIPTION	
MATERIALS	a
LABELING	
TESTING OR OTHER ADDITIONAL	П
CLINICAL DATA	П
STERILITY INFORMATION	
PACKAGING DESCRIPTION	П
510ch Character	۵
STATEMENT OR STATEMENT	D

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 sufficientdetailto enable

Recommendation:

proceed with a comprehensive review of the document ☐ issue a modified K-OR-3.A1 letter

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# Public Health Service

Food and Drug Administration Center for Davices and Radiological Health Office of Davice Evaluation Document Mail Center HFZ-401) 1390 Piccard Drive Rockville, Maryland 2:850

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 previded 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 by 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 account telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.



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



# 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 K931588

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.





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:

Shear testing

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::PEG
Implantation test USP XX
Gross and Macroscopic
Flex testing
Abrasion 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

Director Quality Assurance

Sutter Corporation 619-569-8148 x 2213

Enclosures:

Appendix A Proposed Labeling
Appendix B Surgical Technique

rus M Frekt

Appendix C Equivalent Product Literature

Appendix D Drawing

Appendix E Material properties, testing, previously approved under 510k submission



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.





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.

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Sincerely,

Louise M. Focht

Director Quality Assurance

ours M. Forht

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) 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:

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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.



3/10/94 MNM DATE: 3/19/94

MEMO RECORD

Center/Office: CDRH/ODE FROM: M.N. MELKERSON, Engineer Division/Branch: DGRD/ORDB TO: File

Document Number: K931588

Proximal InterPhalangeal (PIP) Joint Prosthesis, Common Name:

Finger & Toe

Trade Name: Sutter, Proximal Interphalangeal Joint Prosthesis 21 CFR 888.3230, Finger Jt. Polymer 1) Classifications:

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 for total joint arthroplasty of the PIP INTENDED USE: 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

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?

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".

- 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 crosssectional 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<sup>-6</sup>, 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



4

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 Quantity Tear Strength
Millions lbs/in

Dow Corning Wright 190 lbs/in - literature

Abrasion testing, Abrasion wheel method:

Abrasion rate: | inch/hour)

PEHT series

Dow HP silastic >>> 10(4)

of

5

Shear testing:

PEHT- (5)(6)

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 resterilization 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 // M Disc: Mark025, File: MK931588.







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

### 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

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

Yours M. Forht

Appendix E Material properties, testing, previously approved under 510k submission

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Appendix A Proposed Labeling



Page 085 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 086 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 087 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 088 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 089 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 090 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 091 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling



Appendix C Equivalent product literature



# Sutter Implants for the Hand and

**Forearm** 

SUTTER CORPORATION BIOMOTION SPECIALISTS®

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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.



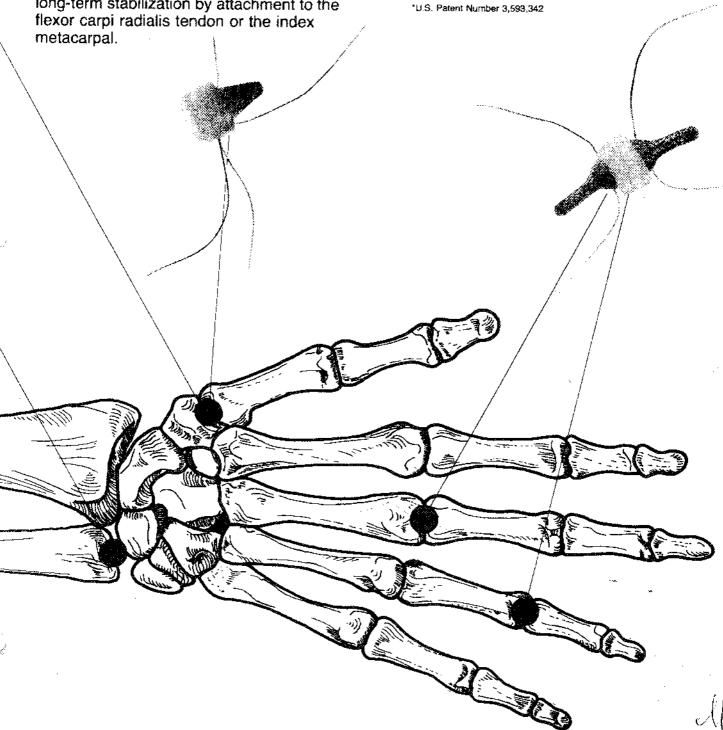


### **Trapezium Implant**

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

### Finger Joint Implant\*

The Sutter Finger Joint Implant is a total joint replacement for the metacarpophalangeal 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.



### **Finger Joint Implant**

90. 00	Picin
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

### 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
TA-305	30

### 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

### **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
BH-305	30

### Distal Ulnar Implant

Catalog	
Number	Size
UH-10	10
UH-20	20
UH-30	30
UH-40	
Sizer	
Catalog	
Number	Size
UH-105	10
UH-205	20
UH-305	30
UH-405	40

### Carpometacarpal Implant

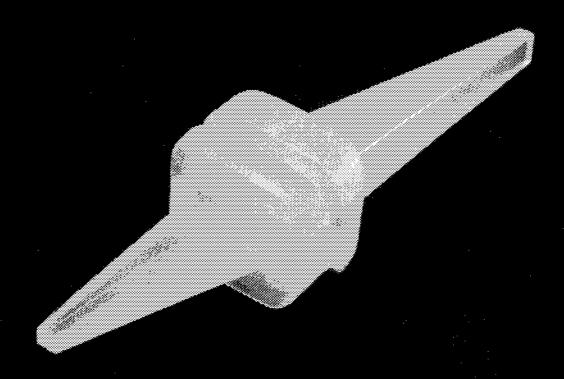
Catalog	
Number	Size
TMC-10	Small
TMC-20	Medium
TMC-30	Large
TMC-15	Replacement Head
TMC-25	Replacement Head

- All Sufter implants, except for the Carpometacarpal implants, are shipped presterilized by gamma radiation.
- Sizers are not for implantation.



Silflex is a trademark of Sutter Corporation © Sutter Corporation 1983. All rights reserved.

# Now. A full range of motion. No volar impingement. Same surgical technique.



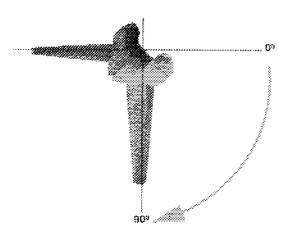
Introducing the Sutter MCP<sup>11</sup> Finger Joint Prosthesis.



# Biomechanically engine

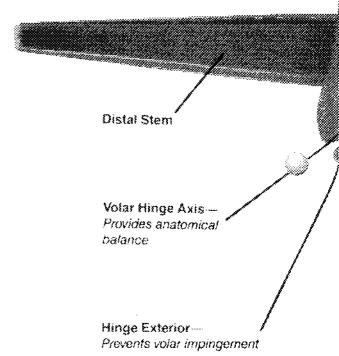
The same surgical technique as other silicone NICP implants

The surgical technique for the Sutter MCP<sup>+</sup> 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.

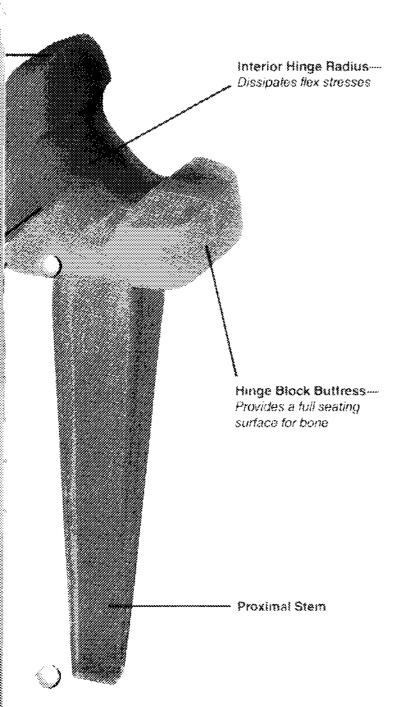


Closely Duplicates Normal Elliptical Joint Motion Bevelled Hinge Block

Allows anatomical glide
of tendon



# 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.)

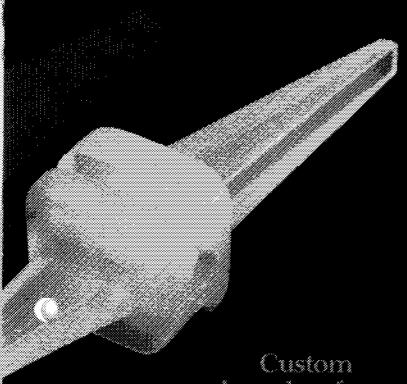
The MCP System also includes the surgical technique reference in print and video versions. The video is available in ½" VHS format.

# 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 colorcoding 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 postsurgical results durability and performance

The new Sutter MCP<sup>\*\*</sup> joint prosthesis, constructed of Silflex<sup>\*\*</sup> 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 handheld broach or awl. An alterna-

tive is the use of power equipment such as a small burr or oscillating broach head.



# 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 subhazation of the metacarpophalangeal joints.
- Painful metacarpophalaogeal joints with limitation of motion.
- Ulnar drift not correctable by soft tissue procedure alone.

### CONTRAINDICAGIONS

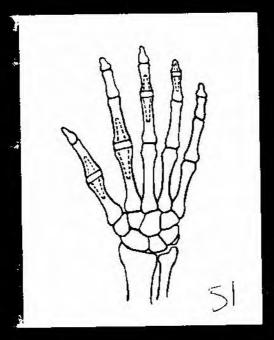
- Psychologically unstable patient.
- Medically compromised patient.
- Infection.
- Inadequate bone stock.
- Irreparable flexor and extensor apparatus.

### TYPICAL DIMENSIONS

			SIZE	A	В	C	D	E
	Ę.		( K)	.618/15.7	206/15.7	7 .483/5.2	.176/4.5	.352/8.9
	<b>}</b>		1.0	.691/17.6	.240/6.10	3 .514/13.1	.19775.0	.396/10.2
13 Comment		,R,	20	.768/19.3	.280/6.6	.602/15.3	.219/5 6	440/11.3
سفسا	J		30	.890/22.6	280/7.1	.700/17.8	.246/6.2	.484/12.4
	لس	0	40	1.03/26.2	308/7.8	.811/20.6	.276/7.0	.592/14.2
	<b>.</b> .		50	1.16/29.5	340/8.6	.902/22.9	.310/7.9	.618/15.9
	F		(50)	1.284/32.6	.394/8	1.000/25.4	.326/8.3	.648/16.5
			SIZE ~INCHES/MILLIMETERS					
TO ORDER								
Sizer		Implant		Broa	Broaches		Broaches, cont.	
CATALOG		CATALOG		CATA	LOG		CATALOG	
NUMBER	SIZE	NUMBER	SI	ZE NUM	BER	SIZE	NUMBER	
MCP-000	00	MCP-00		2		00 Metacarpai	MBR-S Instrument/Sizer Set	
MCP-105	EO	MCP40		10 MBR-P00 Breach 00 Phalangeal		14 Broaches		
MCP-205	20	MCP-20		20 MBR-M10 Broach 10 Metacarpal		1 Awl		
MCP-305	30	MCF530		30 MRE-P10 Broach 10 Phalangeal		t Double-Ended Rasp		
MCP-405	4()	MCP(©)		40 MRR-M20 Broach 20 Metocarpsi		7 Sizers		
MCP5505	50	MCP 50		50 MBR-I	MBR-P20 Broach 20 Phalangeal		I Custom Sterilization Tray	
WCP-605 60	60	MCP-60		2		30 Metacarpal		
				3		30 Phalangcol	MISCELL	ANEOUS
				4		40 Metacarpal	Double-ender	MCP Rasp RSP-001
				5		40 Phalangeat	MCP Awl	SAT-000
						50 Metacarpal	Custom Steril	ization Trav - CST/003
				7		50 Phalangeal		,
						60 Metscarpal		
				MBRA	66 Broad	60 Phalangral 📑		



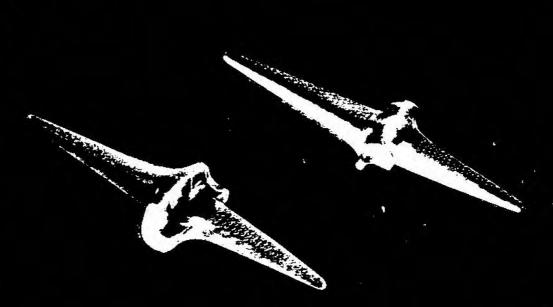




SILASTIC

Finger Joint Implant H.P.

(Swanson\* Design)



DOW CORNING
WRIGHT

### Description

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by Encapsulation

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.<sup>46</sup>

### 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
- Maintains joint space and alignment
- 4. Orients and supports joint encapsulation
- 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

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. <sup>30,37</sup> 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 this excessed by CDRH DID on 3/31/2023 resorption and remodeling phenomena that frequently occur after amputation, as noted in a 15-year study of the finger joint arthropiasty. 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 arthropiasty, 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.

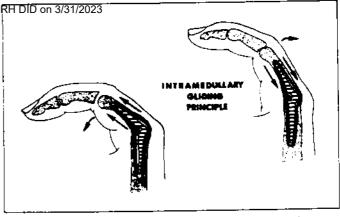


Fig. 1: The stems of the Silastic<sup>®</sup> implant are included in the encapsulation process and the implant glides within the intramedullary canals a distance of 1 or 2 mm, on flexion/extension movements. This gliding allows a greater range of motion to occur and permits the implant to find the best 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.
- 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



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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.

Records Processed by CDRIHD (Dodd/8 to 2022 abductor digiti minimi is exposed on the uinar 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.

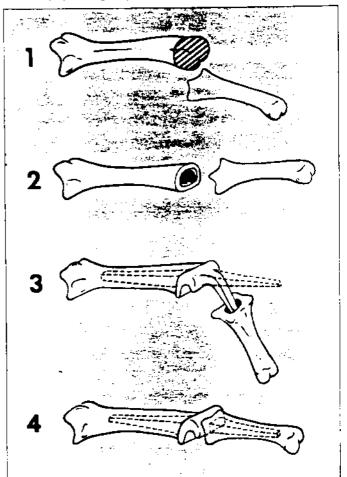


Fig. 3: Resection of metacarpal head and insertion of implant stems into in tramedullary canal. Use the largest implant that can be properly seated. The appropriate joint space should be obtained by bone removal and if necessary soft tissue release. Bone should be removed from the metacarpal head and 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 Intramedulary 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 ubones. 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



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.

end. The largest implant possible should be used implants of Meticulous evaluation and correction of the balance of the sizes 4 through 9 are generally used. A rectangular hole is capsuloligamentous and musculotendinous structures will be rewarded by improved results.

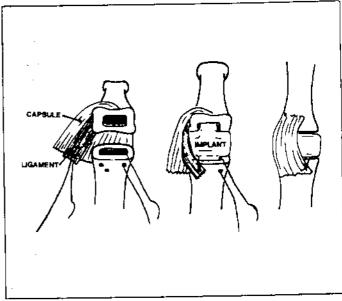


Fig. 4: Radial collateral ligament reconstruction: A: The radial collateral ligament and joint capsule are incised from their attachment to the neck of the metacarpal. Two small drill holes (Tmm) are made on the radio-dorsal aspect and one small drill hole is made on the dorsal ulnar aspect of the neck 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.

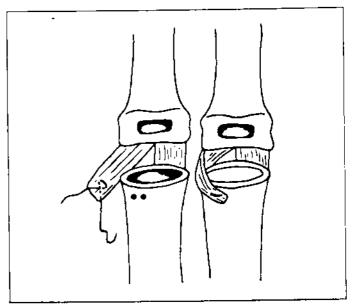


Fig. 5: Collateral ligament reconstruction at the MP joint when the radial collateral ligament is inadequate: The palmar plate and its attachments are incised tongitudinally through the middle. The sesamoid bone, if present, is resected. A distally based flap is made from the radial half of the palmar plate and collateral ligament, which are separated from the underlying intrinsic muscles and flexing rendons. This flap, 1.5 to 2 cm. in length, is attached to the radial aspect of the neck of the melacarpal through a hole in the dorsoradial cortex of the neck of the bone with nonabsorbable sulture material.



#### Closure and Dressing

The skin incision is closed with interrupted 5-0 hylon sutures; two small drains made from strips of silicone elastomer sheeting are inserted into the wound under the skin. A nonadherent dressing such as rayon is applied over the wound 'ong with a Furacin or alternate gauze overlay. A oluminous 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 rains removed. Swelling is generally minimal so use of the \_\_ynamic 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 fatique.

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, Records Processed by CDRHdDIDromy8/84/2098eak 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 culf may be used intermittently to assist flexion movements. Proper use of bracing is essential to insure an adequate range of motion.



<sup>\*</sup>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 ancared by CDRH DII 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<sup>42</sup>(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 om 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 but 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 piace 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 sulures. Arthroplasty for boutonniere and swan-neck deformilies 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 sed by CDBEHNID als 2021 almarward 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 ()mm) 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).

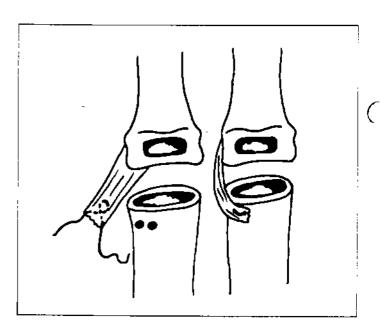


Fig. 10: Technique for reattachment of the collateral ligament of the proximal interphalangeal joint to the neck of the proximal phalanx passing 4-0 Dacron sulures through two one millimeter drill holes made in the dorsal aspect of the neck of the proximal phalanx.

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.

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."

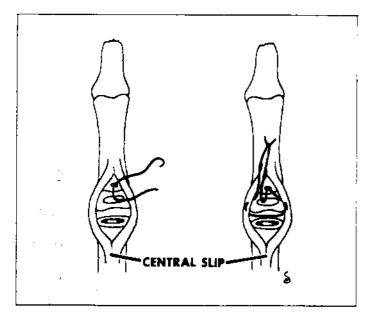


Fig. 11: Technique for repair and reattachment of the central slip to the middle phalanx passing a 3-0 Dacron suture through a one millimeter drill hole made in the dorsal aspect of the middle phalanx.

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 swanneck 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 of the by ODRH DID on 3/31/2023 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.

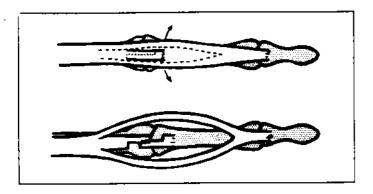


Fig. 12: Technique for a stiff swan-neck deformity. The central tendon is separated from the dorsally displaced taleral tendons, which are allowed to relocate paimarward. The central tendon is step-cut transversely and dissected proximally, thereby lengthening it. After insertion of the implant, the 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 pase 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.

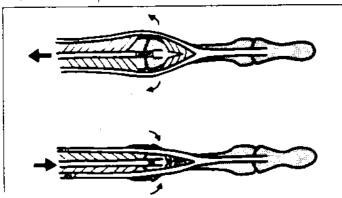


Fig. 13A: The preferred method for repair of the extensor mechanism in boutonniere deformity. The lengthened central tendon is advanced and the lateral tendons are released and relocated dorsaily by suturing their connecting fibers.

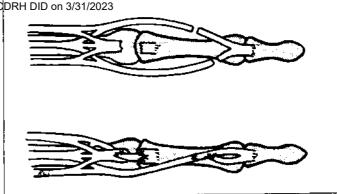


Fig. 13B: Mateu's method of repair of the extensor mechanism in a boutonniere deformity. A lateral tendon, usually on the radial side, is used to reconstruct the central tendon. The other lateral tendon is realtached in a relatively lengthened position distally.

### Post-Operative Care

The type of postoperative care depends on the situation presented.

# Stiff Proximal Interphalangeal Joint

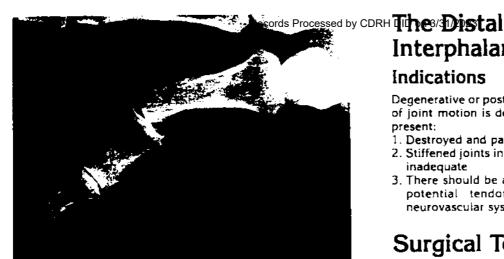
Active flexion/extension movements are started 3 to 5 days after surgery. The ideal range of motion would be full extension to 70 degrees of flexion. A small taped on padded aluminum splint to hold the digit in extension is worn mainly at night for 3 to 6 weeks after surgery depending on the degree of 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.

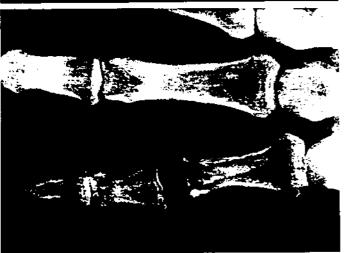
# Swan-Neck Deformity

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.





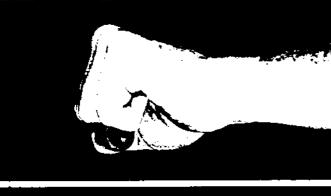




Fig. 14A: Long-standing dislocation of proximal interphalangeal joint of little finger in young athletic man. B: Roentgenogram showing excellent position and tolerance of implant 3 years after surgery. C and D: Patient recovered full use of hand with excellent flexion and extension

# 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
- 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.

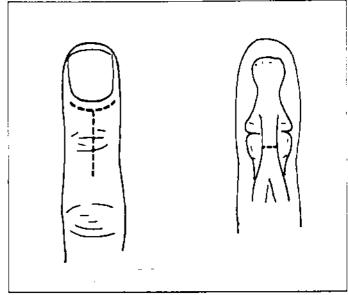


Fig. 15: Technique for implant arthroplasty of the distal interphalangeal joint: Fig. 15A: A "Y" shaped incision is made 3 mm. from the base of the nail and the skin flaps are elevated preserving the underlying tendon and the dorsal nerves and veins

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 salinRetbielsproxiesated by CDTFOID CREATE and Resterilize

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 counded 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.

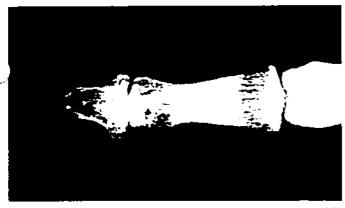


Fig. 16A: Post traumatic painful arthritis of distal interphalangeal joint of 3rd digit of a 35 year old man who desired a surgical procedure which would provide movement as well as pain relief.



Fig. 168: Post-operative silicone flexible hinged implant resection arthroplasty of distal interphalangeal joint. Patient has a stable, painfree, functional joint with ange of motion of .5° to 40°. This method offers an alternative to arthrodesis in selected cases.

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:

- 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 lvory Flakes or lvory 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).
  - 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 sillcone 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 Cliffical Case History

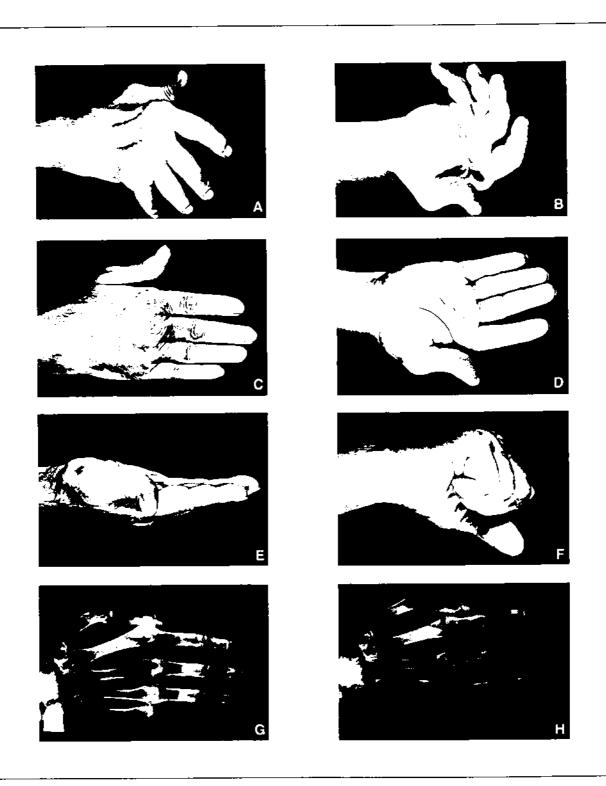
This 58 year old patient with an eight year history of Rheumatoid Arthritis had severe loss of function of the hands. He had marked ulnar drift and subluxation of the MP joints with extensor tendon subluxation and also Boutonniere deformity of the thumb. The patient had implant resection arthroplasty 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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- 47 Tubiana, R., Achach, P., and Rousso, M.: Les arthroplasties par implants en silicone au niveau de la main. Chirurgie, 96:1000-1004, 1970.
- <sup>48</sup>Weigert, M., and Gronert, H.J.: Silicon-Kautschuk in der Handchirurgie, Arch. Orthop. Unfall-Chir., 73:189-200, 1972.
- <sup>49</sup>Wessinghage, D.: Der Fingergelenksersatz als funktionsbessernde Massnahme, Physikal, Med. Rehab., 7(no. 14): 209-211, 1973.



# Typical Dimensions

1 000	<b>A</b>	<b>₹</b>		، ۲	$\int_{3}$		5	ے ا		\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		
-		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)
U	В	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)
	С	.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)

# 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





P.O. Box 100 Arlington, TN 38002 901-867-9971

66



Appendix D Drawing



Page 122 of 267

Withheld pursuant to exemption

(b)(4) Schematics



# 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



#### Records Processed by CDRH DID on 3/31/2023



#### Material Properties

Property	Test Method	Range
Tensile Strength Ultimate Elongation	ASTM D412 ASTM D412	1200-1500 psi 650-950
Tear Propagation Strength, Die B Durometer, Shore A	ASTM 642 ASTM 2240	190-300 45-55.5

Page 125 of 267

Withheld pursuant to exemption

(b)(4) testing

Page 126 of 267

Withheld pursuant to exemption

(b)(4) testing

Page 127 of 267

Withheld pursuant to exemption

(b)(4) testing

Page 128 of 267

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Page 129 of 267

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Page 147 of 267

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Page 148 of 267

Withheld pursuant to exemption

(b)(4) testing

Page 149 of 267

Withheld pursuant to exemption

(b)(4) testing

ACCELERATED FLEX TESTING OF

MDX-4-4515 AND SUTTER PEHT-40

SILICONE ELASTOMERS

By: Jim Christensen Sutter Biomedical August, 1981



Page 151 of 267

Withheld pursuant to exemption

(b)(4) testing

Page 152 of 267

Withheld pursuant to exemption

(b)(4) testing

Page 153 of 267

Withheld pursuant to exemption

(b)(4) testing

ABRASION TESTING OF

MDX-4-4515, DOW HP, AND SUTTER PEHT-40

SILICONE ELASTOMERS

By: Jim Christensen Sutter Biomedical August, 1981



Page 155 of 267

Withheld pursuant to exemption

(b)(4) testing

Page 156 of 267

Withheld pursuant to exemption

(b)(4) testing

Page 157 of 267

Withheld pursuant to exemption

(b)(4) testing

Page 158 of 267

Withheld pursuant to exemption

(b)(4) testing

SHEAR TESTING OF

MDX-4-4515, DOW HP, AND SUTTER PEHT-40

SILICONE ELASTOMERS

By: Jim Christensen Sutter Biomedical August, 1981



Page 160 of 267

Withheld pursuant to exemption

(b)(4) testing

Page 161 of 267

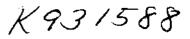
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(b)(4) testing

Page 162 of 267

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(b)(4) testing





#### 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.

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 \_\_\_\_\_\_\_\_.

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

Sincerely

Freedom of Information Staff
Office of Systems Management

Center for Devices and Radiological Health

Food and Drug Administration



MAR 1 0 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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## Page 2 - Ms. Louise M. Focht

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,

Fraul R. Beninger, M.D.

Director

Division of General and Restorative Devices Office of Device Evaluation Center for Devices and Radiological Health



## DO NOT REMOVE THIS ROUTE SLIP!!!!

K-93-1588

ORDIS

4/16/93

PJW

DUE DATE LETTER DATE LOGIN DATE FROM: 03/29/93 | 03/31/93 | 06/29/93 SUTTER CORPORA' ION ATTN: LOUISE M FOCHT TYPE OF DOCUMENT: 9425 CHESAPEAK: DRIVE 510 (k) SAN DIEGO, CA 92123 PHONE NO: 619-569-8148 ESTABLISHMENT NO: 2028601 SHORT NAME: STEER |CONT. CONF.: ? TO: STATUS : R ODE/DMC REV PANEL : OR PAN/PROD CODE(S): OR/ / / SUTTER PROXIMIL INTERPHALANGEAL JOINT DATE: / /
DATE: / /
DATE: / /
DATE: / /
DATE: / / INFO DUE DATE: DECISION: DATE: DECISION DATE: / / DATE: DATE: MAR 1 0 1994 DATE:

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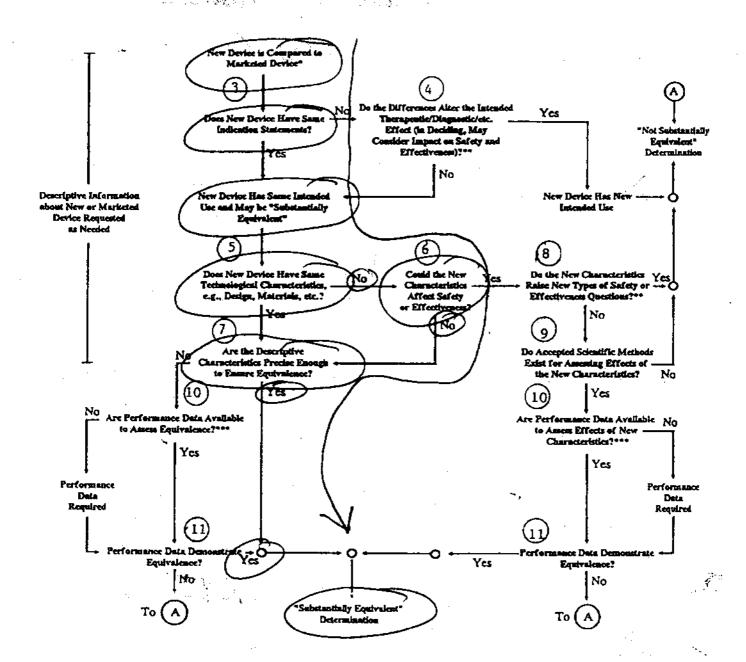


## Memorandum

Date	M = M = M = M = M = M = M = M = M = M =
From	REVIEWER(S) - NAME(S)
Subject	510(k) NOTIFICATION
To	THE RECORD
	It is my recommendation that the subject 510(k) Notification:
	(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 X
	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 Predicate Product Code w/panel and class:
	No Confidentiality
	Confidentiality for 90 days Additional Product Code(s) w/Panel (optional):
	Continued Confidentiality exceeding 90 days
	REVIEW: Deniel J. Melinar O DR BRANCH CODE (DATE)
	FINAL REVIEW: 3/18/49 (DATE)

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.

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<u>к</u> 9	3/588 "SUBSTANTIAL EQUIT	VALENCE" (SÈ)	DECISION MAK	ING DOCUME	ENTATION
REVI	EWER: MXM	_ DIVISION/BE	RANCH: D	GRD/	ORDB
TRAD	E NAME: SUTTEN PIP JT.	COMMON NA	AME: CONSTA	CAINED !	FNGER , POLYMEN
			K8703	100, 7	REAMENDMENTS
	(510(k) NUMBER IF KNOWN)	Swanson'	SILASTIC	FINGOR	
			YES (NO)		
1.	IS PRODUCT A DEVICE?		X	- IF N	O STOP
2.	DEVICE SUBJECT TO 510(k)?		X	- IF N	O STOP
3.	SAME INDICATION STATEMENT?		×	- IF Y	es go to 5
4	DO DIFFERENCES ALTER THE EFFEC OR RAISE NEW ISSUES OF SAFETY EFFECTIVENESS?			- IF Y	ES STOP -NE
51	SAME TECHNOLOGICAL CHARACTERIS	TICS?	×	- IF Y	ES GO TO 7
<b>6</b>	COULD THE NEW CHARACTERISTICS SAFETY OR EFFECTIVENESS?	AFFECT		- IF Y	ES GO TO 8
7.	DESCRIPTIVE CHARACTERISTICS PR ENOUGH?	ECISE	×		O GO TO 10 ES STOP -SE
<b>B</b>	NEW TYPES OF SAFETY OR EFFECTI QUESTIONS?	VENESS		- IF Y	ES STOP -NE
9.	ACCEPTED SCIENTIFIC METHODS EX	IST?		- IF N	O STOP -NE
10.	PERFORMANCE DATA AVAILABLE?			- IF N	O REQUEST DATA
(11)	DATA DEMONSTRATE EQUIVALENCE?				
– NOTI	TO ADDITION TO COMPLETING PA	GR TWO. *YES*	RESPONSES TO	OURSTIONS	S 4. 6: 8. AND

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

3/10/94 mnm DATE: 3/7/94

FROM: M.N. MELKERSON, Engineer

Center/Office: CDRH/ODE Division/Branch: DGRD/ORDB

TO: File

Document Number: K931588 Proximal InterPhalangeal (PIP) Joint Prosthesis, Common Name:

Finger & Toe

Sutter, Proximal Interphalangeal Joint Prosthesis Trade Name: 21 CFR 888.3230, Finger Jt. Polymer Classifications: 1)

Constrained Prosthesis

Class: II

Product Codes: KYJ: Finger Products To Which Compared:

Preamendments Dow Corning Wright (Wright Medical), Swanson Silastic 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





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?

Is this device a kit? no

#### MATERIALS:



## "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. -
- 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 crosssectional 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: 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

<u>RESPONSE</u>: Sponsor removed all recommendations for resterilization either by steam or ETO.



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This page represents \_\_\_\_\_ whole page redaction(s).

510 (k) Number: 931588

# SUTTER CORPORATION SMALL JOINT ORTHOPAEDICS

9425 CHESAFEAKE DRIVE SAN DIEGO, CA 92123 TFI (ROO) 854-7216 FAX (619) 279-8249

March 8, 1994

Food and Drug Administration 150 (k) Document Mail Center (HPZ-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
- Cobalt 60
- 3. Minimum dose 25 kGy, Maximum dose
- Sterility Assurance Level 10E-6
- Sterilization Validation according to AAMI Method 1. Routine audit is performed using AAMI Method 3B.
- 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(12IC) for 35-40 minutes (standard cycle). Ethylene oxide gas sterilization may be used but is not recommended because of the aerotion time necessary to dissipate the absorbed sterilant from the silicone elastomer.

Labeling for implants is being changed to the following:

12 19



### 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 othylene oxide gas sterilization, see below)

1.	Temperature	54°C	±1°C
2.	Humidity	60%	±10%
			* * * * * * * * * * * * * * * * * * * *

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.	Cyclc	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:

### Starilization:

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

13 R



gravity sterilization at  $250^{\circ}$  F (121° C) for 35-40 min, or prevacuum sterilization at  $270^{\circ}$  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.

Sincercly,

Louise M. Focht

Director of Regulatory Affairs

619-569-8148x 2213

14

OI CENTRO

510(k) SUBMISSION

CHECKLIST

x 931588

Based on the draft Orthopedic 510(k) Guidance Document, the information checked in the "MC" column is missing and must be addressed before the review can begin.

	Additional Information Required
MANUFACTURER IDENTIFICATION	Ö
DEVICE IDENTIFICATION	Li .
PROPOSED REGULATORY CLASS.	
INTENDED USE	ם
	ä
DEVICE DESCRIPTION	a
MATERIALS	
LABELING	۵
TESTING OR OTHER ADDITIONAL INFORMATION	
INFORMATION	
	П
STERILITY INFORMATION	а
PACKAGING DESCRIPTION	L
SUBSTANTIAL EQUIVALENCE INFORMATION	Ē
That a man is	
TUCK) SUMMARY OR STATEMENT	٥

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 sufficientletailto enable

Recommendation:

proceed with a comprehensive review of the document ☐ issues modified K-OR-3.A1 Letter

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Public Health Service

Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation Document Hail Center (HFZ-401) 1390 Piccard Drive Rockwille, Maryland 20850

APRIL 16, 1993

SUTTER CORPORATION ATTN: LOUISE M. FOCHT 9425 CHESAPBAKE DRIVE SAN DIEGO, CA 92123

510(k) Number: K931588 03-31-93 Received:

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, excliding 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

16

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 bonor 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

Food and Drug Administration 510(k) Document Mail Center (HFZ-401) 1390 Piccard Drive Rockville, MD 20850 K931588

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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Material testing performed includes:



## 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.

. 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

Director Quality Assurance

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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 THE

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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- b. Classification Name Prosthesis, Finger and Toe
- 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.

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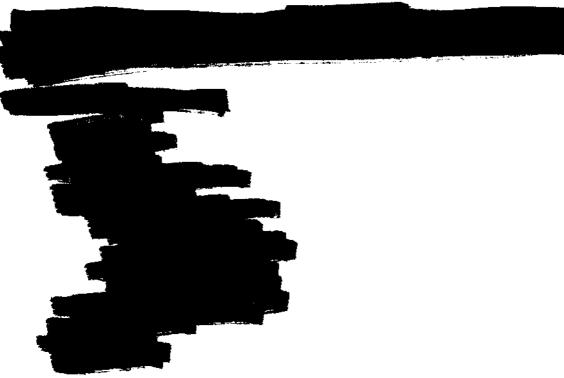
The Sutter implant is substantially equivalent in materials, design principle and intended clinical function to Dow Corning Wright implants. The Silastic Finger Joint Implant manufactured by Dow Corning Wright is used in the metacarpophalangeal (MP), proximal interphalangeal (PIP) and distal interphalangeal (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.

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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.



## 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 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

Director Quality Assurance

ouis M. Forht

Sutter Corporation 619-569-8148 x 2213

Enclosures:

Appendix A

Proposed Labeling

Appendix B

Surgical Technique

Appendix C

Equivalent Product Literature

Appendix D

Drawing



## SUTTER CORPO **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 submission is to notify the Agency of our intent to market a new device as an extension of our ordinal implant product line. We intend to continue production and distribution of our other devices.

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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

PERFORMANCE STANDARDS: 4.

N/A

### REPRESENTATIVE LABELING: 5.

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.

### SIMILARITIES TO DEVICES IN DISTRIBUTION: 6.

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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MEMO RECORD

3/10/94 MMM 3/19/94 DATE:

FROM: M.N. MELKERSON, Engineer

Center/Office: CDRH/ODE Division/Branch: DGRD/ORDB

TO: File

Document Number: K931588

Common Name: Proximal InterPhalangeal (PIP) Joint Prosthesis,

Finger & Toe

Sutter, Proximal Interphalangeal Joint Prosthesis Trade Name: 21 CFR 888.3230, Finger Jt. Polymer 1) Classifications:

Constrained Prosthesis

Class: II

Product Codes: KYJ: Finger Products To Which Compared:

Preamendments Dow Corning Wright (Wright Medical), Swanson Silastic 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

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?

Is this device a kit? no

## MATERIALS:

## "BUBSTANTIAL 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 crosssectional areas) and should not adverse effect the mechanical properties of the device. The modifications did not change ratios of dimensions.

- IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE 7. CHARACTERISTICS ARE NOT PRECISE ENOUGH. - Yes, the sponsor supplied drawings with dimensions allowing for the comparison to predicates dimensions and geometry.
- IF THE ANSWER TO QUESTION 8 IS YES OR NO, EXPLAIN THE NEW 8. TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW. - N/A
- IF THE ANSWER TO QUESTION 9 IS NO, EXPLAIN WHY THE EXISTING 9. SCIENTIFIC METHODS CAN NOT BE USED. - N/A
- IF THE ANSWER TO QUESTION 10 IS NO, EXPLAIN WHAT PERFORMANCE 10. DATA IS NEEDED. - N/A
- IF THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE 11. 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 sterils. Radiation Type: gamma, Radiation source: 1 Sterility validation method: And 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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This page represents 21 whole page redaction(s).

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: ji This page represents 29 whole page redaction(s).

29



Appendix A Proposed Labeling

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Page 193 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 194 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 195 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 196 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 197 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

Page 198 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling

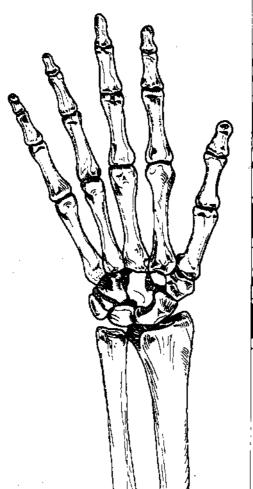
Page 199 of 267

Withheld pursuant to exemption

(b)(4) Draft Labeling



Appendix C
Equivalent product literature



# Sutter Implants for the Hand and Forearm

SUTTER CORPORATION BIOMOTION SPECIALISTS®

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## Proximal Radius Implant

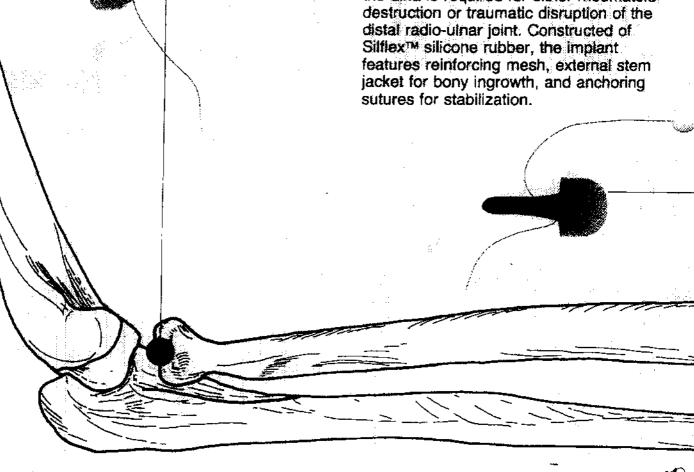
The Sutter Proximal Radius Implant replaces the proximal radial head when radial head resection is indicated in the presence of rheumatoid degeneration. traumatic arthritis, or radial head fracture. The implant has a smooth Silflex Misilicone articular head and a stem with a polyester ingrowth surface for stability. Immediate stabilization is possible with the anchoring sutures.

## Carpometacarpai Impiant

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 ballin-socket prostnesis 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 sutures for stabilization.







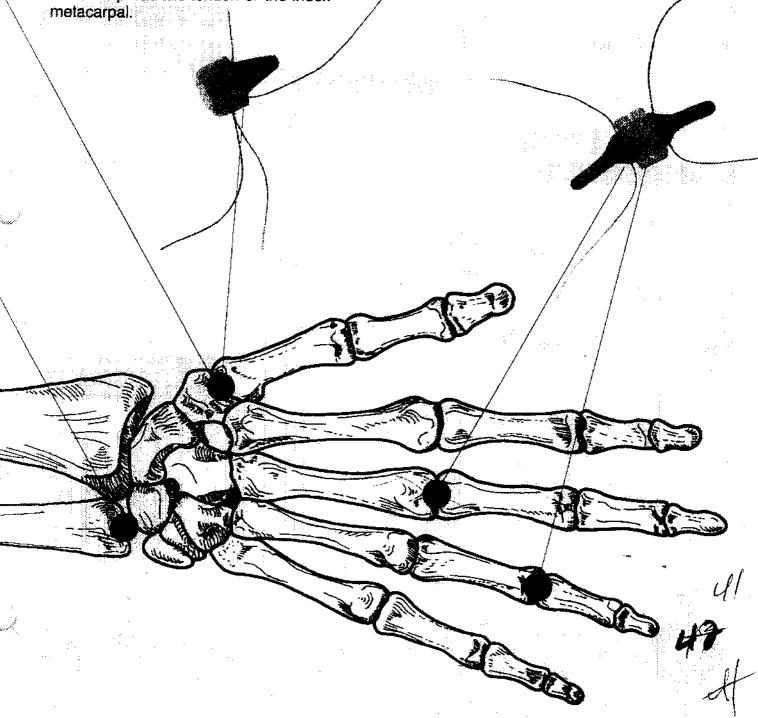
## Trapezium Implant

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 flexer carpi radialis tendon or the index

## Finger Joint Implant\*

\*U.S. Palent Number 3,593,342

The Sutter Finger Joint Implant is a total joint replacement for the metacarpophalangeal and proximal interphalangeal joints. The prosthesis consists of Sifflex™ 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.



Finger Joint Implant		
Catalog		
Number	Siza	
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	

Finger Joint Broach		
Catalog	· · ·	
Number	Size	
FJBR-00	00	
FJBR-10	10	
FJBR-20	20	
FJBR-30	30	
FJBR-40	40	

30

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**MPIP-305** 

**MPIP-405** 

Standard Stem Trapezium Implant	
Catalog	
Number	Size
TR-10	10
TR-20	20
TR-30	30
Stzer	
Catalog	
Number	Size
TR-105	10
TR-205	20
TR-305	30

Short Stem Trapezium Impla	nt
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	

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	

Distal Ulnar Implant			
Catalog			
Number	Size		
UH-10	10		
UH-20	20		
UH-30	30		
<u>UH-40</u>	40		
Sizer			
Catalog			
Number	Size		
UH-105	10		
UH-205	20		
UH-305	30		
UH-405	40		

implant	
Catalog	
Number	Size
TMC-10	Small
TMC-20	Medium
TMC-30	Large
TMC-15	Replacement Head
TMC-25	Replacement Head

Carpometacarpal

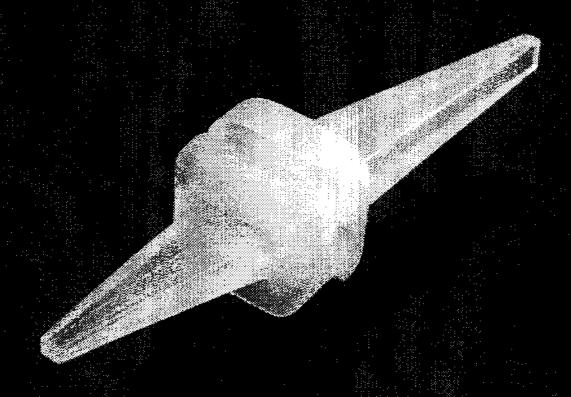
- · All Sutter implants, except for the Carpometecarpal Implants, are shipped presterilized by gamma radiation.Sizers are not for implantation.



SUTTER CORPORATION BIOMOTION SPECIALISTS®

9425 CHESAPEAKE DRIVE SAN DIEGO, CA 92123 (619) 569-8148 | FAX: (619) 279-8249 | (800) 854-2216 Siffex is a trademark of Sutter Corporation © Sutter Corporation 1983. All rights reserved.

## Now. A full range of motion. No volar impingement. Same surgical technique.

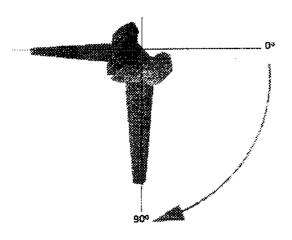


Introducing the Sutter MCP\*\* Finger Joint Prosthesis.

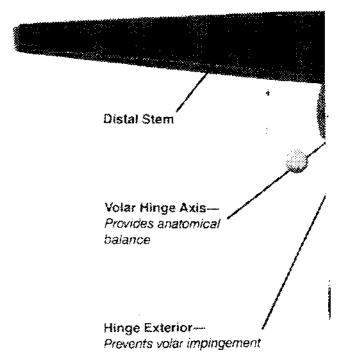
## Biomechanically engine

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.

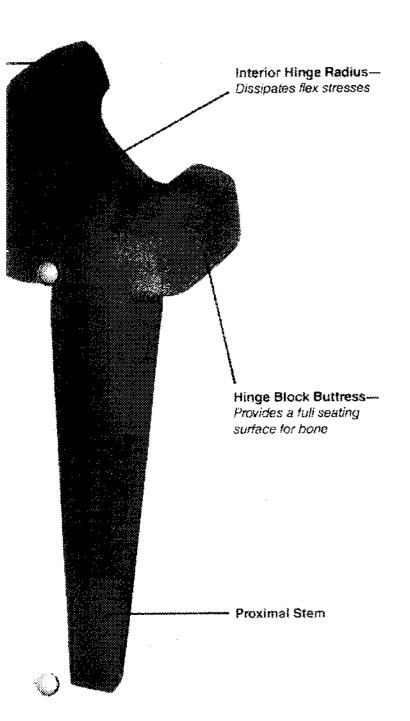


Closely Duplicates Normal Elliptical Joint Motion Bevelled Hinge Block— Allows anatomical glide of tendon



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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.



## The Complete Sutter

## Compiete 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.]

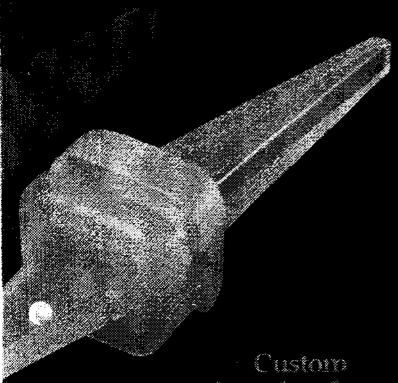
The MCP System also includes the surgical technique reference in print and video versions. The video is available in 1/2" VHS format.

## 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 colorcoding 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 postsurgical 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 handheld broach or awl. An alterna-

tive is the use of power equipment such as a small burr or oscillating

broach head.







## 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<sup>™</sup> 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 extensox apparatus.

### TYPICAL DIMENSIONS

	\$0 20 30 40 50 1 60	A B C 618/15/7 206/15/7 48/85/2 691/17/6 244/66/10 514/13/1 768/19/5 266/9/6 602/15/3 890/22/6 280/7/1 700/17/8 103/26/2 30/8/7/8 811/20/6 16/29/5 240/8/6 962/22/9 284/32/6 384/8 1.009/25/4 SIZE -INCHES/MHILIMETERS	.245/6.2 .484/12.4
TO ORDER Sizer	implant	Broaches	Broaches, cont.
CATALOG           NUMBER         SIZE           MCP-000         90           MCP-005         10           MCP-205         20           MCP-305         30           MCP-405         40           MCP-505         50           MCP-605         60	CATALOG NUMBER SIZE MOP-00 00 MCP-00 10 MCP-26 20 MCP-36 30 MCP-40 40 MCP-80 50 MCP-60 60	CATALOC NUMBER MER-MOO Broach MBR-P10 Broach MBR-P10 Broach MBR-P10 Broach MBR-P20 Broach MBR-P20 Broach MBR-P20 Broach MBR-P20 Broach MBR-P20 Broach MBR-P30 Broach MBR-P30 Broach MBR-P40 Broach MBR-P40 Broach MBR-P40 Broach MBR-P40 Broach MBR-P40 Broach MBR-P40 Broach MBR-P50 Broach MBR-P50 Broach MBR-P50 Broach MBR-P50 Broach MBR-M50 Broach MBR-M50 Broach MBR-M50 Broach MBR-M60 Broach MBR-M60 Broach MBR-M60 Broach MBR-P60 Broach MBR-P60 Broach MBR-P60 Broach MBR-P60 Broach MBR-P60 Broach MBR-P60 Broach	CATALOG NUMBER MBR-S Instrument/Sizer Set 14 Broaches 1 Awl 1 Double-Ended Rasp 7 Sizers 1 Custom Sterilization Tray  MISCELLANEOUS Double-eraled MCP Rasp RSP-001 MCP Awl SAL-002  Custom Sterilization Tray CST003



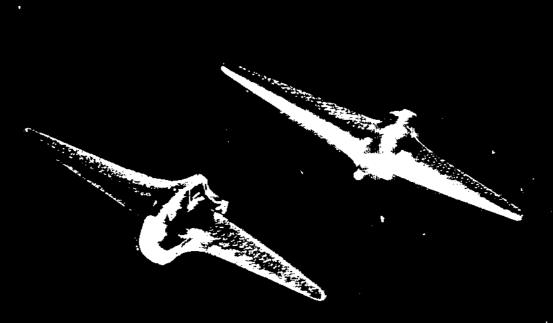




## BRAND

## Finger Joint Implant H.P.

(Swanson\* Design)



DIOMINGSMING

4 pain constso

WINGH

## 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.<sup>46</sup>

## 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 sillcone 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

- i. 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
- 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

## чеопееры органиаціо 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 impostability. 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 forcespare 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 excessed by CDRH DID on 3/31/2023 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 arthropiasty, 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 arthropiasty 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.

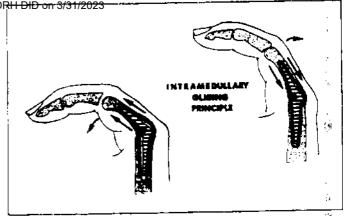


Fig. 1: The stems of the Silastic\* implant are included in the encapsulation process and the implant glides within the intramedullary canals a distance of 1 or 2 mm. on flexion/extension movements. This gliding allows a greater range of motion to occur and permits the implant to find the best position 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.
- Contracted intrinsic and extrinsic musculature and ligament system.
- 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





Records Processed by CDRH Dip 1003/31/2022 abductor digiti minimi is exposed on the

Fig. 2: The dislocated extensor tendon is released by incision on its ulnar border The ulner intrinsics are released if light. The segittal 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.

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.

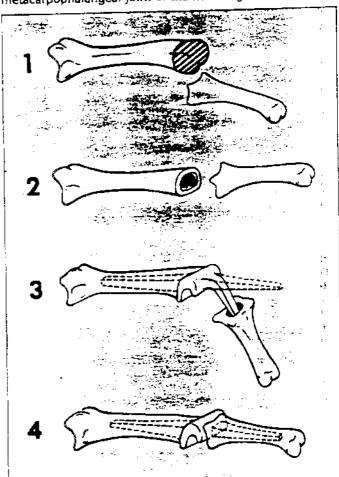


Fig. 3: Resection of metacarpal head and insertion of implant stems into intramedullary canal. Use the largest implant that can be properly sealed. The appropriate joint space should be obtained by bone removal and if necessary soft lissue release. Bone should be removed from the metacarpal head and also the base of the proximal phalanx particularly if it is eroded. A comprehensive soft lissue 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 Receivest 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.

end. The largest implant possible should be resed de replaces of by CDRMetiguipons reverges and correction of the balance of the sizes 4 through 9 are generally used. A rectangular hole is capsuloligamentous and musculotendinous structures will be rewarded by improved results.

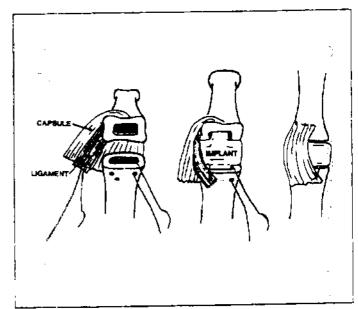


Fig. 4: Radial collateral ligament reconstruction: A: The radial collateral ligament and joint capsule are incised from their attachment to the neck of the metacarpal. Two small drill holes (1mm) are made on the radio-dorsal aspect and one small drill hole is made on the dorsal ulnar aspect of the neck of the metacarpal.

BEC: 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.

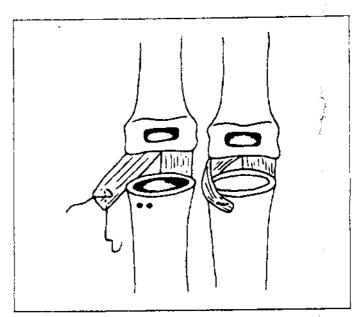


Fig. 5: Collateral ligament reconstruction at the MP joint when the radial collateral ligament is inadequate: The palmar plate and its attachments are incised longitudinally through the middle. The sesamoid bone, if present, is resected. A distally based flap is made from the radial half of the palmar 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.



of active flexion; this is especially true of the little finger, Records Processed by CDRH DID on 3/3/2020 Reak 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 siing 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.

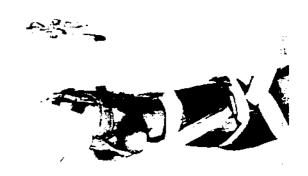


Fig. 7: The flexion cuff may be used intermittently to assist flexion movements. Proper use of bracing is essential to insure an adequate range of mo

Post-Operative Care and Bracing

wrapped in a conforming bandage such as Kling.

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

long with a Furacin or alternate gauze overlay. A

columinous 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

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 airis removed. Swelling is generally minimal so use of the ...ynamic 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 1/4" 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 ilmits 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. be tension of the rubber bands should be tight enough to support the digits and yet loose enough to allow 70 degrees





<sup>\*</sup>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<sup>42</sup>(Fig. 8).

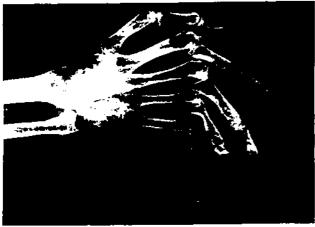


Fig. 8A: Preoperative radiogram showing severe and typical deformities in a rheumatoid hand.



Fig. 8B: Radiogram 4 years after implant arthropiasty 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.
- 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 Arthritle Joint: A: The longitudinal "5" shaped incision is made over the dorsum of the PIP joint. B: The extensor mechanism is incised longitudinally and proximally om 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 lightly contracted, the bone may have to be removed piecemeal before the lendon 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 Othrough 4 are usually used for PIP arthroplasty. Implant in place with the linger in extension. Proper bone removal and soft lissue 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 swamneck 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

sed by CDRH DID on 3/31/2023 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 middie 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).

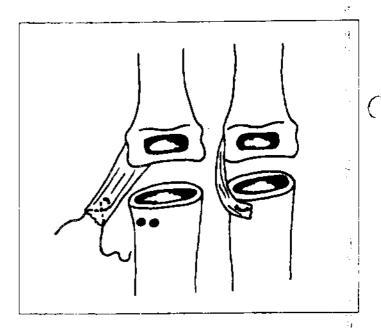


Fig. 10: Technique for reattachment of the collateral ligament of the proximation terphalangeal joint to the neck of the proximal phalanx passing 4-0 Dacron sutures through two one millimeter drill holes made in the dorsal aspect of the neck of the proximal phalanx.

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

Gising 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 metacar-pophalangeal 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."

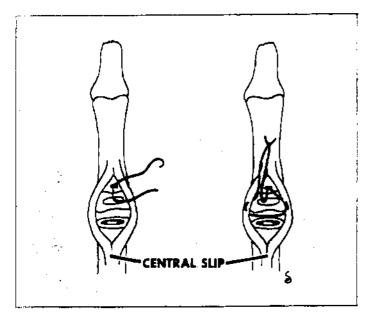


Fig. 11: Technique for repair and reattachment of the central slip to the middle phalanx passing a 3-0 Decron suture through a one millimeter drill hole made in the dorsal aspect of the middle phalanx.

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 haives 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 swanneck 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 flexal

Sirease the flex

ion force on the proximal interphalangeal joinstatisting classed by CDRH DID on 3/31/2023 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.

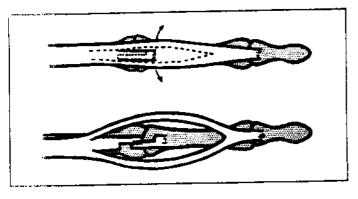


Fig. 12: Technique for a stiff swan-neck deformity. The central tendon is separated from the dorsally displaced lateral tendons, which are allowed to relocate palmarward. The central tendon is step-cut transversely and dissected proximally, thereby lengthening it. After insertion of the implant, the cut ends of the central tendon are reapproximated with interrupted sutures, with the knots

## **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 pase 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.

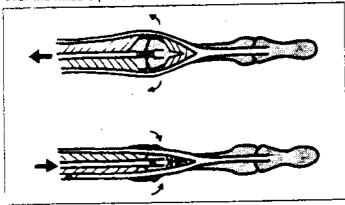


Fig. 13A: The preferred method for repair of the extensor mechanism in boulon niere deformity. The lengthened central tendon is advanced and the lateral tendons are released and relocated dorsally by suturing their connecting libers.

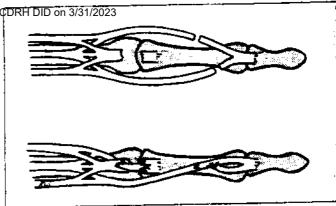


Fig. 13B: Mateu's method of repair of the extensor mechanism in a boutonniere deformity. A lateral tendon, usually on the radial side, is used to reconstruct the central tendon. The other lateral tendon is reattached in a relatively lengthened position distally.

## Post-Operative Care

The type of postoperative care depends on the situation presented.

## Stiff Proximal Interphalangeal Joint

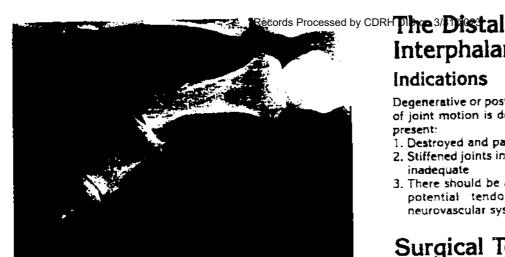
Active flexion/extension movements are started 3 to 5 days after surgery. The ideal range of motion would be full extension to 70 degrees of flexion. A small taped on padded aluminum splint to hold the digit in extension is worn mainly at night for 3 to 6 weeks after surgery depending on the degree of 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.

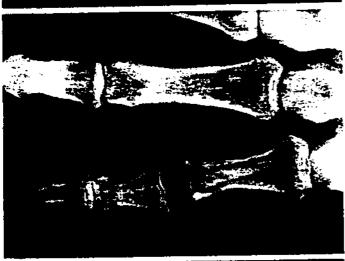
## Swan-Neck Deformity

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 week





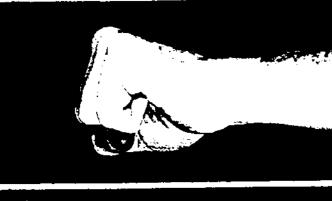




Fig. 14A: Long-standing dislocation of proximal interphalangeal joint of little linger in young athletic man. B: Roentgenogram showing excellent position and tolerance of implant 3 years after surgery. C and D: Patient recovered full use of hand with excellent flexion and extension

# 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

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 is then selected. The cut bone ends must be smoothened.

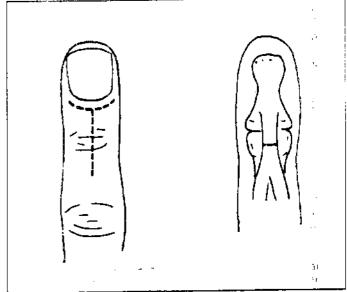


Fig. 15: Technique for implant arthropiasty of the distal interphalangeal joint: Fig. 15A: A "Y" shaped incision is made 3 mm. from the base of the nail and the skin flaps are elevated preserving the underlying tendon and the dorsal nerves and veins.

Fig. 15B: the extensor tendon is incised transversely one centimer proximal to the distal interphalangeal joint and carefully elevated from the bone.



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.

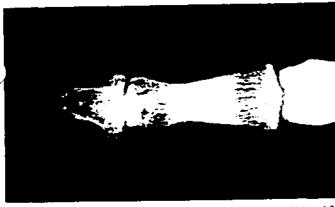


Fig. 16A: Post traumatic painful arthritis of distal interphalangeal joint of 3rd digit of a 35 year old man who desired a surgical procedure which would provide movement as well as pain relief.

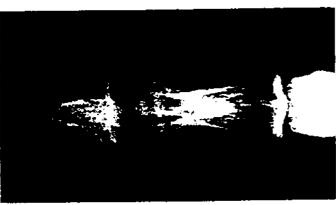


Fig. 16B: Post-operative silicone flexible hinged implant resection arthroplasty of distal interphalangeal joint. Patient has a stable, painfree, functional joint with ange of motion of -5° to 40°. This method offers an alternative to arthrodesis in selected cases.

## Following irrigation of the wound with saline, the progressed by CDTH DICT 23112023 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
- 2. Rinse thoroughly with distilled water.
- 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% (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

### 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 Cinical Case History

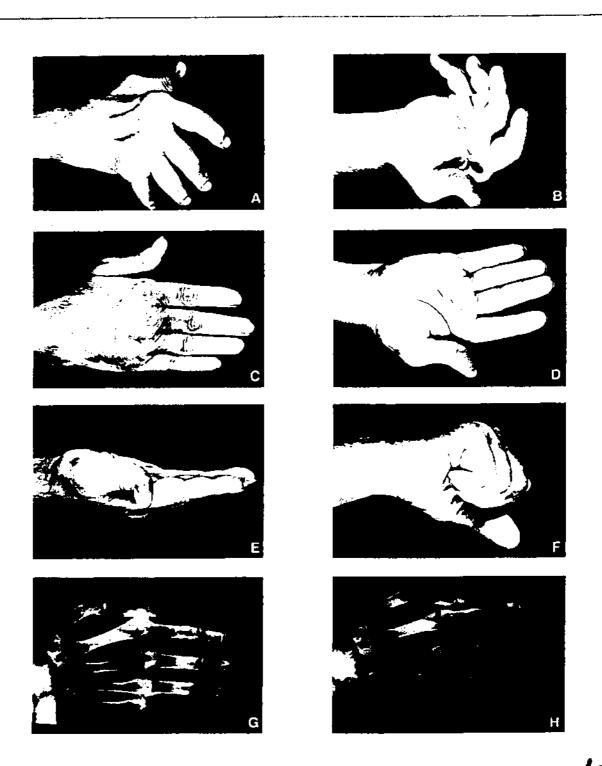
This 58 year old patient with an eight year history of Rheumatoid Arthritis had severe loss of function of the hands. He had marked ulnar drift and subluxation of the MP joints with extensor tendon subluxation and also Boutonniere deformity of the thumb. The patient had implant resection arthroplasty 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.



E 63

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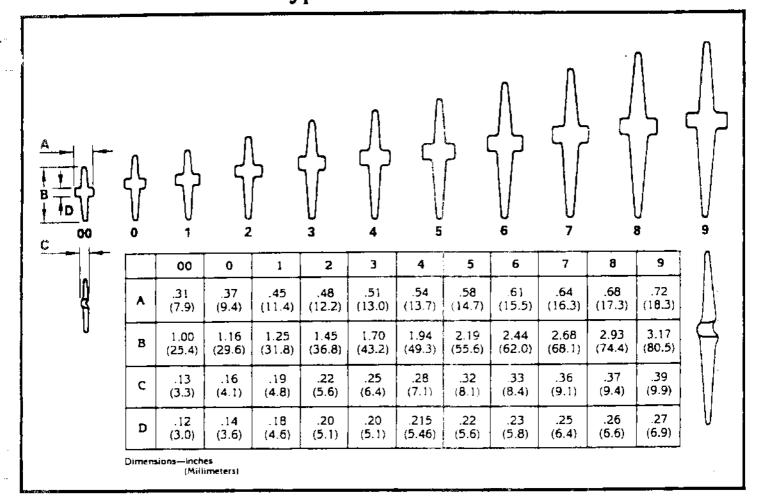
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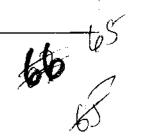
#### Records Processed by CDRH DID on 3/31/2023 I ypical Dimensions



## How Supplied

The SILASTIC® Finger Joint Implant H.P. (Swanson Design) has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
I 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
I 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 sizíng 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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P.O. Box 100 Arlington, TN 38002 901-867-9971

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Appendix D Drawing



## Memorandum

Dave 3-15-94

Mark Wright , Clerk-Typist, (CDRH, ODE, DMC) HFZ-401 From Subject Premarket Notification Number(s) K931588[A] Division Director Yσ 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 M Mulhern

Panel:

Date:

OR

3/15/14 101

Attachment

Re: Device Name Dated: Received:

Dear	The Collection
ucar ———	<del></del>
referenced it does not design, com referenced responsibilits labeling effectivened you have supposed to the su	notification (K ) previously submitted for the device above. Based solely on the information that you have provided, appear that you have significantly changed or modified the above (see 21 CFR 807.81(a)(3)). It is, however, your ity to determine if the change or modification to the device or gould significantly affect the device's safety or applied will be added to the file.
contact	any questions regarding the contents of this letter, please 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 Facht

9425 CHESAPEAKE DRIVE SAN DIEGO, CA 92123 TEL (800) 854-2216 FAX (619) 279-8249

March 8, 1994

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

- Gamma Sterilization
- 2. Cobalt 60
- Minimum dose 25 kGy
- Sterility Assurance Level 10E-6
- 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:

104



510 (k) Number: 51588 5



### 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)

ì.	Temperature	54°C	±1°C
2.	Humidity	60%	±10%

6-7 psig of 12/88 Ethylene Oxide/dichlorodifuoromethane. 3. Gas concentrations

4 hours Exposure time 4. 18 hours 5. Aeration cycle

## STEAM STERILIZATION METHOD

1.	Cycle	Standard Gravity
2.	Temperature	250°F (121°C)
3.	Exposure time	35-40 min.

Prevacuum 1. Cycle 270°F (132°C) 2. Temperature 15-20 min. 3. Exposure time

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:

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