Indications for MatrixPRO[®] II Driver

INDICATIONS:

- The MatrixPRO® II Driver has been designed and tested for thoracic and mandible surgery applications with DePuy Synthes MatrixMANDIBLE, MatrixRIB, and Titanium Sternal Fixation System screws listed below...
 - 2.0 mm Ø MatrixMANDIBLE Self-Drilling Locking screws 6 8 mm lengths (04.503.546, 04.503.548)
 - 2.0 mm Ø MatrixMANDIBLE Self-Tapping Locking screws 5−18 mm lengths (04.503.605, 04.503.606, 04.503.608, 04.503.610, 04.503.612, 04.503.614, 04.503.616, 04.503.618)
 - 2.4 mm Ø MatrixMANDIBLE Self-Tapping Locking screws 8−18 mm lengths (04.503.638, 04.503.640, 04.503.642, 04.503.644, 04.504.646, 04.503.648)
 - 2.9 mm Ø MatrixMANDIBLE Self-Tapping Locking screws 8−18 mm lengths (04.503.668, 04.503.670, 04.503.672, 04.503.674, 04.503.676, 04.503.678)
 - 2.9 mm \varnothing MatrixRIB Self-Tapping Locking screws 6–20 mm lengths (04.501.016, 04.501.018, 04.501.020, 04.501.022, 04.501.024, 04.501.028, 04.501.030)
 - 2.9 mm Ø MatrixRIB Self-Drilling Locking screws 8 −20 mm lengths (04.501.208, 04.501.210, 04.501.212, 04.501.214, 04.501.216, 04.501.218, 04.501.220)
 - 3.0 mm \varnothing Ti Sternal Self-Drilling Locking screws 10–20 mm lengths (04.501.110, 04.501.112, 04.501.114, 04.501.116, 04.501.118, 04.501.120)
 - 3.0 mm Ø Ti Sternal Self-Tapping Locking screws 10–24 mm lengths (413.580, 413.582, 413.584, 413.586, 413.588, 413.590, 413.592, 413.594)

CONTRAINDICATIONS:

Use of the MatrixPRO® II Driver to drive screws other than DePuy Synthes MatrixMANDIBLE®, MatrixRIB®, and Titanium Sternal Fixation System **locking screws** may result in the torgue-limiting feature not functioning properly, and should therefore never be attempted.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information. CAUTION: USA Law restricts these devices to safe by or on the order of a physician. Not all products are currently available in all markets.

Distributed by (United States): Manufactured by (United States):

Synthes USA Products, LLC 1302 Wrights Lane East West Chester, PA 19380 To order (USA): 800-523-0322 To order (Canada): 844-243-4321 Fax: (866) 851-9339

Pro-Dex, Inc. 2361 McGaw Avenue Irvine, CA 92614 Telephone: (800) 562-6204



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Ready to go. Knows when to stop.

MatrixPRO[®] II Driver

VERSATILE. ADAPTABLE. INTELLIGENT.





Matrix PRO[®] II Driver

The MatrixPRO[®] II Driver's patented Adaptive reliability and versatility in screw insertion.



Torque Limiting technology delivers



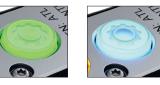
Patented Adaptive Torque Limiting Technology is designed to detect when a screw is seated and/or

locked to the plate and cuts power to the motor to prevent stripping.



Dynamic mode settings provide versatility, with the ability to disengage ATL for full torque drilling.

Green - ATL Blue - NTL



Non-torque Limiting (NTL) mode disengages Adaptive Torque Limiting allowing for full torque drilling.



Hex Collet

Interchangeable collets are compatible with existing DePuy Synthes hex and j-latch driver blades and drill bits to reduce equipment needed in the OR.

90-Degree collets (short & long) interface with the DePuy Synthes 90-Degree Screw driver for powered cordless insertion during a minimally invasive approach.

Instructions for use overview*



Insert Collet

To install the collet, orient the nose cone away from the driver and slowly rotate the collet attachment as necessary while pushing it into the driver until it seats into the collet cavity and a click is heard from the locking mechanism. Firmly pull on the collet attachment to confirm that it is locked in place.



Insert Bit/Blade/Accessory

To install the screwdriver blade, insert the proximal end of the blade or into the collet attachment. Once inserted depress the collet grip spring assembly and rotate the screwdriver blade until it has fully seated into the collet then release the collet grip spring assembly to lock the screwdriver blade in place. Gently pull on the screwdriver blade to confirm that it is locked in place.



Insert Battery

To install the MatrixPRO[®] II Single Use Battery, orient the Driver so the buttons are facing down. Open the battery door by pulling the door latch in the direction of the arrow located on the door latch while opening the battery door completely. Hold the battery with the contacts facing down and the flat edge of the battery facing the flat edge of the battery cavity. Insert battery into the cavity. Once the battery is approximately one-third of the way into the device, release the battery so it can drop into the cavity. Close the battery door until it engages with the latch and locks the door securely in place. Gently pull on the battery door to confirm that it is locked in place.

* The above steps are only an overview of the complete instructions for use required for the MatrixPRO[®] II Driver. Prior to performing any surgical procedure with the MatrixPRO[®] II Driver, please ensure to fully review the MatrixPRO[®] II Driver Instructions For Use (IFU), which includes full instructions for use, indications, contraindications, warning, and precautions.



Self-diagnostics Check

After battery insertion the hand piece will be ready to use. To operate, press either the Forward or Reverse button and hold for at least 2 seconds to start the internal self-diagnostic check. The buttons will illuminate green (forward button), yellow (reverse button) and green (mode button). Directly below the three buttons, 3 green L.E.D. lights will indicate the charge level of the battery.



(optional) Drill

Pre-drilling Holes (If Required): Ensure the Driver is in NTL Mode, indicated by the mode button being illuminated blue, and the correct collet is attached to the MatrixPRO[®] II Driver. Position the tip of the drill bti on the bone in desired location and hold down the forward button and drill until desired hole depth is achieved.



Load Screw

Select the appropriate length screw and align the screw driver blade with the screw head recess and push down to engage the screw head.

Instructions For Use Overview (continued)*



Insert Screw

Ensure the driver is in ATL Mode indicated by the mode button being illuminated green. Position the tip of the screw on the bone in the desired location and hold down the forward button and drive the screw until the device stops. Once the screw is seated, remove the users finger from the button and gently rock the hand piece once from side to side to release the screwdriver blade from the screw head.



After Use, Remove Battery, Screw Driver Blade and Collet Attachment

To remove the battery, position the driver so that the handle is pointing up. Pull back on the battery door latch and pull open the battery door. Pick up the battery to remove the battery from the hand piece. Do Not Remove the battery with the handle facing downward, removal of the battery with the handle facing down may cause the battery to fall out To remove the screw driver blade, drill bit or accessory see collet attachment instructions for use. To remove the collet attachment press the collet release lever at the bottom nose of the handpiece. Hold in that position while removing the collet attachment from the nose of the handpiece.

Installation of the MatrixPRO[®] II Driver 90° Collet and Shaft for 90° Screwdriver



To install the MatrixPRO[®] II 90° Collet orient the threaded end away from the Driver and slowly rotate the collet attachment as necessary while pushing it into the Driver until it seats into the collet cavity and a click is heard from the locking mechanism.

Firmly pull on the collet attachment to confirm that it is locked in place.



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To install the Shaft for 90° Screwdriver, slide the locking nut towards the most distal end.

Align the partial shaft collar on the Shaft for 90° Screwdriver housing to the corresponding relief cut on the MatrixPRO[®] II 90° Collet.

Turn the Shaft for 90° Screwdriver assembly to ensure the housing is fully inserted and bottomed out on the MatrixPRO[®] II 90° Collet.

Thread the Shaft for 90° Screwdriver locking nut onto the threads on the MatrixPRO[®] II 90° Collet.

Hand-tighten the locking nut to the MatrixPRO[®] II 90° Collet until it can no longer be turned.



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Insert Screw

Ensure the driver is in ATL Mode indicated by the mode button being illuminated green. Position the tip of the screw on the bone in the desired location and hold down the forward button and drive the screw until the device stops. Once the screw is seated, remove the users finger from the button and gently rock the hand piece once from side to side to release the screwdriver blade from the screw head.





Cleaning and Sterilization

The MatrixPRO II Driver Hand Piece (05.000.030) <u>must be cleaned and sterilized</u> after every patient use according to the following guidelines:

Important: Ensure the battery has been removed.

Ensure the collet attachment has been removed. Clean and sterilize collet attachment per separate IFU.

The device should be cleaned within 30 minutes after use, preferably immediately after use, to minimize debris drying & caking on the device.

Rinse the device with warm distilled or warm soft tap water. Gently scrub the device in multiple directions with a clean soft nylon brush or a clean, soft, lint-free cloth until all visible debris has been removed.

Mechanical Cleaning Method:

- Mechanical Cleaning must be performed with the MatrixPRO[®] II Driver inside the MatrixPRO[®] II Driver Graphic Case (60.000.015).
- A Neutralize cycle may be performed as required after the wash cycle(s).

Sterilizing the MatrixPRO[®] II Driver:

- Sterilization to be performed with the MatrixPRO[®] II Driver either inside the MatrixPRO[®] II Driver Graphic Case (60.000.015) or out of the MatrixPRO[®] II Driver Graphic Case.
- Sterilization to be performed with devices wrapped.

Cycle	Time (minutes)	Water/Temperature	Comments
Fill and Pre-Wash 1	3	Cold tap water 21°C–32°C (70° F – 90°F)	
Pre-Wash 2	5	Hot tap water, 45°C–46°C (113°F–115°F)	Tec Wash III or equivalent (pH 7.0 – 9.0)
Wash	10	Hot tap water, 66°C–72°C (151°F–162°F)	Tec Wash III equivalent
Rinse	1	De-ionized water, 50°C–55°C (122°F–131°F)	(pH 7.0 – 9.0)
Final Rinse	10	De-ionized water, 92°C–94°C (198°F–201°F)	

Cycle Type	Minimum Sterilization Time	Minimum Sterilization Exposure Temparature	Minimum Dry Time (minutes)	
Pre-Vacuum	4	132°C (270° F)	40 minute minimum dry time, 15 minute open-door time, and 30 minute cool-down time.	
Pre-Vacuum	3	134°C (273°F) EU	40 minute minimum dry time, 15 minute open-door time, and 30 minute cool-down time.	

MatrixPRO[®] II Driver Components



MatrixPRO[®] II Driver Components:

05.000.030	MatrixPRO [®] II Driver Handpiece	
Note: MatrixPRO [®] II Driver Battery - Sterile sold separately.		
05.000.0315*	MatrixPRO [®] II Driver Single Use Battery - Sterile	

Single use battery is provided sterile unless package is open or damaged. Important: Do NOT sterilize. Do NOT recharge.

*Note: For more information please see MatrixPRO[®] II Driver Single Use Battery - Sterile Instructions for Use.

03.000.500	MatrixPRO [®] II Driver Hex Collet
03.000.501	MatrixPRO [®] II Driver J Latch Collet
03.000.502	MatrixPRO [®] II Driver 90 Degree Collet, Short
03.000.503	MatrixPRO [®] II Driver 90 Degree Collet, Long
60.000.015	MatrixPRO [®] II Driver Graphic Case

Additional Items Available

03.505.041	1.5 mm Drill Bit, for 90° Screwdriver, 6 mm stop
03.503.066	MatrixMandible Screwdriver Blade, short, non-self retaining
03.503.070	MatrixMandible/Rib Screwdriver Blade, self retaining-short
03.503.071	MatrixMandible/Rib Screwdriver Blade, self retaining-medium
03.503.072	MatrixMandible/Rib Screwdriver Blade, self retaining-long

