MatrixPRO™ Driver
Instructions for Use

DESCRIPTION:

The **MatrixPRO Driver (05.000.020)** is designed to insert DePuy Synthes MatrixNEURO™ Self-Drilling Screws (3-4mm lengths) and Low Profile Neuro Self-Drilling Screws (3-4mm lengths) and features a unique torque-limiting capability. The **MatrixPRO Driver** features a custom collet designed to interface with the DePuy Synthes MatrixNEURO Screwdriver Blades and Low Profile Neuro Screwdriver Blades, and operates in both the forward and reverse directions. The MatrixPRO Driver Battery – Sterile has been designed to power the **MatrixPRO Driver.**

Please note that these instructions may differ from other similar surgical drivers you have used. Also review the MatrixPRO Driver Battery – Sterile instructions prior to use of this device.

The **MatrixPRO Driver** has been designed and tested to be safely operated in combination with the following accessories:

- 05.000.021S – MatrixPRO Driver Battery, Sterile
- 03.503.016 – MatrixNEURO Screwdriver Blade/Shaft, Self-Retaining, Hex Coupling, Short
- 03.503.017 – MatrixNEURO Screwdriver Blade/Shaft, Self-Retaining, Hex Coupling, Medium
- 313.931 – Low Profile Neuro Screwdriver Blade/Shaft, Self-Retaining, Cruciform, Hex Coupling, Short
- 313.932 – Low Profile Neuro Screwdriver Blade/Shaft, Self-Retaining, Cruciform, Hex Coupling, Medium

The torque-limiting feature of the **MatrixPRO Driver** has been designed and tested to control the insertion of DePuy Synthes MatrixNEURO Self-Drilling Screws (3mm & 4mm lengths) and Low Profile Neuro Self-Drilling Screws (3mm & 4mm lengths) when implanted using the respective screwdriver blades.

Indications:
The **MatrixPRO Driver** has been designed and tested for cranial surgery applications with DePuy Synthes MatrixNEURO Self-Drilling Screws (3mm& 4 mm lengths) and Low Profile Neuro Self-Drilling Screws (3mm & 4mm lengths).

Contraindications:
Use of the **MatrixPRO Driver** to drive screws **other than** DePuy Synthes MatrixNEURO Self-Drilling Screws and Low Profile Neuro Self-Drilling Screws (3mm& 4 mm lengths) may result in the torque-limiting feature not functioning properly, and should therefore never be attempted.

Use of screwdriver blades **other than** the DePuy Synthes MatrixNEURO Screwdriver Blades or Low Profile Neuro Screwdriver Blades with the **MatrixPRO Driver** may result in damage to the **MatrixPRO Driver** and/or screwdriver blades, and should therefore never be attempted.

INSTRUCTIONS FOR USE:

The driver is controlled by two push-button switches. The forward button marked ⩙ provides clockwise rotation when pressed, which will drive the screw into the bone. The reverse button marked ⩛ provides counter-clockwise rotation when pressed, which will back the screw out of the bone. The driver will continue to operate until either the switch is released or the torque-limiting feature shuts off the motor. The no-load forward speed is 1,800 RPM to 2,200 RPM. The no-load reverse speed is 225 RPM to 325 RPM.

1) Insert Screwdriver Blade:
The collet has been designed to interface only with the DePuy Synthes MatrixNEURO Screwdriver Blades and Low Profile Neuro Screwdriver Blades. Do not attempt to use other screwdriver blades with this device. To install a screwdriver blade, pull the collet grip (nose cone) back and hold in that position while inserting the screwdriver blade into the collet shaft. Slowly rotate the screwdriver blade as necessary while pushing it into the collet shaft until it drops and seats into the internal hex interface. Release the collet grip to allow it to spring forward to the locked position. Pull on the screwdriver blade to ensure it is locked into the collet.

MatrixPRO™ Driver
Instructions for Use

Warning: Failure to insert the screwdriver blade properly may cause personal injury, damage to the device, and may void the warranty. Prior to use always ensure that the screwdriver blade is properly seated and locked into the collet by visually confirming that the collet grip (nose cone) is in the forward position, and giving the screwdriver blade a firm pull.

Note: Only MatrixNEURO Screwdriver Blades (03.503.016 & 03.503.017) and Low Profile Neuro Screwdriver Blades (313.931 & 313.932) can be used.

2) Battery Installation, Self-Diagnostics Check:

Orient the black arrow on the battery with the white arrow on the driver. Firmly insert the battery onto the battery mount ring until the tabs "click" and lock the battery securely in place. Gently pull on the battery to confirm that it is locked in place.

After battery insertion, the hand piece will be ready for use. To operate, press either the Forward ⍓ or ⍒ Reverse buttons and hold for at least 1 second. The buttons will illuminate and the hand piece will do an internal self-check of the electronics, buttons and motor. If the system passes the internal checks, the inserted screwdriver blade will rotate in the direction as determined by the selected button (forward or reverse).

Should any of the internal checks fail, the lights will flash indicating an internal failure. Replace the battery with a fresh, unused one and repeat the operation. If the lights flash again, return the hand piece for repair or replacement.

Precaution: If the lights under the button pad begin to flash, this indicates that the device has failed the self-diagnostics check and it will not function properly. Do not attempt to use it.

Warning: The MatrixPRO Driver has been designed and tested to operate only with the MatrixPRO Driver Battery-Sterile. Do not attempt to use another power source with this device. Use of a power source other than the MatrixPRO Driver Battery-Sterile may present a risk of fire, explosion, or other damage, and should therefore never be attempted.

3) Load Screw:

Select the appropriate length Self-Drilling screw (3 mm & 4 mm lengths) and align the screwdriver blade with the screw head recess and push down to engage the screw head.

4) Insert Screw:

Cranial Bone: Position the tip of the screw on the bone in desired location and hold down the forward button (do not remove finger from button) and drive the screw until it stops. Once the screw is seated, remove your finger from the button and gently rock the hand piece once from side to side to release the screwdriver blade from the screw head.

DePuy Synthes PEEK Patient Specific Implant (PSI): Only 4mm long screws can be inserted into PEEK PSI using the **MatrixPRO Driver**. Prepare the screw hole by predrilling a Ø1.1mm hole, 4mm deep into the PEEK PSI away from the surgical site. Position the screw in the prepared hole and hold down the forward button (do not remove finger from button) and drive the screw until it stops. Once the screw is seated, remove your finger from the button and gently rock the hand piece once from side to side to release the screwdriver blade from the screw head.

Precautions:

- If the screw does not fully seat, complete screw insertion by hand.
- DO NOT re-engage the screwdriver on a screw that has not fully seated.
- DO NOT press the forward button a second time after the screw is fully seated, as this may cause the screw to strip.
- The MatrixPRO Driver is not indicated for use with 5mm long MatrixNEURO Self-Drilling Screws and Low Profile Neuro Self-Drilling Screws as they may be difficult to remove.
- Do not use the MatrixPRO Driver to Insert a MatrixNEURO Self-Drilling 3mm screw into a MaxtrixNEURO Contourable Mesh 0.6 mm Rigid (Pink).

Note: The average no-load forward speed is 2,000 RPM.

5) Remove Screw (if necessary):
Reengage the screwdriver blade with the screw head recess and push the reverse button.
Notes:

- If the screw does not reverse, help initiate screw removal by holding the reverse button and rotating your wrist ¼ turn counter clockwise at the same time (repeat if necessary).
- The average no-load reverse spped is 275 RPM.

6) After Use, Remove Battery and Screwdriver Blade:
To remove the battery, press the movable latches on the battery together and pull the battery from the hand piece.

To remove the screwdriver blade pull the collet grip back and hold in that position while removing the screwdriver blade from the collet shaft. Release the collet grip and allow it to again spring forward to the locked position.

Use Environment and User Qualifications:
The **MatrixPRO Driver** is to be used by a trained and qualified surgeon indoors within the sterile field of a typical operating room environment. The MatrixPRO Driver may be operated in any orientation as required by the user, depending on the circumstances of the surgery being performed.

CLEANING & STERILIZATION INSTRUCTIONS:
Precautions:

- Do not use abrasive cleaners on the **MatrixPRO Driver**.
- Do not immerse/submerge the **MatrixPRO Driver** in any liquid
- Do not ultrasonically clean the **MatrixPRO Driver**
- Failure to follow proper infection control guidelines may result in patient or user infection
- Clean the **MatrixPRO Driver** within the guidelines prescribed in this IFU. The device has not been designed or tested for cleaning using any other method, therefore successful cleaning cannot be guaranteed with such processing and may damage the device and void the warranty.

The MatrixPRO Driver Hand Piece (05.000.020) must be cleaned and sterilized after every patient use according to the following guidelines:

- **Important: Ensure the battery has been removed.**
- Ensure the screwdriver blade has been removed.
- 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.

Complete the device cleaning per either the **Manual Cleaning Method** or the **Mechanical Cleaning Method** as outlined below.

Manual Cleaning Method:

- Clean the device using an enzymatic detergent with a neutral pH (7.0 to 9.0). Gently scrub the entire outer surface area of the device in multiple directions for a minimum of 3 minutes using a clean soft nylon brush. Pay particular attention to seams and areas where debris is visibly noticeable. Detergent may be applied using a plunger syringe to flush heavily soiled areas.
- Thoroughly rinse the device with warm de-ionized (DI) or purified (PURW) water for a minimum of 2 minutes. Visually inspect for debris and repeat the scrubbing step until all visible soils are removed.
- Dry the device using a clean, soft, lint-free cloth or clean compressed air.

Mechanical Cleaning Method:

- Mechanical Cleaning may be performed with the **MatrixPRO Driver** either inside the MatrixPRO Driver Graphic Case (60.000.010) or out of the MatrixPRO Driver Graphic Case.
- A Neutralize cycle may be performed as required after the wash cycle(s).

Cycle	Time (minutes)	Water/Temperature	Comments
Fill and Pre-Wash 1	3	Cold tap water, 10°C - 24°C (50°F - 75°F)	
Pre-Wash 2	5	Hot tap water, 55°C (131°F)	Tec Wash III or equivalent (pH 7.0 – 9.0)
Wash	10	Hot tap water, 60°C (140°F)	Tec Wash III equivalent (pH 7.0 – 9.0)
Rinse	1	De-ionized water, 10°C - 24°C (50°F - 75°F)	-
Final Rinse	10	De-ionized water, 93°C (199.4°F)	-

Sterilizing the MatrixPRO Driver:

- Sterilization to be performed with the MatrixPRO Driver inside the MatrixPRO Driver Graphic Case (60.000.010).
- Sterilization to be performed with devices wrapped.

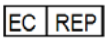
Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)
Pre-Vacuum	4	132°C (270°F)	40 minute minimum dry time, 15 minute open-door time, and 30 minute cool-down time.
Pre-Vacuum	3	134°C (273°F) EU	30 minute dry time.

TROUBLESHOOTING:

Issue	Potential Remedy
Button pad fails to light after button is pressed.	• Remove battery and re-insert. Allow self-diagnostics check to successfully complete as indicated by a steady light beneath the buttons. • If issue persists replace battery with a new (unused) battery and again allow self-diagnostics check to successfully complete. • If issue persists **do not use MatrixPRO Driver** – return driver to DePuy Synthes for repair or replacement.
Self-diagnostics check does not complete within 5 seconds as indicated by lights on continuously.	• Remove battery and re-insert. Allow self-diagnostics check to successfully complete as indicated by a steady light beneath the buttons. • If issue persists replace battery with a new (unused) battery and again allow self-diagnostics check to successfully complete. • If issue persists **do not use MatrixPRO Driver** – return driver to DePuy Synthes for repair or replacement.
Self-diagnostics check fails (indicated by fast flashing lights under button pad).	• Remove battery and replace with a new (unused) battery. Allow self-diagnostics check to successfully complete as indicated by a steady light beneath the buttons. • If issue persists **do not use MatrixPRO Driver** – return driver to DePuy Synthes for repair or replacement.
Driver will not turn on.	• Confirm that self-diagnostics check has successfully completed as indicated by a steady light under the button pad. • If issue persists remove battery and replace with a new (unused) battery. Allow self-diagnostics check to successfully complete as indicated by a steady light beneath the buttons. • If issue persists **do not use MatrixPRO Driver** – return driver to DePuy Synthes for repair or replacement.
Driver is sluggish.	• Remove battery and replace with a new (unused) battery. Allow self-diagnostics

	check to successfully complete as indicated by a steady light beneath the buttons. • If issue persists **do not use MatrixPRO Driver** – return driver to DePuy Synthes for repair or replacement.
Screws do not fully seat. (Complete the screw insertion process manually for all screws that did not fully seat. Do not re-engage screwdriver on a screw that has not fully seated.)	• Remove battery and replace with a new (unused) battery. Allow self-diagnostics check to successfully complete as indicated by a steady light beneath the buttons. • If issue persists **do not use MatrixPRO Driver** – return driver to DePuy Synthes for repair or replacement.
Screwdriver blade falls out of collet, or freely spins independently of collet shaft.	• Remove screwdriver blade and re-insert per directions in this IFU. • Be sure that collet grip (nose cone) springs back to the forward position. • Confirm screwdriver blade is seated and locked by visually confirming that the collet grip (nose cone) is in the forward position, and giving the screwdriver blade a firm pull.

SYMBOLS:

	Battery/Driver Alignment Arrow		Do not immerse
	Forward button		Caution
	Reverse button		Type B applied equipment
	Manufacturer/Date of Manufacture		Consult instructions for use
	Serial Number		Autoclave
V	Volts	**DC**	Direct Current
	Catalogue Number		Batch Code
CE 0297	Conforms to European Medical Device Directive		Quantity
	Authorized representative in the European community		Humidity Range for Shipping and Storage
	Temperature Range for Shipping and Storage		Keep Dry
	Pressure Range for Shipping and Storage		
	Underwriters Laboratories for Canada and United States With respect to electrical shock, fire and mechanical hazards only, in accordance with ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012)/CAN/CSA c22.2 No. 60601-1 (2008)		

Medical Equipment
ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012)
CAN/CSA c22.2 No. 60601-1 (2008)

TECHNICAL SPECIFICATIONS:

Product Number: 05.000.020

Classification: complies with ANSI/AAMI 60601-1:2005(R) 2012/A1:2012, CSA C22.2 NO 60601-1:14, IEC 60601-1:2005+AMD1:2012

Voltage: 8.0 VDC

Mode of operation: Non-continuous – S3 20% (1 second on, 4 seconds off)

Protection against harmful ingress of water: Ordinary – IPXO

Operating conditions: 50°F to 95°F (10°C to 35°C): 20% to 75% Relative Humidity non-condensing, 70 kPa to 106 kPa, indoor use only

Operating altitude: 3000m max

Shipping and storage conditions: -4°F to 140°F (-20°C to 60°C): 5% to 95% Relative Humidity non-condensing, 47 kPa to 106 kPa, indoor use only.

Note: This device complies with IEC 60601-1 regulations (listed above) regarding the emissions of and effect to this device of electromagnetic interference. These specifications provide reasonable assurance that use of this device will not affect and will not be affected by the operation of other electronic devices that may be nearby.

ELECTROMAGNETIC COMPATIBILITY (EMC) INFORMATION

WARNING: Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the Electromagnetic Compatibility (EMC) information provided in the accompanying documents.

WARNING: Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

WARNING: The Medical Equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it is used.

NOTE: The EMC tables and other guidelines that are included in this IFU provide information to the customer or user that is essential in determining the suitability of the Equipment or System for the Electromagnetic Environment of use, and in managing the Electromagnetic Environment of use to permit the Equipment or System to perform its intended use without disturbing other Equipment or Systems or non-medical electrical equipment.

EMC Table 1 (IEC 60601-1-2, Ed 3)

Guidance and manufacturer's declaration - electromagnetic emissions		
The SYN-1000 series is intended for use in the electromagnetic environment specified below. The customer or the user of the SYN-1000 series should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The SYN-1000 series uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The SYN-1000 series is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions	Not Applicable	

IEC 61000-3-3		

EMC Table 2 (IEC 60601-1-2, Ed 3)

Guidance and manufacturer's declaration – electromagnetic immunity			
The SYN-1000 series is intended for use in the electromagnet environment specified below. The customer or the end user of the SYN-1000 series should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electromagnetic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SYN-1000 series requires continued operation during power mains interruptions, it is recommended that the SYN-1000 series be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

EMC Table 4 (IEC 60601-1-2, Ed 3)

Guidance and manufacturer's declaration - electromagnetic immunity			
The SYN-1000 series is intended for use in the electromagnetic environment specified below. The customer or the user of the SYN-1000 series should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the SYN-1000 series including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** Not Applicable d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SYN-1000 series is used exceeds the applicable RF compliance level above, the SYN-1000 series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SYN-1000 series. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

EMC Table 6 (IEC 60601-1-2, Ed 3)

Recommended separation distance between
Portable and mobile RF communications equipment and the SYN-1000 series

The SYN-1000 series is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SYN-1000 series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SYN-1000 series as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{v_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.34	0.34	0.74
1	1.7	1.7	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Product Warranty:

Subject to a limited warranty.

The warranty applies only if the product has been maintained per these instructions. The warranty will not apply if the product has been subject to misuse or abuse. Sole liability under this warranty is limited to the repair or replacement, at our option, of the product. No other warranties are expressed or implied. The product must be returned to DePuy Synthes with proof of purchase (copy of dealer invoice) and transportation prepaid.

Pro-Dex Inc., as the manufacturer and DePuy Synthes, as distributor, do not assume any liability for direct or consequential damage resulting from improper use or handling, in particular as a result of failure to comply with the operating instructions or as a result of incorrect care or maintenance.

Precautions:

- Correct care, handling, and maintenance procedures must be maintained to ensure proper function. Prior to use, inspect for proper function. If the device shows visible signs of damage, foreign substances, or fails to operate properly, discontinue use immediately. Devices that have experienced extensive use or excessive damage may be susceptible to failure.
- If the screw does not fully seat, complete screw insertion by hand.
- **DO NOT** re-engage the screwdriver on a screw that has not fully seated.
- **DO NOT** press the forward button a second time after the screw is fully seated, as this may cause the screw to strip.
- The **MatrixPRO Driver** is not indicated for use with 5mm long MatrixNEURO Self-Drilling Screws and Low Profile Neuro Self-Drilling Screws as they may be difficult to remove.
- No field-modification of the **MatrixPRO Driver** may safely be performed. There are no user serviceable components in this device. The **MatrixPRO Driver** must be returned to the DePuy Synthes for repair or service.
- Clean the **MatrixPRO Driver** within the guidelines prescribed in this IFU. The device has not been designed or tested for cleaning using any other method, therefore successful cleaning cannot be guaranteed with such processing and may damage the device and void the warranty.
- Do not expose the **MatrixPRO Driver** to any environment that exceeds 135°C (275°F)
- Do not use abrasive cleaners on the **MatrixPRO Driver**
- Do not submerge the **MatrixPRO Driver** in any liquid
- Do not ultrasonically clean the **MatrixPRO Driver**
- **Do not thermally clean or disinfect the MatrixPRO Driver**
- Do not use the MatrixPRO Driver to Insert a MatrixNEURO Self-Drilling 3mm screw into a MatrixNEURO Contour Mesh 0.6mm Rigid (Pink)
- Failure to follow proper infection control guidelines may result in a hazard of infection to patient or user
- Consult with local authorities for the proper manner of disposal of this device

Federal law (USA) restricts this device to sale by or on the order of a physician.

Distributed by DePuy Synthes

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