MatrixPRO II Single Use Battery Instructions for Use (Do Not Reuse the Sterile Battery)

DePuy Synthes MatrixPRO II Single Use Battery (05.000.031S)

Description & Indications:

DePuy Synthes MatrixPRO II Single-use batteries are for use with the DePuy Synthes MatrixPRO II Driver. Please refer to the MatrixPRO II Driver instructions for complete description of battery use with the MatrixPRO II Driver (05.000.030).

WARNINGS:

- Do not reuse, do not wash, do not sterilize, and do not autoclave
- Do not heat battery above 176°F/80°C

Cautions:

- Avoid placing battery with contacts facing down on metal surfaces
- Dispose of battery according to hospital policy or local laws
- Do not connect multiple battery packs to the MatrixPRO II Driver

Instructions for Use 05.000.031S - MatrixPRO II Single Use Battery (Single Use Only - Do Not Re-sterilize)

The battery pack has been sterilized using the gamma irradiation method. Prior to use, visually inspect the tray and Tyvek lid for signs of damage. If the tray or lid shows evidence of damage, do NOT use the battery pack. There is no approved method to resterilize the battery.

1) Battery installation:

Remove the battery pack from tray according to hospital protocol and employ aseptic transfer procedures when completing the battery installation.

To install the MatrixPRO II Single Use Battery, orient the MatrixPRO II 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 (see Figure 1.) 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.

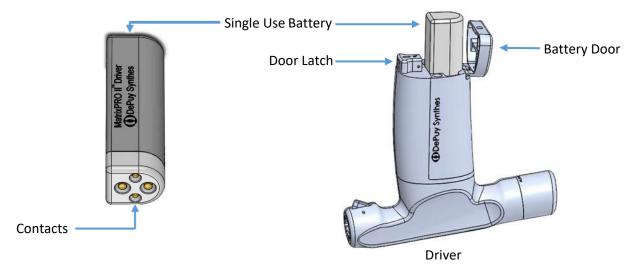


Figure 1. Battery and Battery Insertion

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Refer to the instructions for use of the MatrixPRO II Driver for complete operating instructions (Pro-Dex P/N 9769).

DISPOSAL

Waste disposal must be in accordance with the applicable Federal, State and the Local regulations.

Troubleshooting:

Problem	Solution
Driver stops during operation and won't restart with button pressed	Battery is drained. Use fresh battery.
Driver will not turn on	 Confirm that self-diagnostics check has successfully completed as indicated by a steady green light under the mode button. If issue persists remove battery and replace with a new (unused) battery. Allow self-diagnostics check to successfully complete as indicated by a steady green light beneath the mode button. If issue persists do not use MatrixPRO II Driver – return driver to DePuy Synthes for repair or replacement.

SYMBOLS

***	Manufacturer/Date of Manufacture	$\overline{\Sigma}$	Use by
V	Volts	DC	Direct Current
REF	Catalogue Number	LOT	Batch Code
STERILE R	Sterilized using irradiation	QTY	Quantity
	Do NOT Reuse	NS ^C C	Do not Autoclave
	Separate collection	®	Do NOT incinerate
\otimes	Do not immerse	1	Battery /driver alignment arrow
R	Federal law (USA) restricts this device to sale by or on the order of a physician.	7	Keep dry
i	Consult instructions for use	$\dot{\mathbb{L}}$	Caution
	Do not use if package is damaged	1	Temperature Range for Shipping and Storage
%	Humidity Range for Shipping and Storage	\$• \$	Pressure Range for Shipping and Storage
€ 0297	Conforms to European Medical Device Directive	EC REP	Authorized representative in the European Community / European Union

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Technical Specifications: Product Number: 05.000.031S

Classification: Self-contained electrical power source. Complies with IEC 60601-1:2005/A1:2012, 3.1 Edition (3rd edition +

Amendment 1), ANSI/AAMI 60601-1:2005(R) 2012/A1:2012, CSA C22.2 NO 60601-1:14.

Power Rating: 4.2V, 2450mAh

Type: Primary (non-rechargeable), Lithium-ion

Chemistry: Lithium-ion

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): 15% to 90% Relative Humidity non-condensing, 50 kPa to 106

kPa, indoor use only.

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

Distributed by DePuy Synthes:



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