



Instructions For Use

Sterile Pressure Protective Gel Pad[®]
and Cohesive Wrap for
De Mayo Knee Positioner[®]

Catalog Number **803-GP-10**

Doc Title **IFU-IMP-0016**

Version **0**



Indications for Use: The Sterile Pressure Protector Gel Pad is used with the De Mayo Knee Positioner and the intended use is to reduce pressure sores, abrasions and possible neurological impairment while securing the foot into the boot.

Contraindications: This device is not designed, sold or intended for use except as indicated.

Warnings/Precautions

- Do not use device in a manner that doesn't follow these instructions for use.
- Untrained personnel - review and understand the IFU
- Incorrect set up – follow IFU
- Max number of reuses:
 - Single use

Risks:

- Patient movement could dislodge pad and damage sterile field
- Skin sensitivity
- Light may discolor the pad

Complaints and Adverse Events: For complaints and adverse events, contact IMP and the appropriate regulatory authorities for specific country.



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Product Identification

Part No	Product Name	GTIN
803-GP-10	Sterile Patient Protective Pad for IMP Knee Positioners® Gel Memory Foam & Cohesive Wrap	00696588002880

Consumables: Not applicable

Disposal of unit:

Sterile Pressure Protective Pads are to be disposed of in accordance with applicable laws, rules, and regulations for the disposal of biohazardous waste. Follow all guidelines for biohazardous waste in accordance with the Centers for Disease Control and Prevention guidelines as well as applicable federal/national, state and local regulations.

Acceptable Accessories: Not Applicable

Symbol Glossary

Symbol	Title	Description	Standard
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2016
	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016



Symbol	Title	Description	Standard
	Catalog number	Indicates the manufacturer's catalogue number so that the medical device can be identified. The manufacturer's catalogue number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2016
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself.	ISO 15223-1:2016
	Complies with European Directives		
	Consult instructions for use		ISO 15223-1:2016
	Date of manufacture	The date must be presented in the following format: YYYY-MM-DD	FDA 21 CFR 801
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1:2016
	Medical device		ISO 15223-1:2016
	Not made with natural rubber latex		Manufacturer defined
	Serial Number	The manufacturer's serial number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2016
	Unique device identifier		ISO 15223-1:2016

Instructions for Use:

<p>1. Hold package at the edge and lift the base of the white sealed paper</p>	
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<p>2. In one motion, peel the white seal off the opening of the sterile package.</p>	
<p>3. Advance the inner blue wrapped foam and cohesive wrap to easily present to the sterile scrub technician</p>	
<p>4. Unwrap the sterile foam pads and cohesive wrap</p>	
<p>5. Place the foam pad in the boot, covering the entire edge of the boot</p>	<p>6. Secure the patient's foot in the boot with the cohesive wrap.</p>

Safety Test

1. Ensure Pressure Protective Pad® covers the entire edge of boot
2. Patient's foot is securely held by cohesive wrap
3. The Distractor block on the boot is NOT covered by cohesive wrap

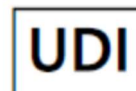


For patient's safety, always use *IMP*[®] Patient Protective Pads[®].

Scan for additional documentation



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