Positioned to Perform

Innovative Medical Products™

Instructions For Use

Sterile Pressure Protective Pad and Cohesive Wrap for IMP® Knee Positioners.

Catalog Number **803-GP-10**

Doc Title **IFU-IMP-0016**

Version **3**

Indications for Use: The Sterile Pressure Protector 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.

Innovative Medical Products
87 Spring Lane
Plainville, CT 06062
USA
P: 860-793-0391
F: 866-459-1805
info@IMPmedical.com

Product Identification

Part No	Product Name	GTIN
803-GP-10	Sterile Patient Protective Pad for IMP Knee Positioners® & Cohesive Wrap (10 / Case)	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.

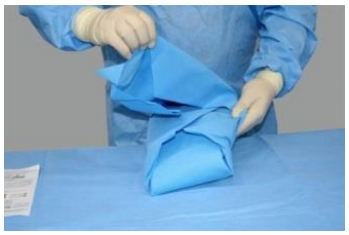
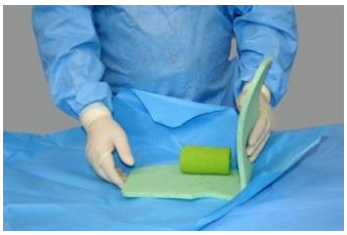
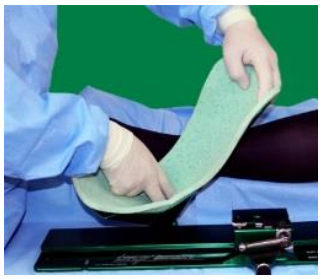
Acceptable Accessories: Not Applicable

Symbol Glossary

Symbol	Title	Description	Standard
EC REP	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	ISO 15223-1:2016

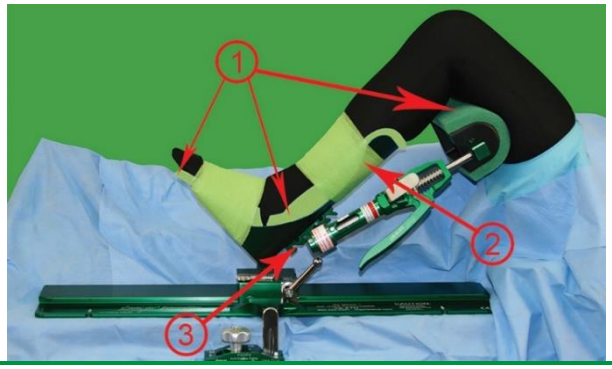
Symbol	Title	Description	Standard
		or lot can be identified.	
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified. The manufacturer's catalog number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2016
	Caution	Indicates 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
CE	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
3	Do not use if package is damaged		ISO 15223-1:2016
9	Expiration Date	Use by date	ISO 15223-1:2016
	Keep Dry		ISO 15223-1:2016
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1:2016
MD	Medical device		ISO 15223-1:2016
	Not made with natural rubber latex		Manufacturer defined
	Single Use	Do not reuse	ISO 15223-1:2016
Э	Sterilized using ethylene oxide		ISO 15223-1:2016
UDI	Unique device identifier		ISO 15223-1:2016

Instructions for Use:

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

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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F: 866-459-1805
info@IMPmedical.com

UDI

(01) 0 0696588 00288 0
(17) 270104
(10) I12345678

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