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Instructions For Use

Sterile Pressure Protector Pad®

for De Mayo Universal Distractor®

Catalog Number **907-GP-10**

Doc Title **IFU-IMP-0017**

Version **0**

Intended Use/Intended Users: The Sterile Pressure Protector Pad is used with the De Mayo Universal Distractor and the intended use is to reduce pressure sores, abrasions and to be used as a support for surgery patients, improving stability and pressure distribution on the operating room table. Orthopedic surgeons are the intended users.

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

Warnings/Precautions

- Do not use device in a manner that does not 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
907-GP-10	Sterile Pressure Protector Pad® for De Mayo Universal Distractor®	00696588002897

Consumables: Not applicable

Disposal of unit:
Sterile Pressure Protector 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

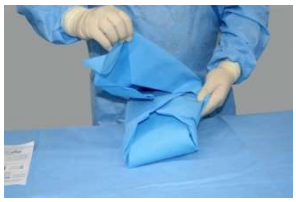
Symbol	Title	Description	Standard
	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified. The manufacturer's catalogue number shall 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

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. Present the sterile wrapped pads and cohesive wrap to the sterile field with the appropriate sterile technique protocol

4. Unwrap the sterile foam pads and cohesive wrap

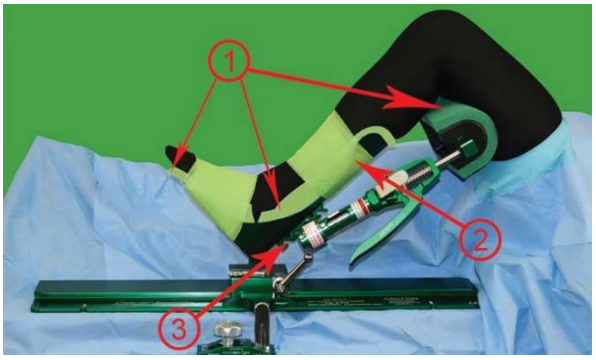



5. Place Pressure Protector Pad onto the distractor. Position and secure.


6. Place the foam pad in the boot, covering the entire edge of the boot. Secure the patient's foot in the boot with the cohesive wrap.


Safety Test

1. Ensure Pressure Protective Pad® is secure & Boot Foam 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

UDI

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