



Instructions For Use

Clip-On™ Patient Protective Pads

Catalog Number 1007-CPM, 1007-RPM, 1007-LPM, 1101-CPM, 707-CPM, 617-CPM

Doc Title **IFU-IMP-0014**

Version **1**



Intended Use/Intended Users: The Clip-On™ Patient Protective Pads 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.

Target Patient Group:

Patients requiring hip surgery.

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
707-CPM	Clip-On™ Single Patient Protective Pad	00696588002941
1007-CPM	Clip-On™ Patient Protective Pads for De Mayo Hip Positioner®	00696588002033
1007-LPM	Clip-On™ Patient Protective Pads for the Universal Lateral Positioner®	00696588002040
1007-RPM	Clip-On™ Patient Protective Pads for the Universal Lateral Positioner®	00696588002057
1101-CPM	Clip-On™ Patient Protective Pads for De Mayo Hip Positioner®	00696588002095
617-CPM	Clip-On™ Patient Protective Pads for Exact-Fit® De Mayo Lateral Positioner®	00696588007083

Consumables: Not applicable

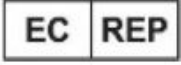












Disposal of unit:

Clip-on 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
	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	ISO 15223-1:2016



Symbol	Title	Description	Standard
		adjacent to it	
UDI	Unique device identifier		ISO 15223-1:2016

Instructions for Use:

CAT # 1007-CPM		AND	CAT # 1007-RPM	
Anterior Support, Base Plate & Contoured Lumbar Pads			Anterior Support, Rotated Base Plate & Contoured Lumbar Pads	
1. Base Plate Pad: <ul style="list-style-type: none"> a. Attach the double clip side of the Base Plate Pad to the base plate b. Stretch the single clip over the opposite side of the base plate 				
2. The Anterior Support Pad has a top and a bottom and can only be "snapped" on the metal plate in one direction. Seat the top edge of the metal plate into the clip and snap the bottom of the clip over the plate. To Remove: Push the extension wall over the edge of the metal plate.				
3. The Contoured Lumbar Pad attaches to the Lumbar Support with the VELCRO® strip. Note the thick portion of the pad is oriented to the head of the patient.				

CAT # 1007-LPM	
Anterior Support, Base Plate & Lumbar Sleeve Pads	
Refer to steps 1 & 2 above	
3. The Lumbar Pad has a pocket which slides over the back plate of the ULP	



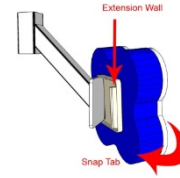
CAT # 1101-CPM & 617-CPM

De Mayo Hip Positioner® & Exact-Fit® De Mayo Lateral Positioner®

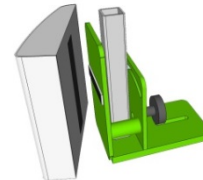
Anterior Support, Contoured Lumbar Pads

The Anterior Support Pad has two extension walls and can only be “snapped” on the metal plate in one direction. Seat the side edge of the metal plate into the clip and snap the extension wall of the clip over the other side of the plate.

To Remove: Push the Extension Wall over the edge of the metal plate.



The Contoured Lumbar Pad attaches to the Lumbar Support with the VELCRO® strip. Note the thick portion of the pad is oriented to the head of the patient.



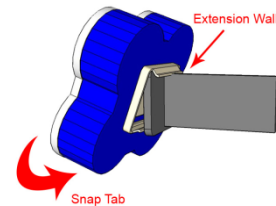
CAT # 707-CPM

De Mayo Hip Positioner®

Adjustable Lateral Support Pad

The Adjustable Lateral Support Pad has a top and a bottom and can only be “snapped” on the metal plate in one direction. Seat the top edge of the metal plate into the clip and snap the bottom of the clip over the plate.

To Remove: Push the Extension Wall over the edge of the metal plate.



Safety Test



Ensure all pads are positioned and attached securely

For patient’s safety, always use IMP® Patient Protective Pads



Scan for additional documentation



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