Positioned to Perform

Innovative Medical Products™

Instructions For Use

Abduction Pillow

Catalog Number **1190, 993, 699**

Doc Title **IFU-IMP-0001**

Version **0**

Indications for Use: The intended use of the abduction pillow is to prevent the patient from moving following hip surgery which would cause dislocation of the new hip joint.

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 foam

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	UDI-DI
699	Pediatric Abduction Pillow 16" x 10.5" x 6"	00696588003795
993	Universal Abduction Pillow 23.5" x 14.25" x 7"	00696588003818
1190	Slimline™ Abduction Pillow 25" x 7.5" x 4"	00696588003580

Consumables: Not applicable

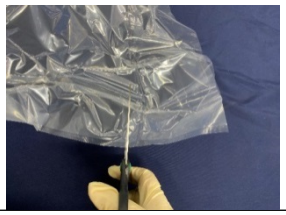
Disposal of unit:
Abduction pillows are to be disposed of in accordance with applicable laws, rules, and regulations for the disposal of biohazardous waste. Follow all guidelines for biohazardous waste in accordance with the Centers for Disease Control and Prevention guidelines as well as applicable federal/national, state and local regulations.

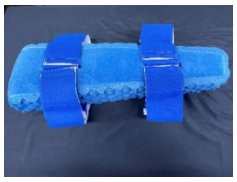
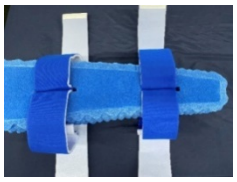
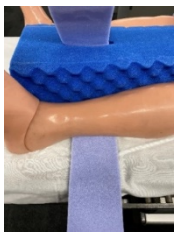
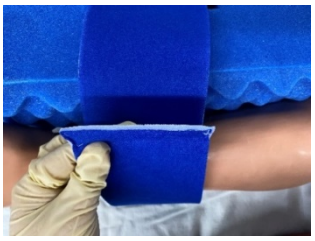
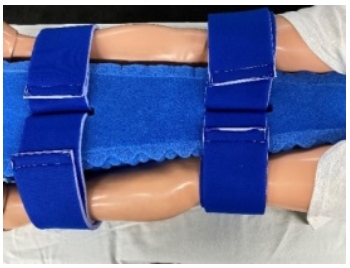
Acceptable Accessories: Not Applicable

Symbol Glossary

Symbol	Title	Description	Standard
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2016

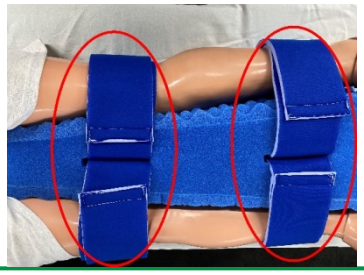
Symbol	Title	Description	Standard
LOT	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified. The manufacturer's catalogue number 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
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
	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
LATEX	Not made with natural rubber latex	.	Manufacturer defined
SN	Serial Number	The manufacturer's serial number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2016
UDI	Unique device identifier		ISO 15223-1:2016

1. Obtain a vacuum sealed package and open with a pair of scissors.  	2. Pull out the Abduction Pillow.

	
3. Place on table and allow to re-inflate for 10 to 15 mins prior to using. 	4. Open the straps of the Abduction Pillow 
5. Place the pillow between the legs of the patient and secure the pillow with the straps by wrapping them around the patient's leg and securing with hook strip.  	6. Ensure that straps are attached one above and one below the knee 

Safety Test

Ensure that straps are secure one above and one below each knee



Scan for additional documentation

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UDI

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LATEX