



Instructions For Use

Abduction Pillow

Catalog Number **1190, 993, 699**

Doc Title **IFU-IMP-0001**

Revision **02**



Intended Use/Intended Users: The abduction pillow is intended to maintain proper hip alignment by keeping the legs in an abducted position following hip surgery, reducing the risk of dislocation of the new hip joint. Healthcare professionals such as surgeons and nurses are the intended users

Target Patient Group: Patients requiring hip abduction positioning as directed by a healthcare professional.

Contraindications:

Do not use this device:

- In patients with conditions where forced abduction is contraindicated
- On open wounds unless properly dressed and protected
- If the device is damaged or compromised

Warnings/Precautions

- Always follow the Instructions for Use (IFU) for proper setup and correct product usage.
- Untrained personnel must review and understand the IFU
- Use only as prescribed by a qualified healthcare professional
- Improper use may result in injury or delayed healing
- Ensure straps are not overly tight to avoid circulation impairment
- Monitor skin condition regularly to prevent pressure injuries
- Discontinue use if pain, numbness, or discomfort occurs
- 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

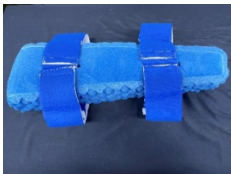
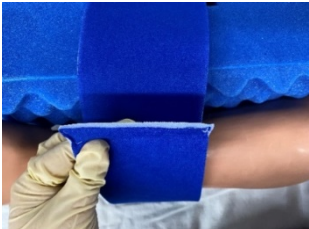
**Disposal of unit:**

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 15223-1:2021
	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021
	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 15223-1:2021
	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 15223-1:2021
	Consult instructions for use		ISO 15223-1:2021
	Date of manufacture	The date must be presented in the following format: YYYY-MM-DD	FDA 21 CFR 801
	Keep Dry		ISO 15223-1:2021
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1:2021
	Medical device		ISO 15223-1:2021
	Not made with natural rubber latex		Manufacturer defined
	Unique device identifier		ISO 15223-1:2021

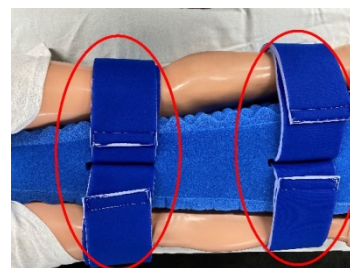


1. Obtain a vacuum sealed package and open with a pair of scissors.  	2. Pull out the Abduction Pillow. 
3. Place on table and allow to re-inflate for 10 to 15 mins prior to using. 	4. Open the straps of the Abduction Pillow 
5. Place the pillow between the legs of the patient and secure the pillow with 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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