

Instructions For Use

OR Table Pad



Catalog Number **398-ABG, 398-LG**

Doc Title **IFU-IMP-0040**

Version **5**



Intended Use/Intended Users: The OR Table pad intended use is to enhance the patient's comfort during surgery and mitigate the risk of pressure ulcers. Additionally, it facilitates the creation of a leg well which keeps the ankle and hip at the same height when using the De Mayo Knee Positioner. Orthopedic surgeons and OR nurses are the intended users.

Target Patient Group: Patient selection depends on the judgment of the surgeon. Surgeons must consider the size of the patient. The heel to popliteal region should be in between 13 inches (33 cm) and 18 inches (46 cm) and tibia should be over 11 inches (28 cm) in length.

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

Warnings/Precautions

- Do not use if pad is punctured
- Use approved cleaning materials. Harsh cleaning chemicals can degrade cover material
- Untrained personnel - review and understand the IFU
- Max number of reuses: Until considerable wear

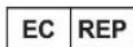
Risks:

- No shelf-life issues.
- Re-usable: avoid cross contamination by cleaning adequately

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
398-ABG	Armboard Pad Set 26" x 6" /	00696588000763
398-LG	OR Table Pads Green (3 pc set) 398AG (1 each) and 398CG (2 each)	00696588004112
398-LG-Kit	OR Table Pads (5 pc set) 398-LG (3 pcs) and 398-ABG (2 pc)	00696588001296

Disposal of unit:

If a device is being returned for repair or disposal, please contact Innovative Medical Products at sales@IMPmedical.com. If the device is not being returned, instruments 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.

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
	Complies with European Directives.		
	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

Instruction for Use:

1. Replace OR Table Pads with green IMP® Pads



Note: It is not necessary to remove X-Ray cassette plates.

2. Position the patient with the gluteal fold at the separation of the pads



3. During Prep of the surgical leg, remove single OR Table Pad



4. Create a 3"-5" fold in the final drape under the buttocks



5. Place the De Mayo D2® Knee Positioner® in the well to achieve maximum flexion



6. Check flexion for final approval of freedom of the drape to allow full range of motion, when the positioner is locked on the drapes





Cleaning Instructions OR Table Pads

Approved products and methods for cleaning and disinfecting of OR Table pads CAT# 398-LG OR Table Pads and 398-ABG Arm Board Pads sold by Innovative Medical Products.

DO NOT APPLY TAPE TO ANY PAD

CLEANING OF SOILS & STAINS

Wash with a generous application of neutral soap suds and lukewarm water up to 103°F (39°C). Rinse with water and dry. Do not immerse.

Or

Use a diluted bleach solution of 10-parts water to 1-part bleach. Wipe dry with a clean cloth. Do not immerse. Bleach MUST be diluted to the 10:1 ratio.

All chemicals/solutions MUST be diluted to the manufacturer's recommendations. No chemical or solution should be left to dry on the pad surface. After the allotted time has passed to ensure disinfection, the pad surface should be wiped again with a wet cloth to remove the remaining chemical or solution.

DISINFECTING

Use Lysol Brand III I.C. Disinfectant Aerosol Spray by Reckitt Benckiser Inc., per manufacturer's instructions.

Or

Use a diluted bleach solution of 10-parts water to 1-part bleach. Wipe dry with a clean cloth. Do not immerse. Bleach MUST be diluted to the 10:1 ratio.

All chemicals/solutions MUST be diluted to the manufacturer's recommendations. No chemical or solution should be left to dry on the pad surface. After the allotted time has passed to ensure disinfection, the pad surface should be wiped again with a wet cloth to remove the remaining chemical or solution.

The following Steris products are also approved for use in cleaning and disinfecting our pads:

- Steris Coverage Plus wipes 1608-WC, -GS, -G4
- Steris Coverage Spray HB Plus 1624-77
- Steris Coverage Spray TB Plus 1629-B4, -08

The use of ANY cleaning/disinfecting chemical other than those on this list will void the warranty on any Table Pads sold by IMP.



CLEANING DOS AND DON'TS for HEALTHCARE FABRICS

Cleaning Dos	Cleaning Don'ts
clean all stains promptly	machine wash or machine dry
use only fabric-safe cleaning agents or disinfectants	use harsh cleaners or solvents
dilute all disinfectants and germicides in accordance with manufacturer's instruction	use cleaning agents designed for use on hard, non-porous or metal surfaces
wipe fabric clean with neutral soap suds and lukewarm water	use iodophor type disinfectants, such as Betadine, because they will stain the fabric
rinse thoroughly	use household bleach or concentrated cleaning agents, disinfectants, or germicides without diluting the product according to the manufacturer's instructions
allow adequate drying time before returning to service	allow any cleaning agent to remain in contact with the fabric or "dwell" on the fabric for a prolonged life
use a soft sponge with liquid cleaner as specified on the manufacturer's product label for hard-to-clean areas	fail to adequately rinse the cleaning agent or disinfectant from the fabric
clean daily to control or prevent odors on long term incontinent applications	
use a scented cleaner or disinfectant that is designed for use on fabrics if needed to control odors on long term incontinent applications	
disinfect blood contamination with a 1:10 dilution of household bleach (5.25% sodium hypochlorite) as recommended by the CDC (Center for Disease Control, US Department of Health and Human Service, February 1989); a weaker dilution, e.g. 1:100 may be used, but may not be in accordance with CDC recommendations.	
be aware that staining chemicals and cleaning agents can affect fabric strength, finish, and color	
inspect mattresses frequently to ensure that new stains can be treated promptly	
ask your support surface manufacturer for additional information related to the care and cleaning of the support surface	



Scan for additional documentation.



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