Innovative Medical Products™

Positioned to Perform

Instructions For Use

SuperBump®

WEIGHTED STERILE SURGICAL BUMP

Catalog Number **091101**

Doc Title **IFU-IMP-0031**

Revision **01**

Intended Use/Intended Users: SuperBump® is a medical device used to position the leg, typically for knee surgery. Orthopedic surgeons and operating room staff are the intended users.

Target Patient Group: SuperBump® can be used on any patient requiring knee surgery.

Contraindications:
Do not use the device:
- On patients where elevation or pressure at the application site is contraindicated
- On open wounds without appropriate protective dressings
- If the device is damaged, deformed, or compromised

Warnings/Precautions
- Check for package integrity to ensure product is sterile before use. Once unpacked, verify all components to ensure they are in good condition.
- Skin must be intact in areas with direct contact with the foam.
- Inspect device prior to each use

Risks:
- Device is not attached to side rails and may move.
- Contamination from External Sources: The surgical bump may become contaminated if it comes into contact with non-sterile surfaces or equipment during surgery, increasing the risk of infection.
- Handling and Disposal: Proper handling and disposal of used surgical bumps are crucial to prevent the spread of contamination and infection after surgery. Mishandling can result in inadvertent exposure to pathogens.
- Tissue Damage: Improper placement or handling of the surgical bump can potentially cause tissue damage, including abrasions, lacerations, or pressure sores, particularly in sensitive areas.
- User Error: Human error such as improper handling or incorrect placement of the surgical bump can lead to complications or surgical site infections.
- Positioning Errors: Incorrect positioning of the surgical bump can lead to difficulties during the procedure, including restricted access to the surgical site or discomfort for the patient.
- Pressure injuries due to prolonged use or improper positioning
- Patient instability or slippage: Especially during repositioning or table tilting
- Skin irritation: From prolonged contact with device materials

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
091101	Sterile SuperBump® 5/Case	00696588002910
091102	SuperBump® Weight (5 lbs each)	00696588003436

Consumables: Not applicable

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

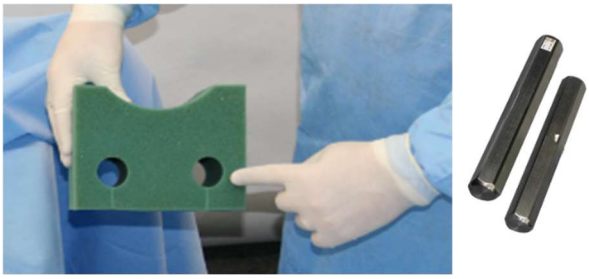
Symbol	Title	Description	Standard
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2021
	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021
	Catalog number	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
	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
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1:2021
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1:2021
	Keep Dry		ISO 15223-1:2021
	Manufacturer	This symbol shall be accompanied by the name	ISO 15223-1:2021

Symbol	Title	Description	Standard
		and address of the manufacturer.	
MD	Medical device		ISO 15223-1:2021
LATEX	Not made with natural rubber latex		Manufacturer defined
STERILE EO	Sterilized using ethylene oxide		ISO 15223-1:2016
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021

Instruction for Use

1. Drape patient's leg

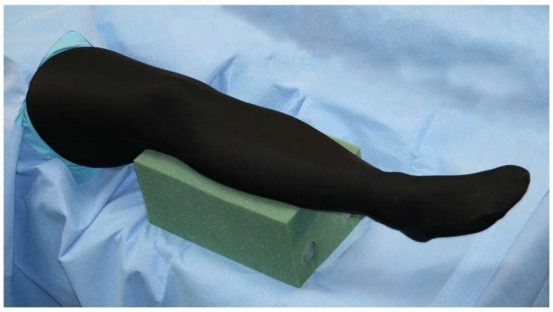
2. Insert weights into SuperBump®



3. With knee at 90°, pull drape taut.
   Position weighted SuperBump® under the patient's foot

4. Adjust position as needed

5. Turn the SuperBump® 90° to contour the leg during closure



Set Up Test Procedure

1. Check that weights are fully inserted into foam

Cleaning and Sterilization Procedure (for weights)

NOTE: ALL SOLUTIONS MUST BE COMPATIBLE WITH ALUMINUM & STAINLESS STEEL

Recommended Washer / Decontaminator Instructions:
• Soak the product in an enzyme solution. Follow the manufacturer's direction for dilution and soaking time. • Put through washer / decontaminator according to manufacturer's instructions with a detergent up to a pH of 9.0 (Select cycle that does not include lubrication).

Recommended Hand Cleaning Instructions:
• Pre-Soak the product / components in an enzyme solution. Follow the manufacturer's direction for dilution ratio and soaking time.
• Rinse the product in warm tap water.
• Wash the product with an instrument detergent up to a pH of **9.0** or enzyme product
• Rinse the product in warm tap water
• Soak or wipe the product down with a hospital approved and / or EPA approved germicide according to instructions.

• Rinse the product in warm tap water
• Dry thoroughly and wrap

Recommended Sterilization Instructions:
• Ensure that all parts are thoroughly cleaned.
• *DO NOT PLACE POSITIONER IN A MILK BATH OR LUBRICATE*
• Pre-Vac sterilization can either be unwrapped or double wrapped in two disposable or reusable wraps.
• Run normal vacuum cycle for your institution
• **STEAM STERILIZATION ONLY- ALL OTHER STERILIZATION METHODS NOT VALIDATED**

MINIMUM PARAMETERS PRE-VAC STERILIZATION

Product Part Number	Temperature Setting	Exposure Time	Dry Time
091102	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes

Sterilization Parameters Certified by:

- Micro Test Laboratories (now Accuratus Lab Services)
- Accuratus Lab Services
- HIGHPOWER Validation Testing and Lab Services

Scan for additional documentation

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UDI

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STERILE EO