Innovative Medical Products™

Positioned to Perform

Instructions For Use

SuperBump®

WEIGHTED STERILE SURGICAL BUMP

Catalog Number **091101**

Doc Title **IFU-IMP-0031**

Version **0**

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

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.

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.

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

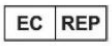
Part No	Product Name	GTIN
091101	Sterile SuperBump® 5/Case	00696588002910
091102	SuperBump® Weight (5 lbs each)	00696588003436

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

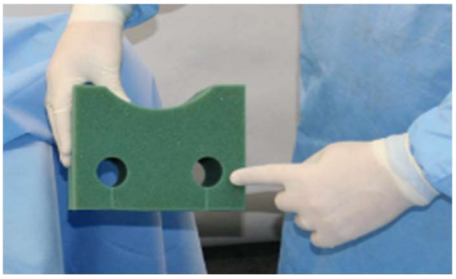
Symbol	Title	Description	Standard
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2016
	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016
	Catalog number	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 15223-1:2016
	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
	Keep Dry		ISO 15223-1:2016
	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 adjacent to it.	ISO 15223-1:2016
	Unique device identifier		ISO 15223-1:2016

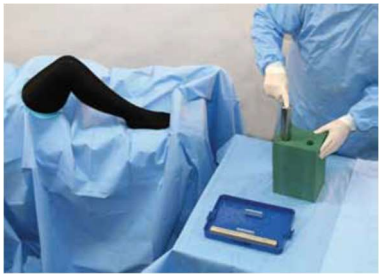
Instruction for Use

1. Drape patient's leg

2. Take weights out of sterilization case

3. Insert weights into SuperBump®

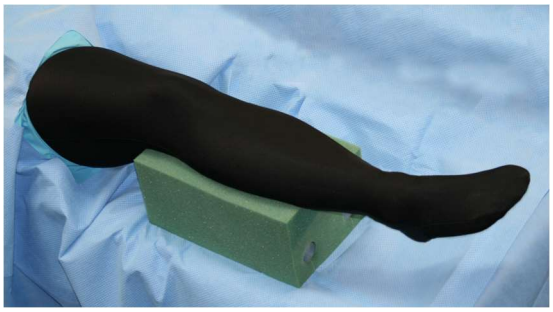




4. With knee at 90°, pull drape taut.
   Position weighted SuperBump® under the patient's foot

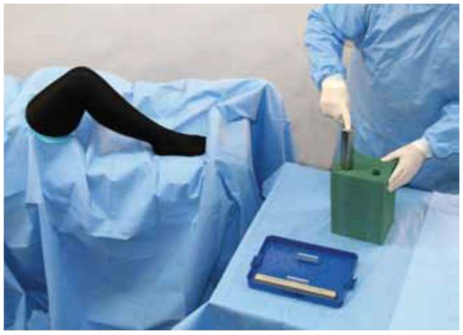
5. Adjust position as needed

6. 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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