Innovative Medical Products™

Positioned to Perform

Instructions For Use

SteriBump®

STERILE SURGICAL BUMP

SteriBumpUE™

STERILE SURGICAL UPPER EXTREMITY BUMP

Catalog Number **508, 508-S**

Doc Title **IFU-IMP-0030**

Version **1**

Intended Use/Intended Users: SteriBump® is a medical device used to elevate and hold patient's extremities during a surgical procedure. It can be used in contact with intact skin. Surgeons and operating room staff are the intended users.

Target Patient Group: SteriBump® can be used on any surgical patient.

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
508	SteriBump® Sterile (5/case)	00696588006208
508-S	SteriBump® UE Sterile (5/case)	00696588006949

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
	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
	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 and address of the manufacturer.	ISO 15223-1:2021
	Medical device		ISO 15223-1:2021

Symbol	Title	Description	Standard
	Not made with natural rubber latex		Manufacturer defined
	Unique device identifier		ISO 15223-1:2021

Instructions for Use:

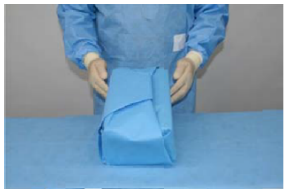
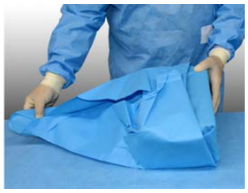
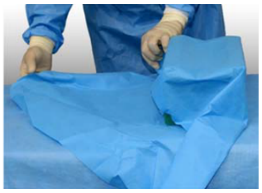
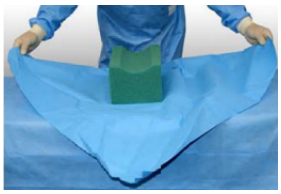
1. Hold package at the edge and lift the base of the white sealed paper.

2. In one motion, peel the white seal off the opening of the sterile package.

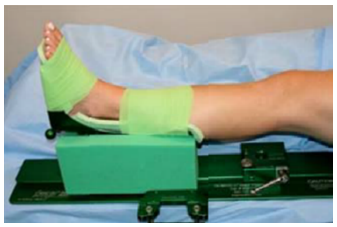


3. Present the SteriBump® to the sterile field with the appropriate sterile technique protocol

4. Unwrap the SteriBump®.

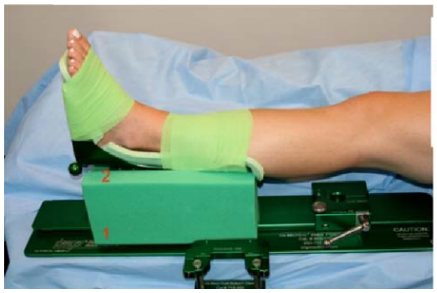





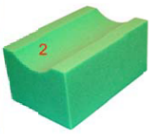
5. Place the SteriBump® under the desired limb per procedure. Curved side of the SteriBump® towards extremity



Safety Test

1. Place flat side of the SteriBump® on a flat surface.
2. Curved side of the SteriBump® toward the patient's extremity.





Cleaning and Sterilization Procedure – Not applicable, single use

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Scan for additional documentation

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