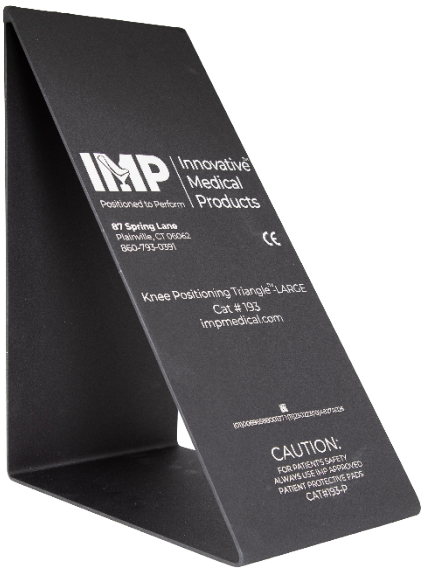
Innovative Medical Products™

Positioned to Perform

Instructions For Use

Knee Positioning Triangle



Catalog Number **193 / 293**

Doc Title **IFU-IMP-0021**

Version **0**

Intended Use/Intended Users: The Knee Positioning Triangle is a medical device used to position the patient's knee in a flexed position to provide support for lower extremity surgery. It may be used during total knee arthroplasty, knee ligament repair and reconstruction and internal fixation of tibial plateau fractures as well retrograde femoral nailings. Orthopedic surgeons are the intended users.

Target Patient Group: The target patient group includes most patients requiring lower extremity surgery (excluding infants and small children). The tibia must be able to hang over the edge of the triangle.

Contraindications: While knee positioning triangles are generally safe and beneficial for many patients, there may be certain contraindications where their use should be avoided**.** Contraindications can vary depending on the patient's specific condition and the type of triangle being used**.**

- Open Wounds or Infections: If a patient has open wounds, surgical incisions, or active infections around the knee area, the use of a knee positioning triangle may be contraindicated. Placing pressure or support on such areas could potentially exacerbate the condition or introduce contaminants.
- Allergies or Skin Sensitivities: Patients with known allergies or sensitivities to the materials used in the knee positioning triangle (e.g., foam) should avoid using these devices or opt for hypoallergenic alternatives to prevent skin reactions.

It is crucial for healthcare professionals to assess each patient's individual needs, medical history, and condition before recommending the use of a knee positioning triangle.

Warnings/Precautions

- Triangle must be cool before use on a patient
- Follow IFU for proper set-up
- Adjust the positioning of the triangle as necessary to maintain comfort and prevent joint stiffness.

Risks:

- Weld fatigue may cause pinch points
- Highly acidic or basic cleaners may remove anodize

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	Photo
193	Large Knee Positioning Triangle™ / 00696588001371	

Part No	Product Name/ GTIN	Photo
293	Small Knee Positioning Triangle™ 00696588002002	

Consumables:

- 193-P Sterile Pads for Knee Positioning Triangles

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
EC REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2016
LOT	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified. The manufacturer's catalogue 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
CE	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
	Manufacturer	This symbol shall be accompanied by the name and address of the	ISO 15223-1:2016

Symbol	Title	Description	Standard
		manufacturer.	
MD	Medical device		ISO 15223-1:2016
LATEX	Not made with natural rubber latex		Manufacturer defined
SN	Serial Number	The manufacturer's serial number shall be placed after or below the symbol and adjacent to it	ISO 15223-1:2016
UDI	Unique device identifier		ISO 15223-1:2016

Instructions for Use:

1. Open patient protective pad by holding the 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 sterile wrapped foam patient protective pad to the sterile field with appropriate sterile technique protocol.

4. Unwrap the sterile foam patient protective pads.

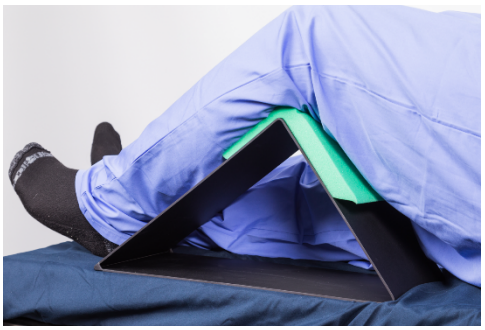

5. Apply the sterile, latex-free protective pad

6. Position the patient supine on the O.R. table. Use appropriate angle of the Knee Positioning Triangle to position under popliteal area to allow for desired flexion of the knee.

Safety Test

1.) Ensure the foam patient protective pad is positioned correctly on the knee triangle.

2.) Confirm the knee triangle and pads are located correctly under the knee.



Cleaning and Sterilization Procedure

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

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**
• Dry thoroughly and wrap

MINIMUM PARAMETERS PRE-VAC STERILIZATION

Product Part Number	Temperature Setting	Exposure Time	Dry Time
193	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
293	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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