Positioned to Perform

Innovative Medical Products™

Instructions For Use

Reznik Universal Shoulder Positioner™

Catalog Number **908**

Doc Title **IFU-IMP-0025**

Version **0**

Intended Use/Intended Users: The Reznik Universal Shoulder Positioner™ is a medical device used to properly position and stabilize the patient's shoulder during shoulder arthroscopies in the lateral position, Beach Chair and for elbow arthroscopies. It is designed to provide stable and adjustable positioning for a wide range of shoulder procedures, improving surgical outcomes and reducing the risk of complications. Orthopedic surgeons are the intended users.

Target Patient Group: The target patient group consists of individuals requiring surgery related to the shoulder. This can encompass a range of conditions and situations such as shoulder arthroscopy. A positioner helps maintain a stable and optimal positioning of the shoulder during the procedure. Patient selection depends on the judgment of the surgeon.

Contraindications: The Reznik Universal Shoulder Positioner is generally considered safe and beneficial for most patients. Some potential contraindications include:

- Patients with severe shoulder instability, such as recurrent dislocations, may not be suitable candidates for shoulder positioning devices that immobilize the joint, as this could exacerbate their condition or cause discomfort.

- Open Wounds or Infections: Patients with open wounds or active infections in the shoulder area should not undergo surgery or positioning with a shoulder positioner until the infection has been appropriately treated and resolved. Using a shoulder positioner in this situation could introduce the risk of further infection.

- Neurological or Circulatory Impairments: Patients with significant neurological or circulatory impairments in the affected arm may be at increased risk of complications, such as pressure sores or nerve compression, when using a shoulder positioner. The positioning device should be used cautiously or alternative positioning methods explored.

- Inability to Maintain Position: Patients who are unable to cooperate or maintain the desired shoulder position due to cognitive impairments, severe pain, or other factors may not be suitable candidates for shoulder positioning devices.

Warnings/Precautions

- Do not use device in a manner that does not follow these instructions for use.
- Follow IFU for proper setup
- Max number of reuses:
  - Until damaged and unrepairable

Risks:

- Highly acidic or basic cleaners may strip 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
908	Reznik Universal Shoulder Positioner™	00696588000978

Consumables:

- Phase 4 Gel Splint

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.

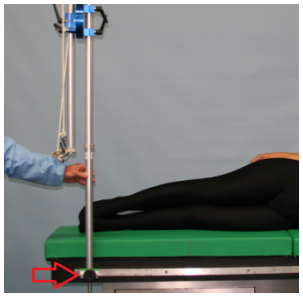
Symbol Glossary

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	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
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
	Keep Dry		ISO 15223-1:2016
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1:2016
MD	Medical device		ISO 15223-1:2016

Symbol	Title	Description	Standard
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:

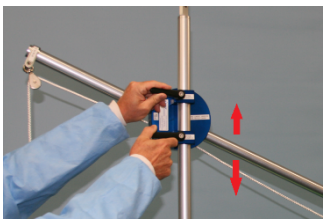
1. Position the Reznik Universal Shoulder Positioner and rail clamp on the side of the table where the patient is facing.

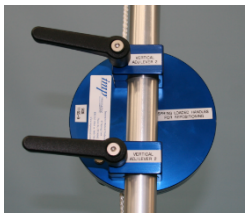


2. Insert the positioner into rail clamp and rotate positioner so the Large Lever No. 1 is facing the operator.

   Release Lever No. 1 to rotate horizontal bar.

3. Release both Vertical Adjusting Levers No. 2 to achieve appropriate height of Horizontal Bar.

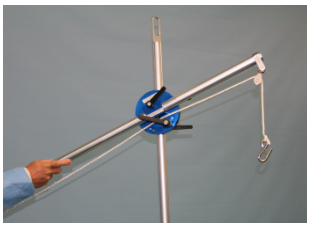




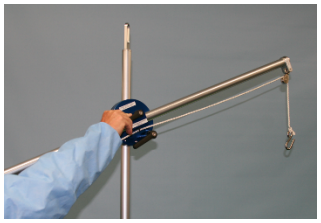
4. Rotate Horizontal Bar so

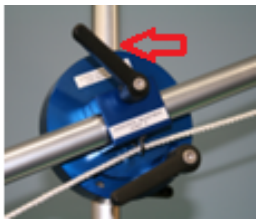
   a.) Head Swivel Pulley faces patient's head,

   b.) Traction Swivel faces foot of table

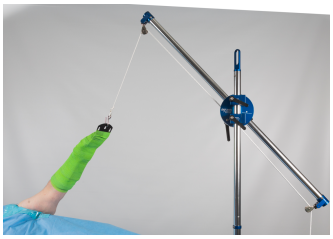
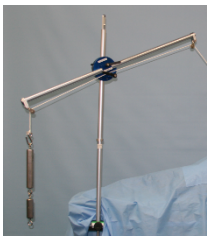


5. Release Horizontal Adjustment Lever No. 3 for horizontal length adjustment.





6. Lock knob on Rail Clamp and check locking of all levers. Lock all knobs and levers securely.

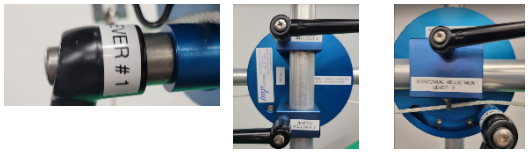
7. After Phase 4 Gel® Splint is applied to patient's forearm, secure hook to forearm splint. 	8. Apply traction weight to opposite hook, per the surgeon's preference. 

Safety Test

Tighten to Lock Knobs and Levers securely:

1. Rail Clamp
2. Large Lever No. 1
3. Vertical Adjusting Levers No. 2
4. Horizontal Adjustment Lever No. 3

2 3 4



Cleaning Procedure

Recommended Instructions:
• Components may be disinfected, as a rule with any hospital grade disinfectant to reprocess the components between cases. These include but are not limited to: **HI-TOR PLUS** **BEAUCOUP GERMICIDAL DETERGENT** **SANI MASTER II OR III** **STARLINE INSTRUMENT DETERGENT**
• A solution of water and liquid bleach (10 parts water to 1 part bleach) may also be used to clean and disinfect. Thoroughly clean the components with your disinfectant. A final wipe down with clean water is recommended to be sure that no residue from the disinfectant is left on the components.

Scan for additional documentation

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UDI

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