Positioned to Perform | Innovative Medical Products™

Instructions For Use

Universal Lateral Positioner®

Catalog Number **1092**

Doc Title **IFU-IMP-0033**

Version **0**

Intended Use/Intended Users:
The Universal Lateral Positioner is a medical device used to position the patient laterally for partial and total hip replacement. Orthopedic surgeons are the intended users.

Target Patient Group:
Patient selection depends on the judgment of the surgeon. Surgeons must consider health and size of the patient. There is no weight requirement for the positioner, but each position has a maximum range.

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

Warnings/Precautions

- Do not use device in a manner that doesn't follow these instructions for use.
- Untrained personnel - review and understand the IFU
- Incorrect set up – follow IFU
- Safety: Always use IMP Patient Protective Pads
- Max number of reuses:
    - Until damaged and unrepairable

Risks:

- Highly acidic or basic cleaners could 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
1092 Kit	Universal Lateral Positioner® - Standard Configuration	00696588000992
1092-L KIT	Universal Lateral Positioner® Large Kit	00696588001005
1092-L-SWIVEL KIT	Universal Lateral Positioner® Large Kit with Swivel Arms	00696588001753

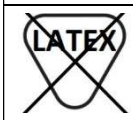
Consumables:

Part No	Product Name	GTIN
1007-CPM	Clip-On™ Patient Protective Pads for the Universal Lateral Positioner®	00696588002033
1007-LPM	Clip-On™ Patient Protective Pads for the Universal Lateral Positioner®	00696588002040
1007-RPM	Clip-On™ Patient Protective Pads for the Universal Lateral Positioner®	00696588002057
1092-P	Patient Protective Pad for IMP Universal Lateral Hip Positioner (ULP)	00696588002026

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
	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
	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 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

Symbol	Title	Description	Standard
UDI	Unique device identifier		ISO 15223-1:2016

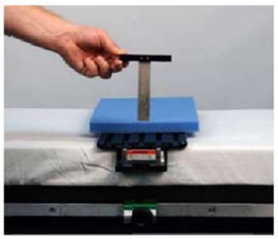
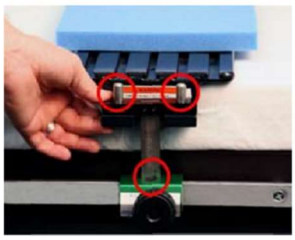
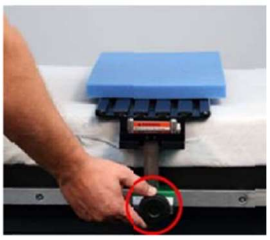
Instructions for Use:

1. Attach Clip-On™ Pads as per the Clip-On™ Pad IFU prior to transferring the patient onto the OR table.



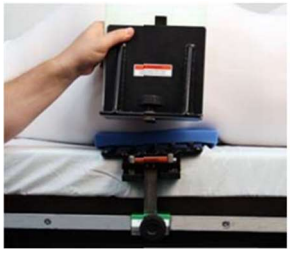
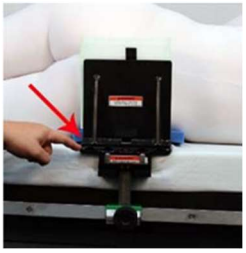
See Clip-On™ Pad IFU

2. Place the Base Plate on the OR table in the approximate location of the patient's Iliac Crest and place the T-Lock over the 2 pins and into the rail clamp and tighten the clamp knob.


3. Position and roll the patient on their side so that their Iliac Crest is located near one of the five grooves in the Base Plate.

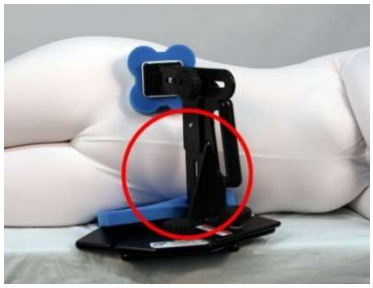
4. Slide the Back Plate into the groove that best aligns the lumbar pad with the patient's anatomy, keeping the edge of the Back Plate in line with the edge of the Base Plate. This allows for more adjustability for the Anterior Support Column.

5. Insert the Anterior Support Column into the groove closest to the patient's head and lock into place.

6. Insert the Hyperflexion Plate into the groove of the Base Plate, whereby the Support Column contacts patient's Iliac Crest.

7. ***Optional****:* Remove the bottom arm to allow more space for the abdomen of larger patients.



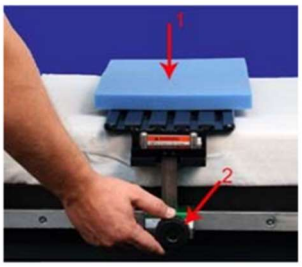
8. Tighten all knobs prior to starting the procedure.

Safety Test

Tighten Clockwise to Loc All Knobs

1. Make sure all *IMP*® Patient Protective Pads are attached.

2. Check All Locking Knobs.



Hand Cleaning Instructions

1. 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.

2. 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.

   Completely dry the components and return them to the storage case to protect them from damage.

3. IMP recommends that all components for each system be kept together as a kit and a component not be used with another kit.
   All components are tested as a kit before shipping.

Scan for additional documentation

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UDI

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