Innovative Medical Products™

Positioned to Perform

Instructions For Use

DE MAYO

ExactFit™

LATERAL HIP POSITIONER

Catalog Number **617**

Doc Title **IFU-IMP-0002**

Version **2**

Intended Use/Intended Users: The Exact-Fit® De Mayo Lateral Positioner® intended use is 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:

- Patients who have undergone recent hip surgery may have specific restrictions or precautions regarding the use of a hip positioner. The surgeon or orthopedic specialist should provide guidance on positioning and immobilizing the hip after surgery.
- Patients with certain neurological conditions or disorders that affect muscle tone or control, such as spasticity, may require special consideration when using a hip positioner to prevent injury.
- Excessive pressure on blood vessels in the hip area can lead to vascular compromise, such as reduced blood flow. This can be a concern for patients with pre-existing vascular conditions. Monitoring for signs of impaired circulation is essential during hip positioning.
- In cases of unstable hip fractures, the use of a hip positioner may not be appropriate, as it may worsen the fracture or dislocation. Stabilization and reduction of the fracture may be required first.
- Patients with cognitive impairment may not be able to communicate discomfort or pain caused by the hip positioner. Healthcare providers should be vigilant in monitoring such patients to avoid complications.

Warnings/Precautions

- Always follow the Instructions for Use (IFU) for proper setup and correct product usage.
- Untrained personnel must review and understand the IFU
- Safety: Always use IMP Patient Protective Pads
- Max number of reuses:
  The maximum number of reuses is not a fixed value. It depends on several factors that influence product wear and safety. The device must be inspected before each use, and reuse should be discontinued if there is irreparable wear.

Risks:

- Device should not come in direct contact with the patient.
- 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
617-SYS KIT	Exact-Fit® De Mayo Lateral Positioner® System Kit	00696588006314

Consumables:

- Patient Protective Pads

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.

Acceptable Accessories:

Part No	Product Name	GTIN
120	Quad® Clamp	00696588006178
617-CASE	Exact-Fit® Storage Case	00696588006321
617-SB	Exact-Fit® Stabilizing	00696588006345
617-CL	Exact-Fit® Rail Clamp	00696588006260
617-LS	Exact-Fit® Adjustable Lateral Support Arm	00696588006338
617-CPM	Clip-On™ Patient Protective Pads for Exact-Fit® De Mayo Lateral Positioner®	00696588007083

Symbol Glossary

Symbol	Title	Description	Standard
EC REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2021
LOT	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021
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 15223-1:2021
⚠	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
CE	Complies with European Directives.		

Symbol	Title	Description	Standard
	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
	Keep Dry		ISO 15223-1:2021
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1:2021
MD	Medical device		ISO 15223-1:2021
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 15223-1:2021
UDI	Unique device identifier		ISO 15223-1:2021

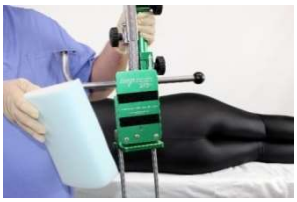
Instructions for Use:

Operating Room Set up

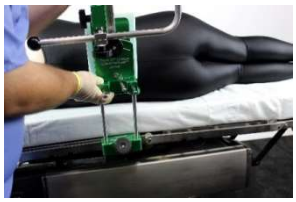
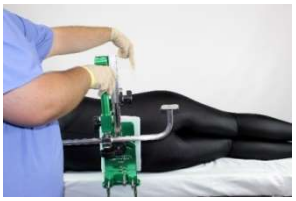
1. Attach the Quad® Clamp (CAT# 120) on the OR table at the back of the patient in line with the patient's iliac crest.

Refer to IFU-IMP-0003 for Quad® Clamp set-up instructions

2. Attach the contoured pad to the back plate of the Exact-Fit® positioner for a right or left hip

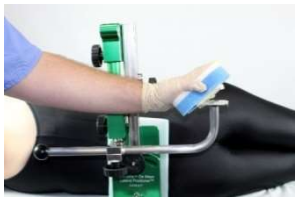


3. Insert the positioner into the Quad® clamp and slide the positioner with the vertical arm aligned with the patient's iliac crest

4. Lock the Quad® Clamp

5. Clip on the Anterior Support Pad



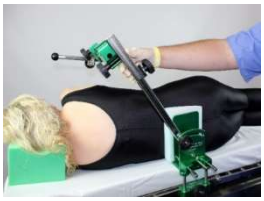
Refer to IFU-IMP-0014 for Clip-On Patient Protective Pads

6. Unlock **Knob 1** and move the horizontal bar up vertically until it stops Then tighten **Knob 1**


7. Using **Knob 2**, unlock the horizontal bar and rotate it over the patient and lock into place


8. Unlock **Knob 3** and turn the anterior support arm so that it roughly aligns with the patient's iliac crest and lock into place


9. Unlock **Knob 4** and move the vertical arm toward the patient's head and lock the knob

10. Unlock **Knob 1** and decrease the height of the horizontal bar until the horizontal arm is 2finger widths above the patient then lock **Knob 1**

11. Unlock **Knob 5 and 3** then position the anterior support arm to the final location of the ASIS (anterior superior iliac spine) and lock **Knob 5**

12. Pull the Anterior support arm tight to the patient and lock **Knob 3**


13. To rotate pelvic tilt more anterior, push the plate with the lumbar pad

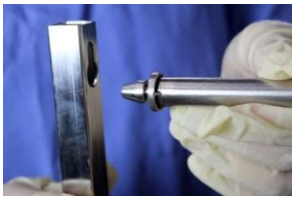
14. To rotate the pelvic tilt more posterior, push the button labeled “push to release” and pull the plate back

15. Ensure all knobs are tight

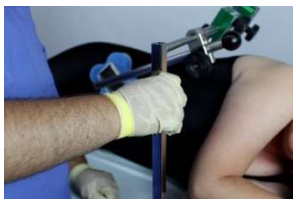
Attaching the Stabilizing Bar

1. Attach the clamp to the side-rail of the OR table on the patient’s front side aligning it with the horizontal bar

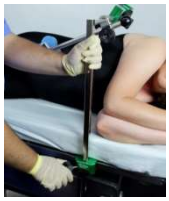
2. Insert the vertical stabilizing bar in the clamp and align the hole with the tapered end of the horizontal bar

3. Load the stabilizing bar by pulling the bar down



4. Lock the stabilizing bar clamp



**Optional: for use with slender patients

Attaching the Adjustable Lateral Support

1. Clip on the Patient Protective Pad® for the adjustable lateral support

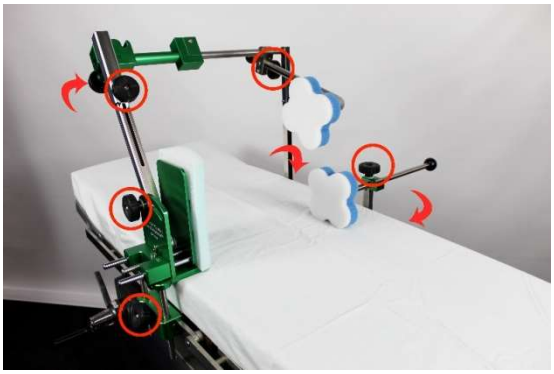
2. Attach the rail clamp to the rail in front of the patient at the level of the iliac crest

3. Insert the adjustable lateral support and locate the pad over the Inferior iliac crest then lock the rail clamp knob

4. Push the horizontal arm with the pad to contact the Iliac Crest and lock **Knob 6**

Safety Test

1. Ensure all knobs are tight including rail clamps
2. Perform a range of motion test on the operable leg prior to draping



Recommended Instructions:

The Family of IMP Hip Positioners and all the positioner's components can be cleaned in the following manner:

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.

4. All components are tested as a kit before shipping.

Scan for additional documentation

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