



Instructions For Use

De Mayo Hip Positioner®

Catalog Number **1101 (discontinued)**

Doc Title **IFU-IMP-0036**

Version **0**

**Intended Use/Intended Users:**

The De Mayo Hip 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. Surgeon must consider the health and size of the patient. There is no weight requirement for the positioner.

Contraindications:

- **Recent Hip Surgery:** 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.
- **Neurological Conditions:** 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.
- **Vascular Compromise:** 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.
- **Unstable Fractures:** 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.
- **Cognitive Impairment:** 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

- Do not use device in a manner that does not 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:

- 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.



Innovative Medical Products
87 Spring Lane
Plainville, CT 06062
USA
P: 860-793-0391
F: 866-459-1805
info@impmedical.com



Product Identification

Part No	Product Name	GTIN
1101	De Mayo Hip Positioner®	00696588001043

Consumables:

- 1101-CPM Clip-On™ Patient Protective Pads for De Mayo Hip Positioner®

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
	Imp rail clamp	

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
	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
	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



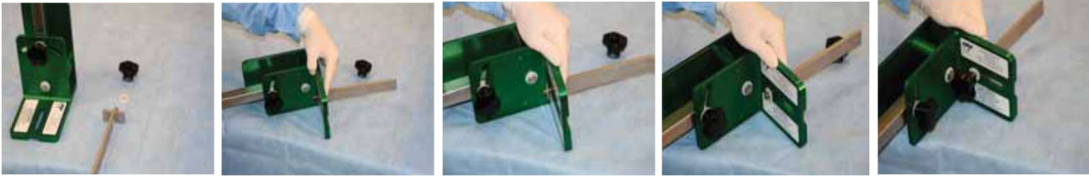
Symbol	Title	Description	Standard
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1:2016
	Medical device		ISO 15223-1:2016
	Not made with natural rubber latex		Manufacturer defined
	Serial Number	The manufacturer's serial number shall be placed after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

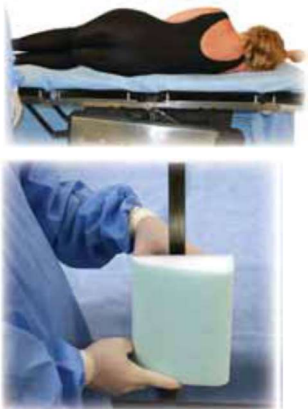
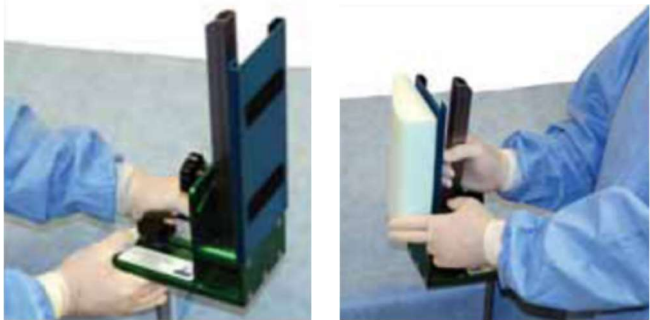
Instructions for Use:

1. Leave OR Table pads in place, then place OR bedsheet on top.



2. Pre-Assemble the Positioner. Assemble flat bar into bottom groove of Lumbar Support Base. Assemble washer and locking knob.



Standard Set up	Bariatric Set Up
<p>3. Roll the patient on their side. Attach Contoured Lumbar Pad for left or right hip application.</p> 	<p>Roll the patient on their side and attach Bariatric Extension plate (1101-BE) Attach contoured lumbar pad for left or right hip application</p> 


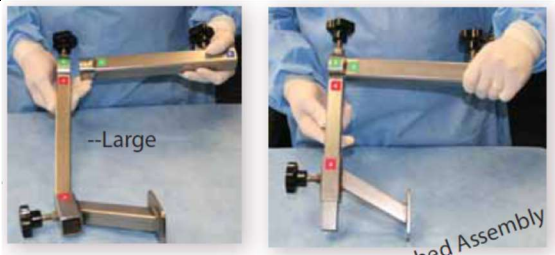




Standard and Bariatric Set Up	
<p>4. Assemble Lumbar Support Base into the IMP® Rail Clamp at a position even with the patient's iliac crest. Use the Vertical Bar in a straight and upright position as a guide to aim at the patient's iliac crest.</p>	<p>Lock Flat Bar Knob in center groove of Support Base.</p>



Standard Set up	Bariatric Set Up
<p>5. Angle the Vertical Support Bar towards the head of the patient. Assemble the Horizontal Crossover Standard Bar #1 onto the Vertical Bar #1. Allow 2 fingerbreadths space between the patient and the Bar.</p>	<p>Angle the Vertical Support Bar towards the head of the patient. Assemble the Horizontal Crossover Large Bar #1 onto the Vertical Bar #1. Allow 2 fingerbreadths between the patient and the bar.</p>

Anterior Support Assembly – Standard includes Anterior Support, Anterior Vertical Support (Std), Anterior Pelvic Support)	Anterior Support Assembly – Large includes Anterior Support, Anterior Vertical Support (Large), Anterior Pelvic Support)
	<p>CAUTION: Make sure the threaded knob fits into groove on #3</p> <p>Attach Anterior Rotation Bar #3 to round end of Horizontal Bar #3/2.</p>



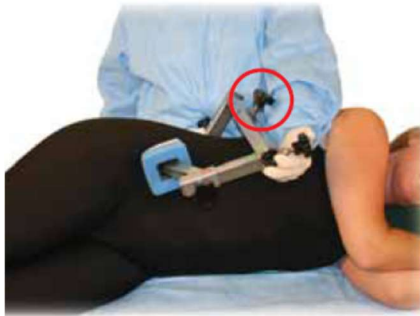
<p>Anterior Support Assembly – Standard includes Anterior Support, Anterior Vertical Support (Std), Anterior Pelvic Support)</p>	<p>Anterior Support Assembly – Large includes Anterior Support, Anterior Vertical Support (Large), Anterior Pelvic Support)</p>
<p>CAUTION: Make sure the threaded knob fits into groove on #3</p> 	 <p>Attach Anterior Pelvic Support #4 to Anterior Vertical Bar #4.</p>

<p>Standard and Bariatric Set Up</p>	
<p>6. Place Anterior Patient Protector Pad onto Anterior Support Assembly</p> 	<p>Attach pre-assembled #2, #3, #4 Anterior Support Assembly* on Crossover Bar #2.</p> 

<p>Standard</p>	<p>Bariatric</p>
<p>7. Rotate Anterior Vertical Bar #3 and adjust Anterior Pelvic Support #4, so that the Anterior Patient Protector Pad contacts the superior iliac crest.</p> 	<p>Slide the “Large” Anterior Support Assembly over Crossover Bar #2. Rotate Anterior Vertical Bar #3, and adjust Anterior Pelvic Support #4, so that the Anterior Patient Protector Pad contacts the superior iliac crest.</p> 



8. Compress Anterior Support Assembly pulling toward Lumbar Support. Lock Anterior Support Knob #2.



Compress Anterior Support Assembly pushing toward Lumbar Support



Lock Anterior Support Knob #2.



Standard and Bariatric

9. Tighten all knobs for security.

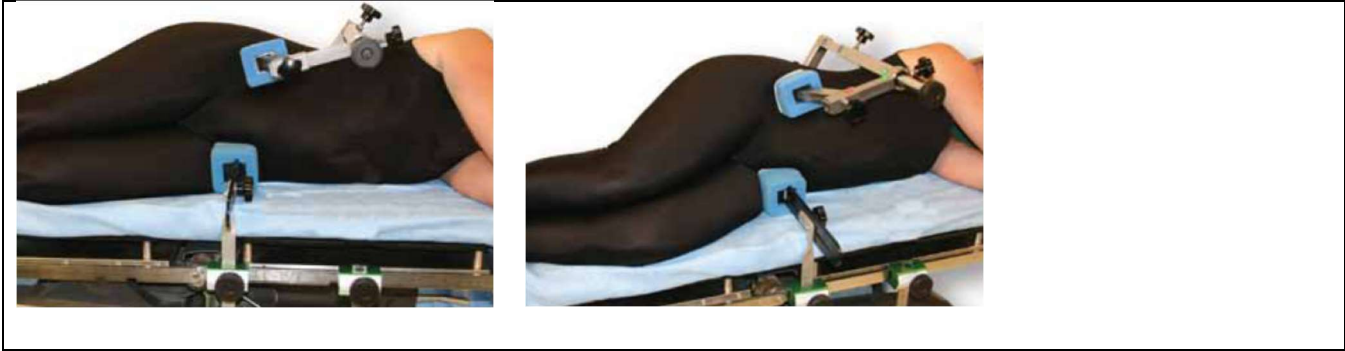


If any readjustments are required, release Compression Knob #2, then adjust any other knobs to achieve greatest stability.

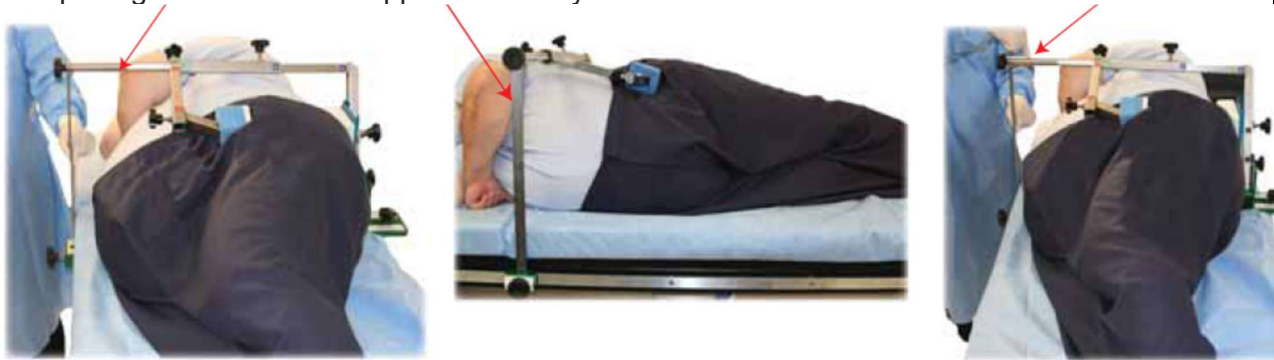


10. On very small patients, the Adjustable Lateral Support (707-L) with Patient Protector Pad (707-CPM) can be used to contact the patient's inferior iliac crest to prevent pelvic tilt and movement. Slide the Vertical Bar into the IMP® Rail Clamp. Adjust Horizontal Bar to make contact with the patient's inferior iliac crest.





11. **Option for bariatric set up:** Stabilizer Bar may be inserted into the Anterior Support Assembly with an additional IMP® Rail Clamp (note: maintain 2 fingerbreadths at the rib cage and Horizontal Crossover Bar). Add the Stabilizing Bar Tube by sliding it from the anterior side of the patient into the opening of the Anterior Support Assembly.



Slide the Stabilizing Bar Hook into the imp® Rail Clamp. Attach to the threads of the Stabilizing Bar Tube and tighten both knobs.

12. In the event (while utilizing the Stabilizing Bar) you cannot seat the Adjustable Support Assembly, loosen compression, and rotate plate. With the Anterior Pelvic Support out of the way, seat the Adjustable Lateral Support and re-engage the Anterior Pelvic Support.





Cleaning Procedure

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



Innovative Medical Products
 87 Spring Lane
 Plainville, CT 06062
 USA
 P: 860-793-0391
 F: 866-459-1805
info@IMPmedical.com



(01) 0 0696588 00104 3
 (11) 231107
 (10) 1234A001



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