Positioned to Perform | Innovative Medical Products™

Instructions For Use

De Mayo V2E® Knee Positioner®

Sterile Extension

Catalog Number **114-EXT**

Doc Title **IFU-IMP-0009**

Version **2**

Intended Use/Intended Users: The De Mayo V2E® Knee Positioner® Sterile Extension was designed for use with the Mayo V²E® Knee Positioner®. Its intended use is to extend the positioner on or off the OR table so that the surgeon can stand between the legs of the patient for greater access approaching the medial compartment. Orthopedic surgeons are the intended users.

Target Patient Group: This product is an accessory to the OR Table

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
- ***DO NOT PLACE POSITIONER IN A MILK BATH OR LUBRICATE***
- 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
P: 860-793-0391
F: 866-459-1805
info@IMPmedical.com

EC REP
Advena Ltd
Tower Business Centre, 2nd Flr,
Tower Street, Swatar, BKR 4013 Malta

Product Identification

Part No	Product Name	GTIN
114-EXT	De Mayo V2E® Knee Positioner® Sterile Extension	00696588001470

Consumables: Not Applicable

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: Not Applicable

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
	Unique device identifier		ISO 15223-1:2016

Instructions for Use:

1. Locate the patient's gluteal fold near the break at the end of the table.

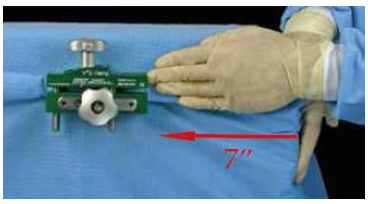
2. Apply a well leg holder to the non-operative leg.

3. Drape the patient, lower the end of the table and remove the pad.

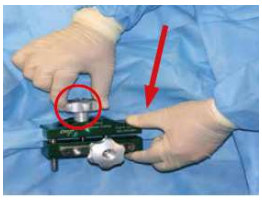
4. To position the clamp:

Method 1:

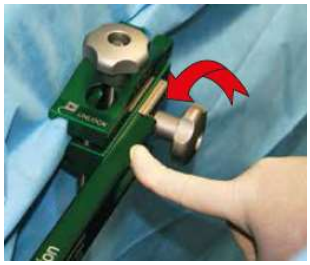
Find the end of the rail at the break and move the clamp proximal approximately 7 inches.



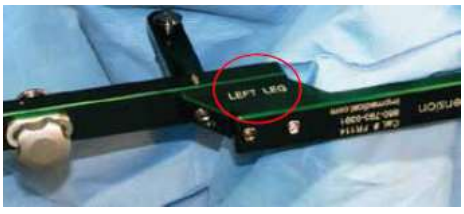
To lock the clamp on the side rail, squeeze the jaws and tighten the top knob.



Loosen the side knob all the way by turning it counterclockwise.



With the appropriate side leg showing on the extension, slide the cut out of the extension over the clamp's metal bar and side knob until it stops

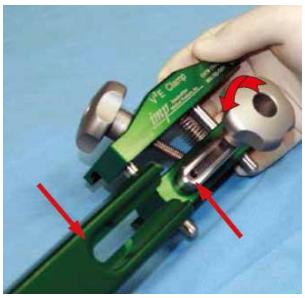


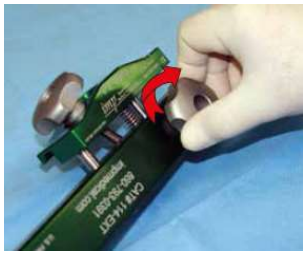
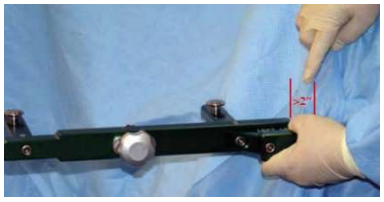
Turn the knob clockwise to tighten. 	Confirm a minimum of 2 inches of space between the end of the table and extension. 

Method 2 :

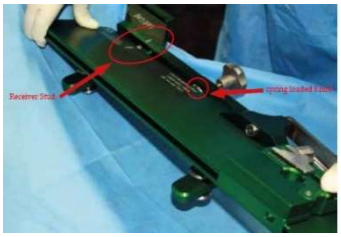
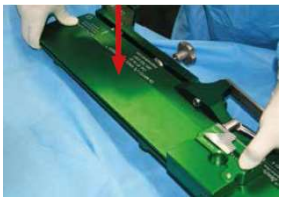
First attach the extension to the clamp assuring the side knob is completely loose by turning it counterclockwise, with the appropriate side leg showing on the extension.

Slide the cut out of the extension over the clamp's metal bar and side knob until it stops,



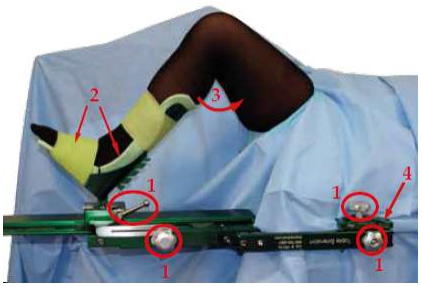
Turn the knob clockwise to tighten. 	Confirm a minimum of 2 inches of space between the end of the table and extension 

To lock the clamp to the side rail, squeeze the jaws and tighten the top knob.

5. Turn the spring-loaded knob counterclockwise all the way in the loose position prior to seating the base plate. 	6. To seat the base plate on the extension, line up the white arrows on the base plate and extension 
7. Pull the base plate at an angle against the receiver stud and end of the spring-loaded knob. 	8. Push down on the base plate for final seating and tighten the knob turning clockwise.   To remove, loosen knob all the way turning counterclockwise then pull the base plate and lift to remove.
Reference IFU-IMP-0008-IFU V2 Knee Positioner for knee positioner set-up	

Safety Test

1. Tighten clockwise to lock knobs and levers:
2. Check all knobs and levers are locked
3. Patient is fully protected by IMP® foam and cohesive wrap
4. Patient's Leg can reach full flexion
5. Sterile Extension Arm is fully seated into V2E® Clamp



Cleaning and Sterilization Procedure

NOTE: ALL SOLUTIONS MUST BE COMPATIBLE WITH ALUMINUM & STAINLESS STEEL

Recommended 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 9.0t
• **NOTE: SELECT CYCLE THAT DOES NOT INCLUDE LUBRICATION**

• Dry thoroughly and wrap.
• Sterilize per Sterilization Procedure

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.
• Make sure that all movable parts are loose and can move freely.
• *DO NOT PLACE POSITIONER IN A MILK BATH OR LUBRICATE*
• If using a sterilization case follow Instructions For Use for the product
• Double wrap in two disposable wraps. Use 48 inch x 48 inch wraps. (Approximately 122 cm x 122 cm).
• Run normal vacuum cycle for your institution
• **STEAM STERILIZATION ONLY- ALL OTHER STERILIZATION METHODS NOT VALIDATED**

Product	**Part Number**	**With Sterilization Case**	**Without Sterilization Case**	**Temperature Setting**	**Exposure Time**	**Dry Time**
De Mayo V2E® Knee Positioner® Sterile Extension	114-EXT	706-S	Double Wrap Only	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes

CAUTION: The positioner must be cool before applying to the patient

Sterilization Parameters Certified by:

- Micro Test Laboratories (now Accuratus Lab Services)
- Accuratus Lab Services
- HIGHPOWER Validation Testing and Lab Services

Scan for additional documentation

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

UDI

(01) 0 0696588 00147 0
(11) 230619
(10) 1234A001

CE MD