Positioned to Perform

Innovative Medical Products™

Instructions For Use

De Mayo V2® Knee Positioner®

Catalog Number **114, 114-S**

Doc Title **IFU-IMP-0008**

Version **1**

Intended Use/Intended Users: The De Mayo Knee Positioner's intended use is to position the patient's leg during a surgical procedure, including but not limited to total knee replacement, partial knee replacement and revision. Orthopedic surgeons are the intended users.

Target Patient Group: Patient selection depends on the judgment of the surgeon. Surgeon must consider size of the patient. The heel to popliteal region should be in between 13 inches (33 cm) and 18 inches (46 cm) and tibia should be over 11 inches (28 cm) in length.

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
- ***DO NOT PLACE POSITIONER IN A MILK BATH OR LUBRICATE***
- Max number of reuses:
  - Unplanned carriage movement
  - Excessive medial lateral movement of boot when the carriage is locked
  - Unrepairable wear and/or damage to the baseplate including locking pins

Risks:

- Device should not come in direct contact with the patient. Patient is protected with Patient Protective Pad
- Sterilized by end user
- No shelf life issues
- Re-usable
- Must be in compliance with the IFU with IMP accessories and components

Complaints and Adverse Events: For complaints and adverse events, contact IMP and the appropriate regulatory authorities for specific country

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Tower Street, Swatar, BKR 4013 Malta

Product Identification

Part No	Product Name	UDI-DI
114 KIT	De Mayo V2® Knee Positioner® (30" w/ 180° Flip Handle Assembly)	00696588001586
114-S KIT	De Mayo V2® Knee Positioner® (25" w/ 180° Flip Handle Assembly)	00696588001593

Consumables:

- Sterile Patient Protective Pads
- Coflex

Disposal of unit:

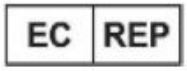
If a device is being returned for repair or disposal, please contact Innovative Medical Products at sales@IMPmedical.com. If the device is not being returned, instruments are to be disposed of in accordance with applicable laws, rules, and regulations for the disposal of biohazardous waste. Follow all 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	UDI-DI
114-CL	De Mayo V2®/V2E® Knee Positioner® Clamp	00696588001500
621	De Mayo Universal Distractor® 2.0	00696588007151
803-ABD	Aluminum Boot with Distractor Block	00696588001463
803-ABDA	Aluminum Boot with Distractor Block 110°	00696588006468
803-CBD	Composite Boot with Distractor Block for De Mayo Knee Positioner®	00696588000794
907*	De Mayo Universal Distractor®	00696588001388

*Denotes discontinued item

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

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

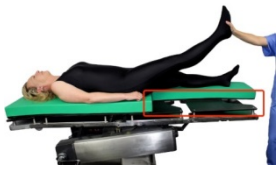
Instruction for Use:

1. Replace OR Table Pads with green IMP pads.

Note: It is not necessary to remove the X-Ray cassette plates.

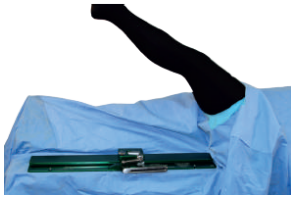
2. Position patient with gluteal fold at separation of pads.

3. During prep of surgical leg, remove single OR Table Pad.

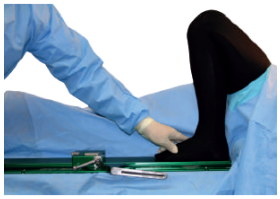


4. To avoid tearing the drape, create a 3"-5" fold in the final drape under the buttocks.

5. Place De Mayo V^2 Knee Positioner in the well to achieve maximum flexion.



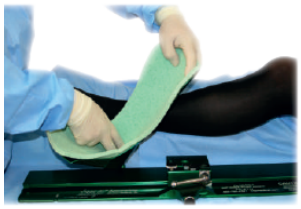
6. Check flexion for final approval of freedom of the drape to allow full range of motion when the Positioner is locked on drapes.



7. Position clamp over drapes so that the groove in the clamp can accept the Vertical Bar from Base.

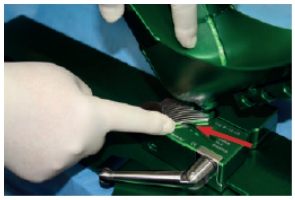
   See Individual Clamp IFUs

8. Insert the IMP Patient Protective Pad® into the sterile boot.

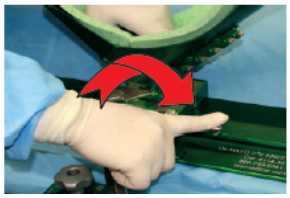


9. Insert the ball of the boot into the carriage and tighten the E-Brake.

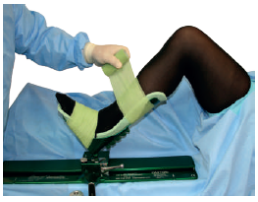
10. Slide the varus tilt lever to closed.

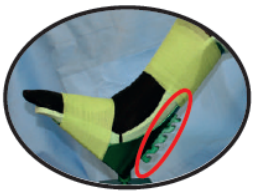


11. Rotate the handle to the right to fully lock the carriage



12. Place the patient's foot in the boot and wrap cohesive bandage around the foot starting with a minimum of six (6) foot wraps, tear, and finish the wrap above the distractor block around the calf.

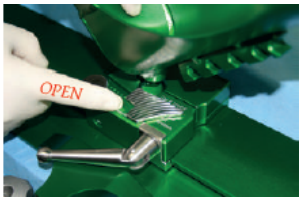


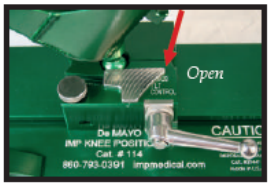


Note: Do not wrap cohesive bandage over the distractor block on the back of the boot.

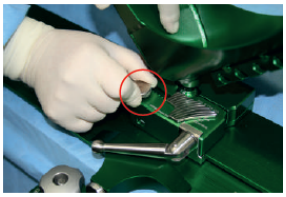
After surgery - recommend spraying the positioner with a pre-treatment prior to resterilization

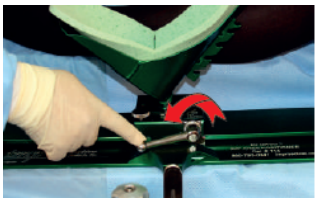
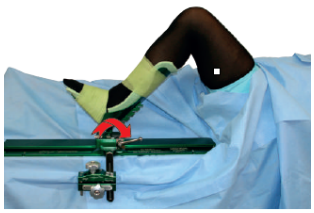
13. To reposition the leg:
    Slide the Varus tilt lever to open





14. Unlock the E-Brake by turning it counterclockwise,

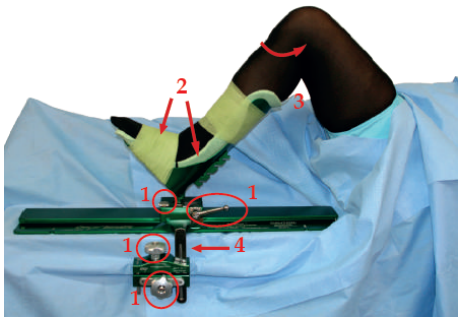


15. Loosen the handle by rotating to the left	16. Rotate the carriage handle to the right to lock the boot.
	

Safety Test

Tighten clockwise to lock knobs and levers:

1. Check all knobs and levers are locked.
2. Patient is fully protected by IMP® foam and Cohesive wrap.
3. Patient's legs can reach full flexion
4. Check that vertical bar is fully seated and locked.



Cleaning and Sterilization Procedure

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

Recommended Washer / Decontaminator Instructions:
• Remove carriage from positioner. Reference De Mayo V2 Knee Positioner Carriage with "Spring Loaded" Handle Instruction for use OR De Mayo V2 Knee Positioner Carriage with Pivot Handle Instruction for Use.
• **Note: All carriage components including the handle, boot and baseplate should be controlled so that the same components all get reassembled together**
• Soak the product in an enzyme solution (example: TRI-POWER ENZYMATIC CLEANER from UNITED BIOTECH www.united-biotech.net or similar). Follow the manufacturer's direction for dilution and soaking time. ***Validated by 3rd party for 15-minute soak time with Tri-Power**
• Put through washer / decontaminator according to manufacturer's instructions **with a detergent up to a pH of 9.0** **NOTE**: Select cycle that does not include lubrication.

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**
• 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
• **DO NOT LUBRICATE THE KNEE POSITIONER PRIOR TO STERILIZATION OR IN THE OR.**
• Assemble carriage to baseplate. Ensure original boot is placed with the assembled baseplate
• 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 Case Part Number**	**Temperature Setting**	**Exposure Time**	**Dry Time**
De Mayo V² Knee Positioner 114 & 114-S	706-S	270°F to 272°F 132°C to 134° C	4 minutes	30 minutes
De Mayo V² E Extension Arm 114 - EXT	706-S	270°F to 272°F 132°C to 134° C	4 minutes	40 minutes
	Without Sterilization Case			
De Mayo V² Knee Positioner 114 & 114-S	Without Sterilization Case Double Wrap Only	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
De Mayo V² E Extension Arm 114 - EXT	Without Sterilization Case Double Wrap Only	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
Accessories				
1 Clamp: 114-CL 1 Boot: 803-ABD, 803-ABDA or 803-CBD 1 Distractor: 907*, 621	706-XS OR 706-M	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
1 Clamp: 114-CL 1 Boot: 803-ABD, 803-ABDA or 803-CBD 1 Distractor: 907*, 621	No Case Wrap Only	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes

*Denotes discontinued item

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

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