Positioned to Perform

Innovative Medical Products®

Instructions For Use

De Mayo D2® Knee Positioner®

Catalog Number **803-114, 803-114-S**

Doc Title **IFU-IMP-0007**

Revision **03**

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. Surgeons must consider the 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.
- Patient is not to be in contact with device for over 24 hours.
- Untrained personnel must review and understand the IFU.
- Follow the IFU to correctly use the product.
- Safety: Always use IMP Patient Protective Pads
- ***DO NOT LUBRICATE POSITIONER OR PLACE IN A MILK BATH***
- 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 any of the following conditions are observed:
  - **Unplanned Carriage Movement:** If the carriage does not remain securely in place during use, indicating a loss of stability or locking integrity.
  - **Excessive Medial-Lateral Movement of the Boot When the Carriage is Locked:** If noticeable side-to-side movement is present when the carriage is in the locked position, suggesting wear or improper function.
  - **Irreparable Wear and/or Damage to the Baseplate, Including Locking Pins:** If any part of the baseplate, including locking pins, shows significant wear, deformation, or damage that cannot be repaired, compromising the device's safety and function.

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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Product Identification

Part No	Product Name	GTIN
803-114-BP	De Mayo D2® Knee Positioner®30" Baseplate w/Removable Carriage	00696588001333
803-114-S BP	De Mayo D2® Knee Positioner® 25" Baseplate w/Removable Carriage	00696588002217

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	GTIN
120*	Quad® Clamp	00696588006178
302*	Threaded Clamp	00696588001272
398-ABG	Armboard Pad Set 26" x 6" (2 per set)	00696588000763
398-LG	OR Table Pads Green (3 pc set) 398AG (1 each) and 398CG (2 each)	00696588004112
621	De Mayo Universal Distractor® 2.0	00696588007151
621-INT	De Mayo Universal Distractor® 2.0	00696588008363
706-M	De Mayo Knee Positioner® Medium Sterilization Tray - 16.5" x 12" x 6.5"	00696588000947
706-S	De Mayo Knee Positioner® Small Sterilization Tray - 32" x 12" x 2.5"	00696588000930
706-XS	De Mayo Knee Positioner® X-Small Sterilization Tray - 14.5" x 12" x 6.5"	00696588000923
713-302*	De Mayo Push Button™ Clamp	00696588001340
713-717	De Mayo Push Button Clamp-Locking Pin	00696588001517
713-717-INT	De Mayo Push Button™ Clamp -Pin Locking	00696588008356
803-ABD	Aluminum Boot with Distractor Block	00696588001463
803-ABD-INT	Aluminum Boot with Distractor Block	00696588008349
803-ABDA	Aluminum Boot with Distractor Block 110°	00696588006468
803-CBD*	Composite Boot with Distractor Block for De Mayo Knee Positioner®	00696588000794
803-GP-10	Sterile Patient Protective Pad for IMP® Knee Positioners & Cohesive Wrap (10 / Case)	00696588002880
903	De Mayo Single Lever Clamp	00696588001494
907*	De Mayo Universal Distractor®	00696588001388

Part No	Product Name	GTIN
907-GP-10	Sterile Pressure Protector Pad® for De Mayo Universal Distractor®	00696588002897
919	Friction Fold Down Pin Clamp Base	00696588005829
923-M	De Mayo Knee Positioner® SteriPod System - Filtered Container & Insert (Boot, Clamp & Distractor)	00696588007595
923-S	De Mayo Knee Positioner® SteriPod System - Filtered Container & Insert (Baseplate)	00696588007601

*Denotes discontinued item

Symbol Glossary

Symbol	Title	Description	Standard
EU 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	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 15223-1:2021
⚠	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.		
	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
	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

Symbol	Title	Description	Standard
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021

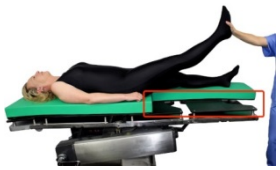
Instruction for Use:

1. Replace OR Table Pads with green IMP® OR Table Pads.

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

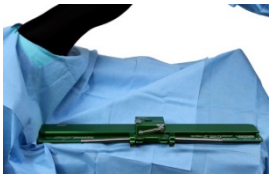
2. Position the patient with the gluteal fold at the separation of the pads.

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

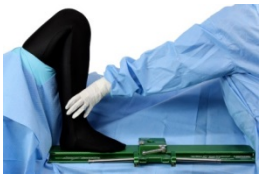


4. Create a 3”-5” fold in the final drape under the buttocks to reduce the possibility of tearing the drape.

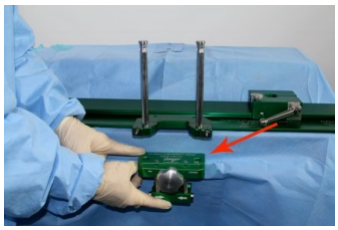
5. **Reference De Mayo D2 Carriage Removal and Replacement Sheet within this IFU.** Place the De Mayo D2® Knee Positioner® in the well to achieve maximum flexion.



6. Check flexion for final approval of freedom of the drape to allow full range of motion.

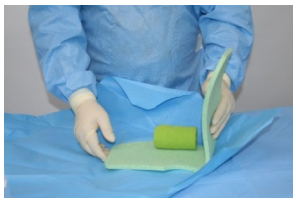


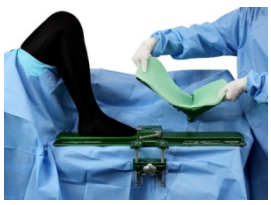
7. Position clamp directly under the guide pins in accordance with the clamp IFU.



See Individual Clamp IFUs.

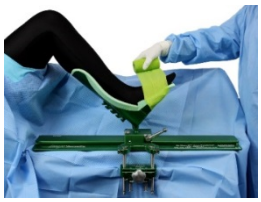
8. Insert IMP® Patient Protective Pad into the sterile boot.





For patient’s safety, always use IMP® Protective Pads. CAT #803-GP-10 and/or 907-GP-10.

9. Place the patient's foot in the boot. Wrap the cohesive bandage around the foot at least six (6) times, tear the wrap, and use the rest of the cohesive bandage to wrap around the calf above the distractor block.



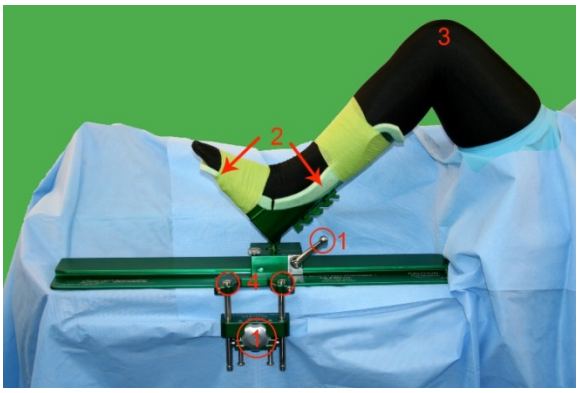
Note: Do not wrap cohesive bandage over the distractor block on the back of the boot.

After Surgery Recommendation - Spray the positioner with a pre-treatment prior to resterilization.

Safety Test

Tighten clockwise to lock the knob and lever

1. Check all knobs and levers are locked.
2. Patient is fully protected by IMP® foam and cohesive wrap.
3. Patient's leg can reach full flexion.
4. Check that both Guide Pins are fully seated.



Cleaning and Sterilization Procedure

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

Recommended Washer / Decontaminator Instructions:
• Remove carriage from positioner
• Optional: Pin Base does not need to be removed from baseplate but if desired, then remove from baseplate per: De Mayo Base Disassembly and Assembly
• **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 • **NOTE**: Use of ultrasonic cleaners are not validated

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
• **DO NOT LUBRICATE THE KNEE POSITIONER PRIOR TO STERILIZATION OR IN THE OR.**
• Assemble carriage to baseplate
• Assemble Pin Base to baseplate prior to sterilizing. 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**

MINIMUM PARAMETERS PRE-VAC STERILIZATION

Product Part Number	With Sterilization Case Case Part Number	Temperature Setting	Exposure Time	Dry Time
De Mayo D2 Knee Positioner 1 Baseplate: 803-114, 803-114-INT & 803-114-S 1 Clamp: 302*, 903, 713-302*, 713-717, 713-717-INT, 120* 1 Boot: 803-ABD, 803-ABD-INT, 803-ABDA or 803-CBD*	706-S	270°F to 272°F 132°C to 134° C	4 minutes	30 minutes

	Without Sterilization Case			
De Mayo D2 Knee Positioner 1 Baseplate: 803-114, 803-114-INT & 803-114-S 1 Clamp: 302*, 903, 713-302*, 713-717, 713-717-INT, 120* 1 Boot: 803-ABD, 803-ABD-INT, 803-ABDA or 803-CBD*	Double Wrap or Sealed Container (923)	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
Accessories				
1 Distractor: 907*, 621, 621-INT	706-XS OR 706-M	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
1 Distractor: 907*, 621, 621-INT	No Case Wrap **or** Sealed Container (923)	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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IMP Innovative Medical Products™
Positioned to Perform

De Mayo D2® Knee Positioner® Carriage Removal and Replacement

D2 COMPONENTS

Thumbscrew	Handle	E-Brake	Base Plate
Threaded Rod with L-Plate	Carriage	Boot	Teflon Pad

CARRIAGE REMOVAL

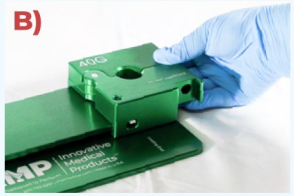
1 **A)** Unscrew the Thumbscrew with attached spring and remove the handle. **B)** Unscrew entire threaded rod with L-Plate using your fingers. If threaded rod with L-Plate is too tight to remove with fingers, put the handle back on and turn counter-clockwise to loosen.

2 Slide the carriage toward the "Loading End" (right side) of the Base Plate. Slide the carriage around the curved end of the top plate. Remove the carriage from the Baseplate.

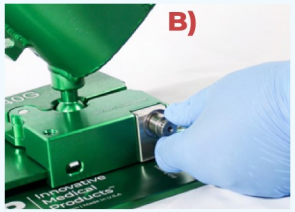
3 Unscrew the E-Break from the carriage. Do not remove Teflon pad.

CARRIAGE REPLACEMENT

1 **A)** While holding the Teflon Pad underneath the carriage, slide the carriage from the "Loading End" onto the base plate. **B)** Then slide the carriage around the curved end of the Base Plate.



2 **A)** Using your fingers, screw in the threaded rod with L-Plate into the carriage until the threads of the rod catch the inside of the carriage. **B)** Insert boot ball into carriage and continue to tighten until finger tight.



3 **A)** Replace the handle in the 11 - 1 o'clock range and **B)** screw in the Thumbscrew with attached spring until tight. **C)** The handle now becomes a spring-loaded handle.

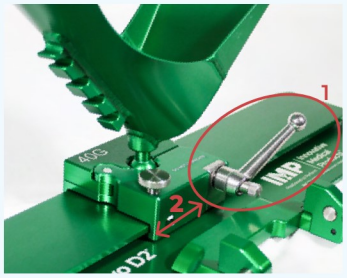
4 With the boot locked into the carriage, pull the spring- loaded handle out and turn either clockwise or counter-clockwise to make any final adjustments. Screw the E-Brake into the carriage.

SAFETY TEST

Unit must be safety tested before final processing.

1 Check that the handle locks the Boot Ball securely in the 12 - 3 o'clock range.

2 Check that the Boot can be removed and carriage can slide freely on the base plate when the handle is unlocked.



This guide is for the D2 Knee Positioner only.
No tools required.

De Mayo D2®
KNEE POSITIONER

Scan for additional documentation

Catalog Number **803-114, 803-114-S**