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**

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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EC REP
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Product Identification

Part No	Product Name	GTIN
803-114-A713-7	De Mayo D2® Knee Positioner® (30" Baseplate w/Removable Carriage, 803-ABD & 713-717)	00696588002477
803-114-S-A713-7	De Mayo D2® Knee Positioner® (25" Baseplate w/Removable Carriage, 803-ABD & 713-717)	00696588002187
803-114 KIT	De Mayo D2® Knee Positioner® (30" Baseplate w/Removable Carriage, 803-ABD & 903)	00696588001456
803-114-S KIT	De Mayo D2® Knee Positioner® (25" Baseplate w/Removable Carriage, 803-ABD & 903)	00696588001791

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
621	De Mayo Universal Distractor® 2.0	00696588007151
713-302*	De Mayo Push Button™ Clamp	00696588001340
713-717	De Mayo Push Button Clamp-Locking Pin	00696588001517
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
903	De Mayo Single Lever Clamp	00696588001494
907*	De Mayo Universal Distractor®	00696588001388
919	Friction Fold Down Pin Clamp Base	00696588005829

*Denotes discontinued item

Symbol Glossary

Symbol	Title	Description	Standard
EC REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community	ISO 15223-1:2016
LOT	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2016
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 15223-1:2016
⚠	Caution	Indicates the need for the user to consult the instructions for use for	ISO 15223-1:2016

Symbol	Title	Description	Standard
		important cautionary information such as warnings and precautions that cannot be presented on the medical device itself	
CE	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
MD	Medical device		ISO 15223-1:2016
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 15223-1:2016
UDI	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 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

5. 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, when the positioner is locked on the drapes

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

See Individual Clamp IFUs

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


For patient’s safety, always use IMP® Patient Protective Pads®.

9. 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

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 – Reference De Mayo D2 Knee Positioner Carriage Instructions for Use
• 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

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. 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 803-114 & 803-114-S	706-S	270°F to 272°F 132°C to 134° C	4 minutes	30 minutes
	Without Sterilization Case			
De Mayo D^2 Knee Positioner 803-114 & 803-114-S	Without Sterilization Case Double Wrap Only	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
Accessories				
1 Clamp: 302*, 903, 713-302*, 713-717, 120 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: 302*, 903, 713-302*, 713-717, 120 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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