

Instructions For Use

De Mayo Adapt2Fit™ Modular Knee Positioner

| | | | | | |
|----------------|---------------------|----------------|---------------------------|-------------|-----------------|
| Catalog Number | 1020 | Effective Date | September 27, 2021 | Status | APPROVED |
| Doc ID | IFU-IMP-0018 | Version | 2 | Page 1 of 6 | |

Intended Use/Intended Users: The De Mayo Adapt2Fit™ Modular 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" and 18"

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:

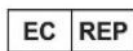
- Device should not come in direct contact with the patient. Patient is protected with Patient Protective Pad
- Sterilized by end user
- No shelf life issues
- Re-usable
- Must be in compliance with the IFU with IMP accessories and components

Complaints and Adverse Events:

For complaints and adverse events, contact IMP and the appropriate regulatory authorities for specific country



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Product Identification

| Part No | Product Name | UDI-DI |
|--------------|--|----------------|
| 1020-SYS KIT | De Mayo Adapt2Fit™ Modular Knee Positioner | 00696588006536 |

Consumables:

- Sterile Patient Protective Pads
- Coflex

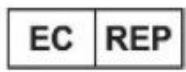









Disposal of unit:



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.





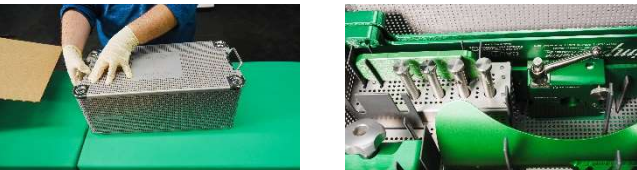

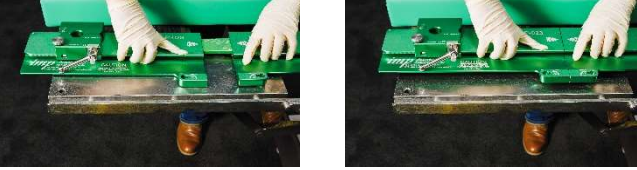

Acceptable Accessories:









| Part No | Product Name | GTIN |
|----------|---|----------------|
| 907 | De Mayo Universal Distractor® | 00696588001388 |
| 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 |

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 |

| Symbol | Title | Description | Standard |
|---|--------------------------|--|------------------|
|  | 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 |

| | |
|---|--|
| <p>1. Replace OR Table Pads with green <i>imp</i>® Pads.</p> <p>Note: It is not necessary to remove X-Ray cassette plates.</p> |  |
| 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. Open the sterilization tray and remove the baseplate halves and the baseplate connector. |  |
| 6. Insert the baseplate connector into one half of the baseplate until it stops. |  |
| 7. Connect the other baseplate by sliding it onto the protruding baseplate connector until the baseplates meet. |  |
| 8. Place the De Mayo Adapt2Fit™ Modular Knee Positioner in the well to achieve maximum flexion. The Adapt2Fit™ is designed to fit perfectly into the well created with no overhang. |  |

| | | |
|--|--|--|
| 9. Check flexion for final approval of freedom of the drape to allow full range of motion, when the positioner is locked on the drapes. |  | |
| 10. Position clamp directly under the holes in the baseplates in accordance with the clamp IFU |  See Quad® Clamp IFU | |
| 11. Insert a guide pin so that the protruding pin fits into the keyhole and goes into the clamp and turn it ¼ turn following the arrow on the baseplate. ***Note: Only 2 guide pins are needed to set up the positioner 2 extra guide pins have been provided in case of dropping or missing pins*** |  | |
| 12. Place the other guide pin into the baseplate and awaiting clamp |  | |
| 13. Tighten the knob of the Quad® Clamp |  | |
| 14. Insert <i>imp</i> ® Patient Protective Pad® into the sterile boot For patient's safety, always use <i>imp</i>® Patient Protective Pads®. | | |
|  |  | |
| 15. 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 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 Adapt2Fit Carriage Instructions 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** 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:

- Insure 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 Adapt2Fit Modular Knee Positioner 1020 | 706-A2 | 270°F to 272°F 132°C to 134° C | 4 minutes | 30 minutes |
| | Without Sterilization Case | | | |
| De Mayo Adapt2Fit Modular Knee Positioner 1020 | Without Sterilization Case Double Wrap Only | 270°F to 272°F 132°C to 134° C | 4 minutes | 20 minutes |
| Accessories | | | | |
| 1 Distractor: 907 | 706-M | 270°F to 272°F 132°C to 134° C | 4 minutes | 20 minutes |
| 1 Distractor: 907 | No Case 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

UDI



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