Positioned to Perform

Innovative Medical Products®

Instructions For Use

De Mayo Push Button™

Clamp-Pin Locking

Catalog Number **713-717**

Doc Title **IFU-IMP-0012**

Revision **04**

Intended Use/Intended Users: The De Mayo Push Button™ Clamp-Pin Locking was designed to lock the pins of the De Mayo knee positioner to the OR table rail, preventing inadvertent movement. 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

- Follow the IFU to correctly use the product.
- Untrained personnel must review and understand the IFU
- 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 movement is hindered and unrepairable.

Risks:

- Do not strike clamp, pins could bend
- Burrs could prevent locking
- Highly acidic or basic cleaners strip anodize

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
713-717	De Mayo Push Button™ Clamp -Pin Locking	00696588001517
713-717-INT	De Mayo Push Button™ Clamp -Pin Locking	00696588008356

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.

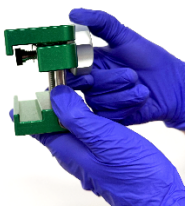
Symbol Glossary

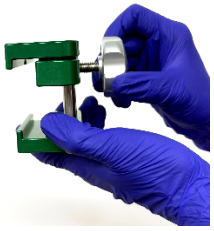
Symbol	Title	Description	Standard
EU REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community	ISO 15223-1:2021
LOT	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2021

Symbol	Title	Description	Standard
REF	Catalog 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
UDI	Unique device identifier		ISO 15223-1:2021

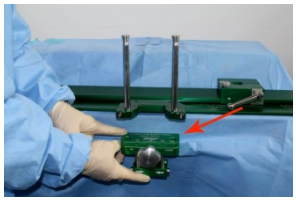
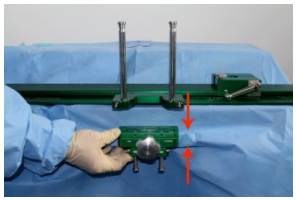
Instructions for Use:

1. Fully loosen the clamp knob by turning it counterclockwise until the black spinner foot sits flush against the upper jaw.
Warning: Stop turning the knob if you feel any resistance.

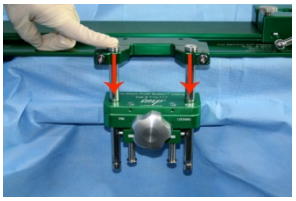




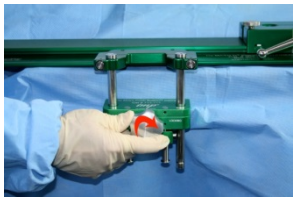
2. Place the clamp over the drapes so that the holes in the clamp align under the guide pins and squeeze the jaws firmly onto the rail.

3. Push the guide pins into the clamp holes.

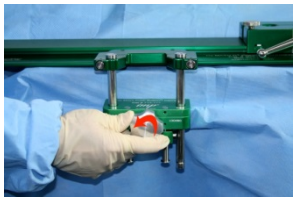


4. Tighten the clamp knob by turning it clockwise.



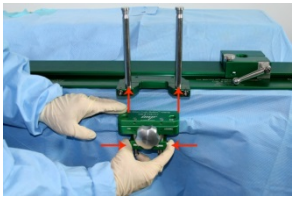
To Remove

1. Turn the clamp knob counterclockwise until it stops.



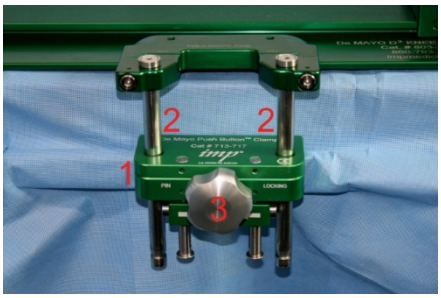
Warning: Stop turning if you feel any resistance

2. Pull the guide pins out of the clamp and lower the bottom jaw by squeezing the release buttons.



Safety Test

1. Check that clamp is locked on side rail
2. Check that both guide pins are fully seated
3. Check that clamp knob is secure



Cleaning and Sterilization Procedure

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

Recommended Washer / Decontaminator 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 9.0
• **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.
• 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**

MINIMUM PARAMETERS PRE-VAC STERILIZATION

Product Part Number	**With Sterilization Tray or Sealed Container Part Number**	**Temperature Setting**	**Exposure Time**	**Dry Time**
713-717, 713-717-INT	706-XS OR 706-M 923-M	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
	Without Sterilization Tray or Sealed Container			
713-717, 713-717-INT	Wrap Only	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes

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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