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Instructions For Use

De Mayo Single Lever Clamp

Catalog Number **903**

Doc Title **IFU-IMP-0013**

Version **1**

Intended Use/Intended Users: The De Mayo Single Lever Clamp was designed to clamp the De Mayo Knee Positioner to the OR table rail with a lever for simple and easy adjustment of the unit. 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

- Do not use device in a manner that doesn't follow these instructions for use.
- Untrained personnel - review and understand the IFU
- Do not strike clamp
- Max number of reuses:
  - Until movement is hindered and unrepairable

Risks:

- Burrs could prevent from 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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EC REP Advena Ltd
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Tower Street, Swatar, BKR 4013 Malta

Product Identification

Part No	Product Name	UDI-DI
903	De Mayo Single Lever Clamp	00696588001494

Disposal of unit:

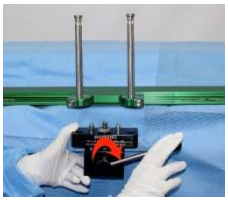
If a device is being returned for repair or disposal, please contact Innovative Medical Products at sales@IMPmedical.com. If the device is not being returned, instruments are to be disposed of in accordance with applicable laws, rules, and regulations for the disposal of biohazardous waste. Follow all 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
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	ISO 15223-1:2016

Symbol	Title	Description	Standard
		identified. The manufacturer's catalogue number shall be placed after or below the symbol and adjacent to it	
	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
	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

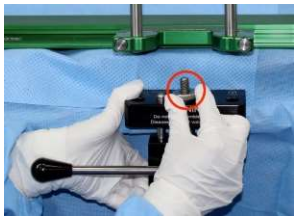
Instructions for Use:

1. Position the clamp onto the OR table rail and with the lever in "unlock" position. 	2. Rotate lever to "lock" position. 

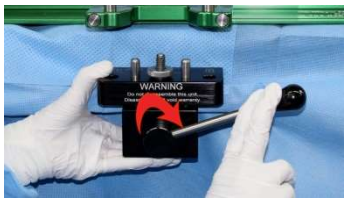
3. Squeeze jaws tight on side rail and tighten knurled knob clockwise all the way.


4. While holding clamp, rotate lever to “unlock”.

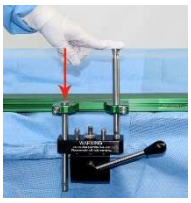
5. Turn knurled knob clockwise 1/4 to 1/2 rotation.



6. Rotate lever to “lock” position requiring only 2 finger pressure to achieve locking. Works like a vice grip and will “snap” into place.

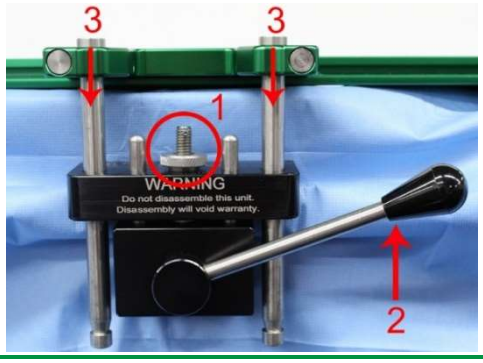


7. Slide and guide pins into holes of the clamp.



Safety Test

1. Ensure clamp knob is tightened
2. Lever in the “locked” position to the right side of the clamp
3. 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:

- 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 IN A MILK BATH
- Prior to each sterilization, we recommend placing at least 2 drops of mineral oil or standard hospital grade lubricant behind the cam (back side of the clamp) while moving the lever between open and close.

- 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
903	706-XS OR 706-M	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
903	No Case - 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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