Innovative Medical Products™

Positioned to Perform

Instructions For Use

Quad® Clamp

Catalog Number **120**

Doc Title **IFU-IMP-0003**

Version **3**

Intended Use/Intended Users: The Quad® clamp 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: The clamp 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:

- Jaws could wear to the point that they no longer lock
- 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
120	Quad Clamp®	00696588006178

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

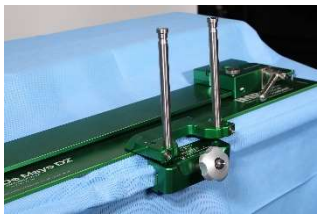
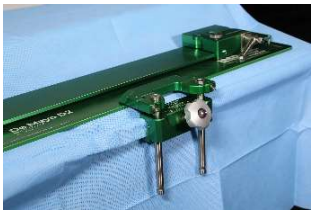
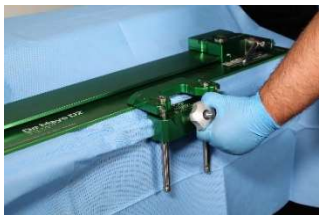
Symbol	Title	Description	Standard
EC REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2016
LOT	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016
REF	Catalog number	Indicates the manufacturer's catalogue number so that the medical device can be identified. The	ISO 15223-1:2016

Symbol	Title	Description	Standard
		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:

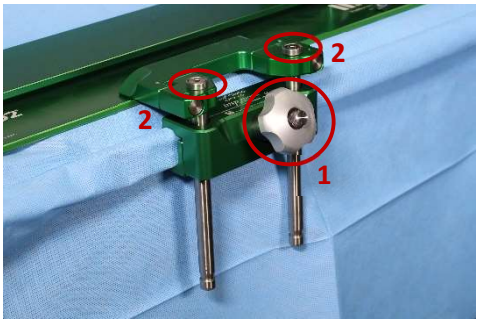
1. Turn the knob of the clamp counterclockwise to ensure that the bottom jaw is loose. Also, make sure the drapes are flat on the rail and they are not bunched up.


2. Place the top jaw of the clamp onto the OR table rail (over drapes) and then swing the bottom jaw underneath the rail.

3. While holding the right and left side of the clamp, squeeze the bottom jaw of the clamp around the OR table rail.  	4. While holding the top and bottom jaw of the clamp closed on the rail with one hand, tighten the knob clockwise with the other hand until you begin to feel resistance. 
5. Turn the knob counterclockwise 1-2 rotations until the knob feels slightly loose. 	6. Place your IMP Positioner and align the pins over the holes of the Quad Clamp. 
7. Push the positioner pins down into the holes of the clamp.   **Note: Use of mallets, hammers, or external tools are not needed to set pins effectively. If pins do not set easily turn the knob counterclockwise an additional 1-2 turns **	8. Now that both positioner pins are in place, fully tighten the knob clockwise. 

Safety Test

1. Ensure that the knob is tight.
2. Ensure that the guide pins are fully set.



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 Case Case Part Number	Temperature Setting	Exposure Time	Dry Time
120	706-XS OR 706-M	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
120	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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