Positioned to Perform | Innovative Medical Products™

Instructions For Use

De Mayo V2® / V2E® Knee Positioner Clamp

Catalog Number **114-CL**

Doc Title **IFU-IMP-0011**

Version **0**

Intended Use/Intended Users: The De Mayo V2®/V2E® clamp was designed to easily attach to side rail by squeezing the jaws to close and to release. A second function is that it can hold accessories on or off the OR table. 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
- Max number of reuses:
    - Until movement is hindered and unrepairable

Risks:

- Do not strike clamp, pins could bend
- 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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Product Identification

Part No	Product Name	GTIN
114-CL	De Mayo V2®/V2E® Knee Positioner® Clamp	00696588001500

Consumables: Not applicable

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.

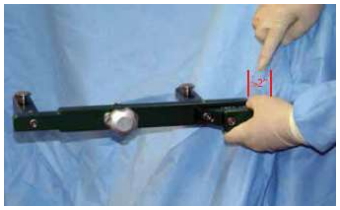
Symbol Glossary

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 catalog number so that the	ISO 15223-1:2016

Symbol	Title	Description	Standard
		medical device can be identified. The manufacturer's catalog 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
	Keep Dry		ISO 15223-1:2016
	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

V²E® Instructions

1. Attach the extension to the clamp assuring the side knob is completely loose by turning it counterclockwise, with the appropriate side leg showing on the extension. Slide the cut out of the extension over the clamp's metal bar and side knob until it stops, turn the knob clockwise to tighten.


2. Confirm a minimum of 2 inches of space between the end of the table and extension. 	3. To lock the clamp to the side rail, squeeze the jaws and tighten the top knob.  

Safety Test

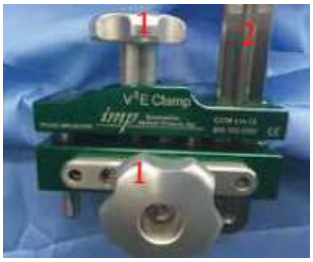
1. Check all knobs are tightened & locked
2. Ensure sterile extension is fully seated into the V2®/V2E®

V2® Instructions

1. Position clamp over drapes so that the groove in the clamp can accept the vertical bar from base. 	2. Squeeze jaws of the clamp loading top knob to middle of the clamp. 
3. Tighten top knob. 	4. Rotate the vertical bar into the groove of the clamp. 
5. Lock side knob on bar. 	The vertical bar must be vertical. Ensure that the vertical bar touches the clamp's slot edge on both the top and bottom jaws before locking side knob.  Vertical Bar is *not* vertical and only touches clamp's top jaw slot edge.  Vertical Bar is in correct position.

Safety Test

1. Check all knobs are tightened & locked
2. Ensure vertical bar position is correct and locked in clamp



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**
• 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
• Sterilize per Sterilization Procedure

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
114-CL	706-XS OR 706-M	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
114-CL	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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