Positioned to Perform

Innovative Medical Products™

Instructions For Use

De Mayo Universal Distractor 2.0®

Catalog Number **621**

Doc Title **IFU-IMP-0022**

Version **2**

Intended Use/Intended Users: The De Mayo Universal Distractor's intended use is to apply pressure to the femur outside the knee joint. For use with De Mayo Knee Positioners. 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
- Incorrect set up – follow IFU
- Safety: Always use IMP Pressure Protective Pads
- Max number of reuses:
    - Excess wear or until the device is unrepairable

Risks:

- Device should not come in direct contact with the patient.
- Distracting force – over distracting
- Highly acidic or basic cleaners may strip anodize

Complaints and Adverse Events: For complaints and adverse events, contact IMP and the appropriate regulatory authorities for specific country.

Innovative Medical Products
87 Spring Lane
Plainville, CT 06062
P: 860-793-0391
F: 866-459-1805
info@IMPmedical.com

EC REP Advena Ltd
Tower Business Centre, 2nd Flr,
Tower Street, Swatar, BKR 4013 Malta

Product Identification

Part No	Product Name	GTIN
621	De Mayo Universal Distractor® 2.0	00696588007151

Consumables:

- Sterile Pressure Protector Pad® for De Mayo Universal Distractor®

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-GP-10	Sterile Pressure Protector Pad® for De Mayo Universal Distractor®	00696588002897

Symbol Glossary

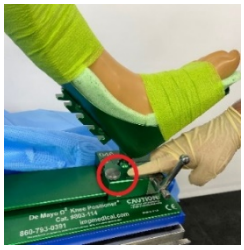
Symbol	Title	Description	Standard
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community	ISO 15223-1:2016
	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016
	Catalogue number	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
	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

Parts list:

Number	Description of Part
1	Support Bar
2	Distraction Handle
3	Release Lever
4	Distractor Body
5	Support Stem
6	Pressure Protector Pad ® (907-GP-10)

Instructions for use:

1. Once the carriage is locked in place, ensure the "E- Brake" is engaged by turning it clockwise.



2. Slide on Pressure Protector Pad® (CAT # 907-GP-10) on Support Bar.

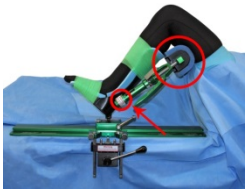
3. Lock the Pressure Protector Pad® into the Support Bar.

4. With the distractor fully closed/collapsed position, place the padded support bar on the back of the patient's thigh. Then using the surgeon's discretion place Support Stem into the appropriate rung of the distractor block on the boot.

5. Squeeze the Distraction Handle to distract 	6. Press Release Lever to release the distraction. 

Safety Test

1. Ensure Pressure Protector Pad® is locked onto the Support Bar.
2. Confirm Support Stem is in the appropriate distractor block.



For patient's safety, always use IMP® Pressure Protector Pads®.

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 thru 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**
• 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
- If using a sealed container, 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	Without Sterilization Case	Temperature Setting	Exposure Time	Dry Time
De Mayo Universal Distractor 2.0	621	706-M	Double Wrap or Sealed Container	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

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info@IMPmedical.com

UDI

(01) 0 0696588 007151
(11) 230523
(10) 1234A001