Positioned to Perform | Innovative Medical Products™

Instructions For Use

De Mayo Ankle Distractor™

Catalog Number **1109**

Doc Title **IFU-IMP-0023**

Version **1**

Intended Use/Intended Users: The De Mayo Ankle Distractor is a medical device used to distract the ankle or reduce a fracture of the ankle or tibia for ankle arthroscopies and trauma procedures. It is used to create controlled distraction between the bones of the ankle joint. Orthopedic surgeons and surgical teams are the intended users.

Target Patient Group: Adults: 15" from bottom of the foot to back of the knee.

Contraindications:

- Active Infection: Ankle distraction should not be performed when there is an active infection present in or around the ankle joint. Applying the distractor in the presence of infection may increase the risk of spreading the infection or hinder the healing process.
- Allergy or Sensitivity: Individuals with known allergies or sensitivities to materials used in the construction of the ankle distractor (e.g., metals) should not receive the device to avoid allergic reactions.
- Severe Osteoporosis: Severe osteoporosis, which weakens the bones, may be a contraindication as the application of an ankle distractor could pose an increased risk of fractures or other complications.
- Unstable Fractures: Ankle distraction may be contraindicated in cases of unstable fractures where the distraction could exacerbate instability or impede proper healing.

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:

- 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.

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Product Identification

Part No	Product Name	GTIN
1109	De Mayo Ankle Distractor™ Base & Bridge	00696588001524

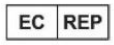
Consumables:

- 1109-P Sterile Pressure Protector Pad® & Ankle Strap

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.

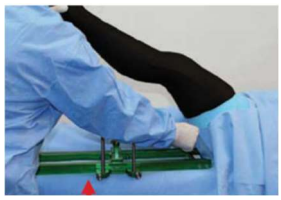
Symbol Glossary

Symbol	Title	Description	Standard
	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
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified. The manufacturer's catalog 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
	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

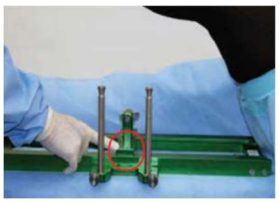
Symbol	Title	Description	Standard
SN	Serial Number	The manufacturer's serial number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2016
UDI	Unique device identifier		ISO 15223-1:2016

Instructions for Use:

1. Drape the leg according to hospital protocol and place Distractor base on the end of the OR table



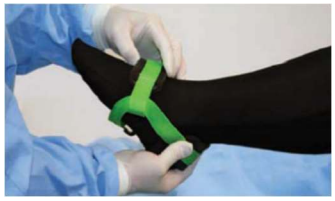
2. Place the sliding "bridge" in the middle of the base.



3. Open Sterile Patient Protector Pad and Ankle Strap and place on sterile table

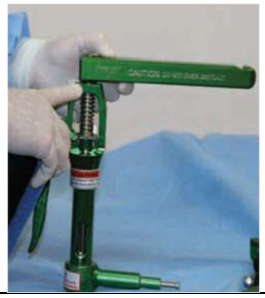
4. Unwrap and remove strap from the Pressure Protector Pad

5. Position the strap on patient's foot with the logo strap on the heel and the dorsal strap on top.

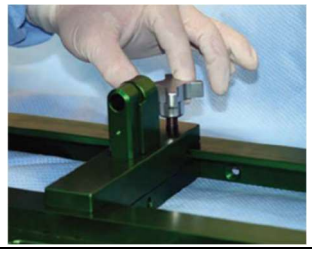


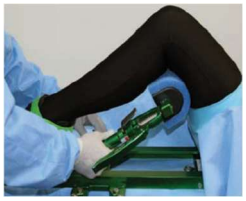
6. Clip the strap to the eye bolt of the base

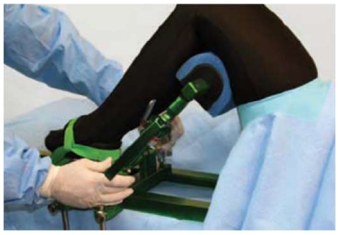
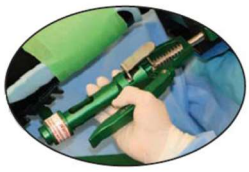
7. With the De Mayo Universal Distractor® in the collapsed position, place the pressure protector pad on the top bar



8. With the bridge locked, pull up the locking clip

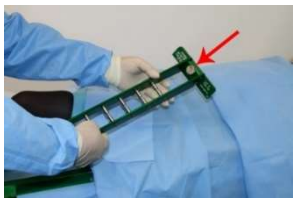
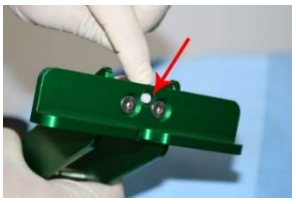


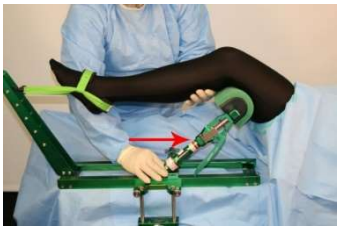
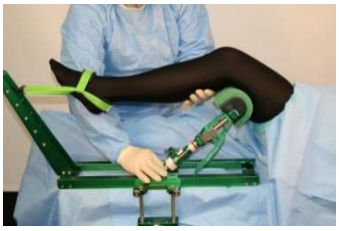
9. Insert the lower bar of the distractor and seat the locking clip 	10. Position the pressure protector pad at the distal femur 

11. Unlock and push the bridge until the strap is tight and lock in place 	12. Squeeze the De Mayo Universal Distractor handle for futher distraction 

Reference IFU-IMP-0012 De Mayo Push Button™ Clamp -Pin Locking or IFU-IMP-0013 Single Lever Clamp for clamp attachment.

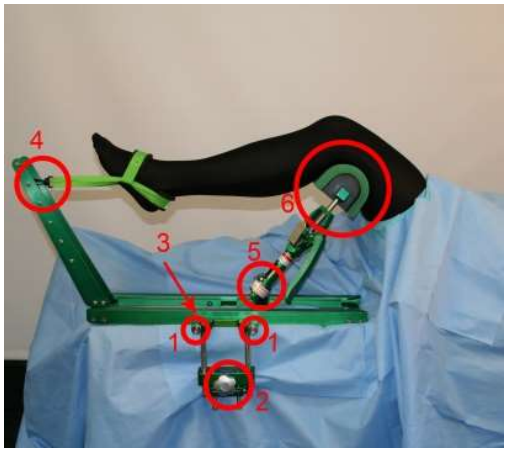
Instructions for Ankle Distractor Accessory

1. Hold the De Mayo Ankle Accessory (for posterior approach) with the knob facing up. 	2. Ensure the plastic tip of the knob is recessed into the hole underneath 
3. Slide attachment onto the base end under the patient's foot 	4. Tighten the knob 

5. Attach the ankle strap clip to any of the cross bars prior to inserting the distractor 	6. Insert distractor lower bar and lock clip 
7. Push distractor until tight 	8. Distract ankle 

9. Set up is complete – patient is ready for surgery

Safety Test



Tighten clockwise to lock the knob and lever

1. Lock both sliding pin knobs
2. Tighten knob on push button clamp
3. Check sliding pins are fully seated
4. Ankle strap locked to cross bar
5. Distractor bottom extension is fully seated and locked in sliding bridge
6. Protective Pad is placed on top distractor extension and properly centered under patient's leg

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 (example: TRI-POWER ENZYMATIC CLEANER from UNITED BIOTECH www.united-biotech.net or similar). Follow the manufacturer's direction for dilution and soaking time. ***Validated by 3rd party for 15-minute soak time with Tri-Power**
• 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** 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
• 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
1109	1109-XS	270°F to 272°F	4 minutes	20 minutes

		132°C to 134° C		
	Without Sterilization Case			
1109	Without Sterilization Case Double Wrap Only	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
Accessories				
1 Clamp: 302*, 903, 713-302*, 713-717 1 Distractor: 907*, 621	1109-XS	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes
1 Clamp: 302*, 903, 713-302*, 713-717, 1 Distractor: 907*, 621	No Case Wrap Only	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes

* Denotes discontinued product

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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