Innovative Medical Products™

Positioned to Perform

Instructions For Use

Sterilization Tray

Catalog Number **706**

Doc Title **IFU-IMP-0043**

Version **0**

Intended Use/Intended Users:

The intended use of a sterilization tray is to provide a secure, organized, and sterile storage solution for medical instruments and devices before, during, and after sterilization processes.

- Sterilization trays are equipped with compartments, trays, or other organizing features to securely hold medical instruments and devices in an organized manner. This facilitates efficient preparation and setup for surgical procedures or other medical interventions.
- The tray serves as a protective enclosure for medical instruments, shielding them from damage during handling, transportation, and storage. This helps maintain the integrity and functionality of the instruments, ensuring they are ready for use when needed.
- Sterilization trays are constructed from materials compatible with various sterilization methods, such as steam sterilization. They are designed to withstand the sterilization process without compromising the sterility of the enclosed instruments.
- By providing a sterile storage environment for medical instruments, sterilization trays contribute to infection control efforts within healthcare facilities. They help minimize the risk of surgical site infections and other healthcare-associated infections by ensuring that instruments remain sterile until they are required for patient care by reducing blue wrap tears and pinholes

Target Patient Group:

The target patient group for sterilization tray is not the patients but rather the healthcare professionals who use these trays to store and organize sterilized medical instruments and devices. This includes:

- Sterile Processing Department and OR staff use sterilization trays to store and transport sterile instruments during surgical procedures. They rely on these trays to have easy access to the necessary instruments while maintaining their sterility throughout the surgical process.
- Sterile Processing Technicians are tasked with sterilizing medical instruments and devices to ensure they are safe for patient use.

While patients themselves do not directly use sterilization trays, they indirectly benefit from the use of these trays through the provision of safe and sterile medical instruments during surgical procedures and other medical interventions.

Contraindications:

While sterilization trays, themselves do not typically have contraindications, there are considerations regarding their use and handling within healthcare settings:

- Material Compatibility: Sterilization trays are designed to withstand the sterilization process, but some materials may not be compatible with certain sterilization methods.
- Compatibility with Instruments: Some specialized medical instruments may not be suitable for sterilization within certain types of sterilization trays. Compatibility with the size, shape, and material of the instruments should be considered to prevent damage or ineffective sterilization.
- Cleaning and Maintenance: Improper cleaning and maintenance of sterilization trays can compromise their effectiveness and lead to contamination of enclosed instruments.
- Proper Sterilization Procedures: Sterilization trays must be properly prepared and loaded according to recommended sterilization procedures to ensure the effectiveness of the sterilization process. Failure to follow proper sterilization protocols can result in inadequate sterilization and compromised instrument sterility.
- Storage and Handling: Sterilization trays should be stored in a clean, dry, and controlled environment to prevent contamination of enclosed instruments. Proper handling practices,

including avoiding contact with non-sterile surfaces, should be followed to maintain the sterility of the tray and its contents.

Warnings/Precautions

- Sterilization trays are intended for use by trained healthcare professionals who understand proper sterilization procedures and infection control practices. They should not be used by individuals without appropriate training or qualifications.
- Follow Instructions For Use: Users should carefully read and follow the manufacturer's instructions for the proper use, sterilization, and maintenance of the sterilization tray. Deviating from these instructions could compromise instrument sterility and patient safety.
- Inspect for Damage: Before each use, inspect the sterilization tray for any signs of damage, wear, or deterioration.
- Proper Loading Properly load instruments into the sterilization tray according to the manufacturer's instructions. Overloading or improper arrangement of instruments could impede sterilization and compromise instrument sterility.
- Store in Clean Environment: Store sterilization trays in a clean, dry, and controlled environment to prevent contamination of enclosed instruments. Avoid storing trays near sources of moisture, chemicals, or potential contaminants.
- Regular Maintenance: Perform regular maintenance and inspection of sterilization trays to ensure their continued functionality and effectiveness. Replace worn or damaged components as necessary to maintain instrument sterility and user safety.

Risks:

- Improper Loading: Incorrect placement of instruments in the tray could block sterilant exposure, leading to inadequate sterilization.
- The weight of positioner and tray may exceed AAMI standard 25 lb. safe weight limit.

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
706-XS	De Mayo Knee Positioner® X-Small Sterilization Tray - 14.5" x 12" x 6.5"	00696588000923
706-M	De Mayo Knee Positioner® Medium Sterilization Tray - 16.5" x 12" x 6.5"	00696588000947
706-S	De Mayo Knee Positioner® Small Sterilization Tray - 32" x 12" x 2.5"	00696588000930

Part No	Product Name	GTIN
706-A2	De Mayo Adapt2Fit® Modular Knee Positioner Sterilization Tray - 20" x 10" x 8"	00696588006482

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.

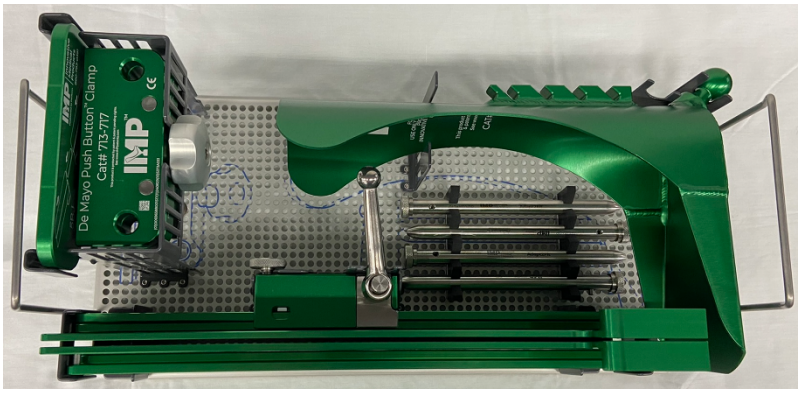
Symbol Glossary

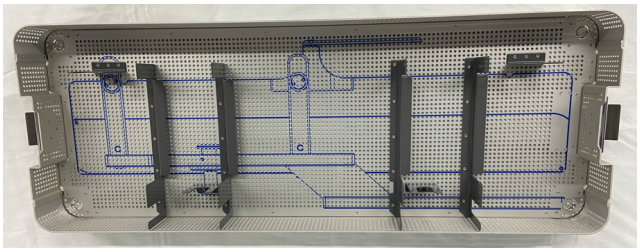
Symbol	Title	Description	Standard
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2016
	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016
	Catalogue number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

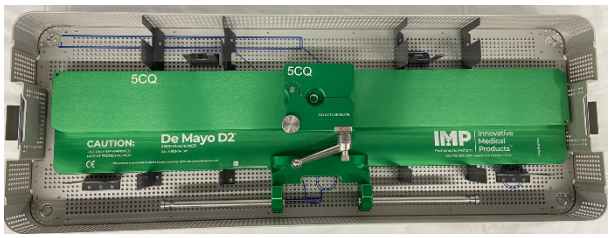
Symbol	Title	Description	Standard
MD	Medical device		ISO 15223-1:2016
UDI	Unique device identifier		ISO 15223-1:2016

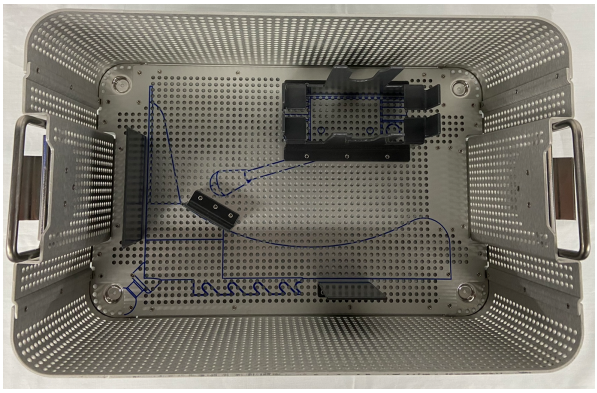
1. Inspect the tray, lid and inserts for cleanliness and damage prior to use.
   CAUTION: Damaged components could have sharp edges

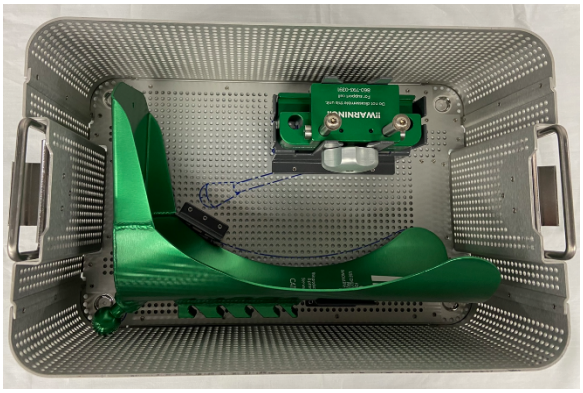
2. Place the instruments within the tray (follow component outlines)

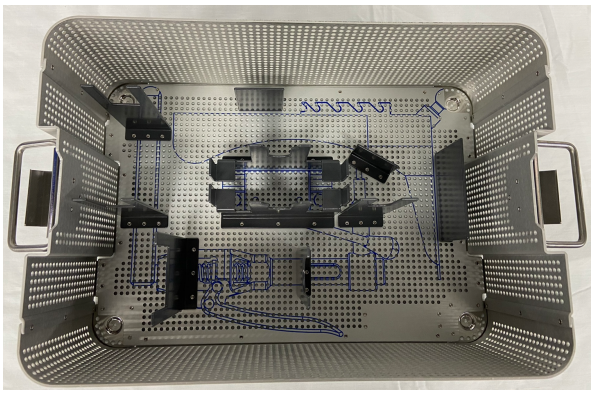


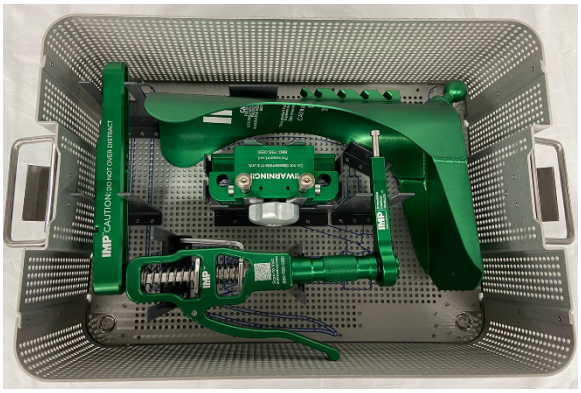












3. Place the tray into the sterilizer, select appropriate cycle. After cycle is complete, allow the tray to cool before handling

Cleaning and Sterilization Procedure

NOTE: ALL SOLUTIONS MUST BE COMPATIBLE WITH ALUMINUM & STAINLESS STEEL

For cleaning and sterilization procedures without using the sterilization tray, see individual product IFU

Recommended Washer / Decontaminator Instructions:
• Remove carriage from positioner – Reference De Mayo Adapt2Fit Carriage Instructions for Use or De Mayo D2 Knee Positioner Carriage Instructions for Use
• **Note: All carriage components including the handle, boot and baseplate should be controlled so that the same components all get reassembled together**
• 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
• Assemble carriage to baseplate
• Assemble Pin Base to baseplate. Ensure original boot is placed with the assembled baseplate
• 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 tray, 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 Tray Tray Part Number**	**Temperature Setting**	**Exposure Time**	**Dry Time**
De Mayo D2 Knee Positioner 803-114 & 803-114-S	706-S	270°F to 272°F 132°C to 134° C	4 minutes	30 minutes
De Mayo Adapt2Fit Modular Knee Positioner 1 Baseplate: 1020 1 Clamp: 713-717, 120 1 Boot: 803-ABD, 803-ABDA or 803-CBD	706-A2	270°F to 272°F 132°C to 134° C	4 minutes	30 minutes
Accessories				
1 Clamp: 302*, 903, 713-302*, 713-717, 120 1 Boot: 803-ABD, 803-ABDA or 803-CBD 1 Distractor: 907*, 621	706-XS OR 706-M	270°F to 272°F 132°C to 134° C	4 minutes	20 minutes

*Denotes discontinued item

Sterilization Parameters Certified by:

- Micro Test Laboratories (now Accuratus Lab Services)
- Accuratus Lab Services
- HIGHPOWER Validation Testing and Lab Services

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UDI

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Scan for additional documentation

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