



INSTRUCTIONS FOR USE

Sterilization Trays

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a dentist or physician.

INDICATIONS FOR USE

Miltex Sterilization Trays are intended for the protection, organization and the delivery to the surgical field of surgical instruments and/or other medical devices. Miltex Sterilization Trays are not designed to maintain sterility by themselves. They are designed to facilitate the sterilization process when used in conjunction with a wrapping material (FDA cleared sterilization wrap) or a specified filtered sterilization container system. Wrapping materials and sterilization containers are designed to allow air removal, steam penetration/evacuation (drying) and maintain the sterility of the internal components.

CONTRAINDICATIONS

- Miltex Sterilization Trays have not been validated for use with flexible endoscopes, or devices with lumens or working channels longer than four inches (3mm ID). Always refer to instrument manufacturer instructions.

WARNINGS

- Do not stack trays in autoclave chamber. Stacking of trays and overloading of the units will adversely effect sterilization and drying effectiveness.
- Do not overload trays. Balance instrument within the trays and arrange to allow steam to come in contact with all objects in the container.

PRECAUTIONS

- Do not load trays into sterilizer on sides or upside down with lid side on the shelf of cart. Load trays on cart or shelf, so that the lid is always facing upward. This will allow for proper drying. Miltex Sterilization Trays are designed to drain in this position.
- Do not use solvents, abrasives cleaners, metal brushes or abrasive pads.
- Always follow instrument manufacturer instructions if their sterilization or drying recommendations exceed these guidelines.
- After the autoclave door is opened, all cases must be allowed to cool thoroughly. The potential for condensation may increase if the case is not allowed to cool properly.

HOW SUPPLIED

Miltex Sterilization Trays are supplied NON-STERILE and packaged one per box.

INSTRUCTIONS FOR USE

- Both physical and chemical (detergent) processes may be necessary to clean soiled items. Chemical (detergent) cleaners alone cannot remove all soil and debris; therefore, a careful manual cleaning of each item with a soft sponge or cloth is essential for maximum decontamination. For difficult access areas, a clean soft bristled brush is recommended.
- Once the items have been cleaned, they should be thoroughly rinsed with clean water to remove any detergent or chemical residue before sterilization.
- Miltex sterilization trays can be placed in mechanical cleaning equipment.
- Always inspect for cleanliness or damage before use. Make sure all latches and handles are secure and in working order.

STERILIZATION INSTRUCTIONS

- Miltex recommends that the sterilization trays be processed according to the sterilization wrap manufacturer's instructions prior to sterilization to maintain sterility of internal components/items and for proper aseptic presentation to the surgical/dental field.
- For Prevacuum Sterilizer:
 - Wrapped trays and instruments should be exposed to 132° C to 135° C (270° F to 275° F) for at least four minutes.
 - Dry 20 to 40 minutes.
- For Gravity Displacement Sterilizer
 - Wrapped trays and instruments should be exposed to 132 C to 135 C (270 F to 275 F) for at least 30 minutes, or 121° C to 123° C (250° F to 254° F) for at least 55 minutes.
 - Dry for 20 to 50 minutes.
- Variables that may affect drying times include: loading density of the tray, instrument configuration, total contents of the sterilizer, steam quality, equipment maintenance and others.

MAINTENANCE OF TRAYS

- Always inspect for cleanliness or damage before use.
- Make sure all latches and handles are secure and in working order.

SYMBOLS USED ON LABELING



Manufacturer



Authorized Representative in the European Community



Catalog number



Lot number



Non-sterile: Sterilize prior to use



CAUTION: See warnings or precautions



Consult instructions for use



Product complies with requirements of directive 93/42/EEC for European Union Class 1 medical devices

Rx ONLY CAUTION: Federal (USA) law restricts this device to sale by or on the order of a dentist.



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