EN

INSTRUCTIONS FOR USE

PLASTIC STERILIZING INSTRUMENT TRAYS

DESCRIPTION AND INTENDED USE

Plastic sterilizing instrument trays are designed to encase instruments during processing and are safe for all standard sterilization methods: Autoclave/dry heat up to 360ºF, ETO, and Cold Solutions.
The tray will last over 1000 cycles when properly handled and processed.

GENERAL INFORMATION

- These INSTRUCTIONS FOR USE are designated only for persons with the required knowledge and training in a healthcare facility.
- All reprocessing instructions provided are general guidelines and will require validation by the end-user at the point of use.
- Cleaning and Disinfection Processing Equipment should be certified and validated.

WARNINGS

- An appropriate sterile barrier will be required to maintain sterility.
- Use of the Plastic Sterilization Instrument Trays must be in accordance with the operating instruction supplied with your particular sterilization equipment and in keeping with your particular sterilization equipment and in keeping with your hospital policy on sterilization validation. Several organizations (e.g., AAMI, AORN and ISO) publish guidance information on sterilization usage should you need additional information.
- Periodic cleaning of the trays after sterilization process is recommended to prolong usable life.
- **Do not use if damaged.**

CLEANING GUIDELINES

- All trays should be cleaned, disinfected and sterilized before use for the first time and then after every use and/or every time they are contaminated.
- During the cleaning stages the trays must be disassembled completely.
- After each use, all components of the Plastic Sterilization Instrument Tray should be washed in a mild, neutral pH enzymatic detergent. For optimal removal of soil and debris, soft sponges and soft cloths may be used to clean the plastic tray components. Hard to reach spaces such as between the pins of the mat may be cleaned using a soft-bristled brush. Abrasive cleaning chemicals, brushes, or pads should not be used.
- Under running water and rinsing thoroughly (or you can use a disinfectant solution rinsing thoroughly) use a soft brush or soft cloth to manually remove impurities. Cleaning the surfaces until there is no more visible contamination and cleaning the holes separately with a fine brush. When visible contamination is gone be sure to rinse all parts thoroughly under the water at least three times, moving parts back and forth to ensure contamination and solution (if applicable) is removed completely.

INSTRUCTIONS

1. The Plastic Sterilization Instrument Tray and mat should be cleaned prior to first use in accordance with the cleaning guidelines above.
2. Configure the tray, mat, and inserts (if applicable) properly to accommodate the instruments that are meant to be sterilized. The mat should be used to help stabilize, separate, and protect the instruments while inside the tray. Instruments should be arranged in a single layer with adequate spacing to prevent them from coming into contact with each other.
3. An approved sterility assurance device (i.e. Multi-parameter chemical indicator) should be placed inside and on each level (when applicable) of the tray in a location that is easily visible to the user.
4. Cover the tray with the lid and press down until the side tabs click shut, securing the lid.
5. Wrap the Plastic Sterilization Instrument Tray with an approved non-woven textile wrap.
6. The tray(s) should always be placed flat on the sterilizer rack prior to sterilization. Stacking of trays inside the autoclave chamber is not recommended.
7. Sterilize the loaded wrapped tray(s) in accordance with the instrument device manufacturer's guidelines for Pre-Vacuum steam sterilization.
8. After cleaning with detergent, the tray should be washed thoroughly with warm tap water for at least one minute. A soft, absorbent towel should be used to dry the tray. Inspections of components should happen after each cleaning in order to verify cleanliness, lack of damage, and proper functionality.
9. This document is intended to be a guide for the application of a sterilization technique for infection control purposes. It is the responsibility of the user to read the instructions thoroughly and perform the infection control techniques correctly. Consult with the device manufacturer for instruction on sterilization procedures for specific instruments.

VALIDATION

- The trays are intended to be used with an overwrap or placed into a sterilization container with filters or valves for the intended purpose of sterilizing the contents and maintaining sterility. It is not possible for a manufacturer of instrument trays to make claims about sterility when the eventual contents are not known. Moreover, it is not possible for instrument trays to maintain sterility of the contents because they are not manufactured for the purpose of providing a barrier for a sterile environment. That is why they must be used with overwraps or placed in a closed sterilization container that maintains sterility.
- The end user is best suited to assess the efficacy of the sterilization process by utilizing current standards and load assessment and to develop procedures for establishing efficacy and shelf-life standards. It is not possible for us to know, or instruct, as to what the contents or eventual use of the tray will be.
- **Testing can only be done once all of the intended components are identified and all of the contents are brought together and assembled. The testing needs to be accomplished with an overwrap or sterilization container for the intended purpose of sterilizing the contents. The end-user normally develops procedures and standards to accomplish this. Certain biological and chemical parameters are used to validate the process as directed by internal standards and procedures at the end-user's facility. The manufacturer has no control over these functions.**

MANUFACTURER CONTACT

PLASTIC STERILIZING TRAY CORPORATION
1520 East Street
Pittsfield, MA 01201, U.S.A.

EC REP
MediMark Europe Sarl
11, rue Emile Zola
F-38033 Grenoble, FRANCE

CE

Last updated: January 5, 2024