

Sterilization Processing Instructions for Plastic Instrument Case/Tray Systems

Instructions for Use/Intended Use

Sontec plastic cases and trays are intended for the protection and organization of medical devices and surgical instruments. These cases and trays are not designed to maintain sterility by themselves but 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, which are designed to allow air removal, steam penetration/drying, and maintain the sterility of internal components.

Recommendations for Care, Cleaning, and Sterilization

Both physical and chemical (detergent) processes may be necessary to clean soiled items. Chemical 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 to access areas, a clean, soft-bristled brush is recommended. Once cleaned, rinse items thoroughly with clean water to remove any detergent or chemical residue before sterilization. Always inspect for cleanliness or damage before use. Make sure all latches and handles are secure and in working order. Do not overload cases and trays. Balance contents uniformly within the container and arrange to allow steam to contact all objects in the container.

Sontec recommends the cases and trays be processed according to the sterilization wrap or filtered container manufacturer's instructions prior to sterilization to maintain sterility of internal components. Complex instruments may require disassembly and extended sterilization times. Always follow the instrument manufacturer's instructions if their sterilization or drying recommendations exceed these guidelines.

1. Pre-vacuum Sterilizers

Wrapped cases, trays, and instruments should be exposed to 132-135°C (270-275°F) for at least 4 minutes. Dry for 20 to 40 minutes.

2. Gravity Displacement Sterilizers

Wrapped cases, trays, and instruments should be exposed to 132-135°C (270-275°F) for at least 30 minutes, or 121-123°C (250-254°F) for at least 55 minutes. Dry for 20 to 50 minutes.

3. Ethylene Oxide Sterilization

Sontec plastic cases and trays have been validated for Ethylene Oxide Sterilization using 10/90 cycle (10%EO/90%HCFC). A minimum two-hour exposure cycle at 52-57°C (125-135°F) is required. Always follow instrument manufacturer instructions regarding use in Ethylene Oxide systems. Cases and trays have been shown to be within acceptable residual ranges after degassing for 12 hours.

4. Filtered Sterilization Container Systems

Sontec plastic cases and trays have been validated for placement inside filtered sterilization container systems and exposure to 132-135°C (270-275°F) temperatures for at least four minutes in pre-vacuum sterilizers only. Sontec cases and trays have NOT been validated for use in filtered sterilization containers in gravity displacement sterilizers and should not be used in such a system.

Contraindications

Sontec cases and trays have NOT been validated for use with flexible endoscopes or devices with lumens or working channels longer than 4 inches. Sontec cases and trays have NOT been validated for ETO sterilization of devices with lumens or working channels longer than 8.5 inches. Stacking of cases and trays and overloading of the units will adversely affect sterilization and drying effectiveness. DO NOT STACK cases and trays in the autoclave chamber.

Notice:

1. Do not load cases into sterilizer on sides or upside down. Load cases on cart or shelf so that the lid is always facing upward. This will allow for proper drying.
2. After the autoclave door is opened, all cases must be allowed to cool thoroughly. Place cases on a rack or shelf with linen cover until cooling is complete. The potential for condensation may increase if the case is not allowed to cool properly.

3. If condensation occurs, check to ensure steps 1 and 2 were followed. In addition, verify that the steam used for sterilization processing has a quality of more than 97%. Also, confirm the sterilizers have been inspected for routine maintenance in accordance with the manufacturer's recommendations.
4. Silicone mat accessories should be placed in alignment with perforations in cases and trays so that sterilant pathways are not obstructed.

Guidance on Tray Sizes and Maximum

Loads:

~4 x 8 x 1" : Max 1 lb. (0.34 kg)
~8 x 17 x 1" : Max 2 lb. (0.68 kg)
~7 x 7 x 4" : Max 8 lb. (3.6 kg)
~7 x 12 x 4" : Max 13 lb. (5.9 kg)
~9 x 19 x 4" : Max 22 lb. (9 kg)
~9 x 19 x 6" : Max 27 lb. (11.3 kg)

