

Cleaning and Sterilization Instructions for Plastic Trays

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Instructions Recommended For Use With ANKLYOS and XiVE Surgical Kit Plastic Trays

Important:

Filled trays must not be cleaned or disinfected.

When using the tray collect used instruments separately and do not replace them in the tray. This will prevent greater contamination and make it unnecessary to clean and disinfect the filled tray.

Clean and disinfect the used instruments, then place them in the tray and sterilize the instrument tray with all the instruments in their places.

The initial disinfection cannot replace the subsequent disinfection step required after cleaning.

Use only neutral cleaning agents and disinfectants without chlorine, ammonia, phenol, aldehydes that are suitable for cleaning and disinfecting plastic instruments. Disinfectants must conform to the applicable national regulations for disinfectants (such as FDA approval, CE mark, DGHM/VAH listing). If disinfectants containing aldehyde are used, they may fix blood or protein. If ultrasonic baths are used, non-foaming cleaning agents and disinfectants must be used.

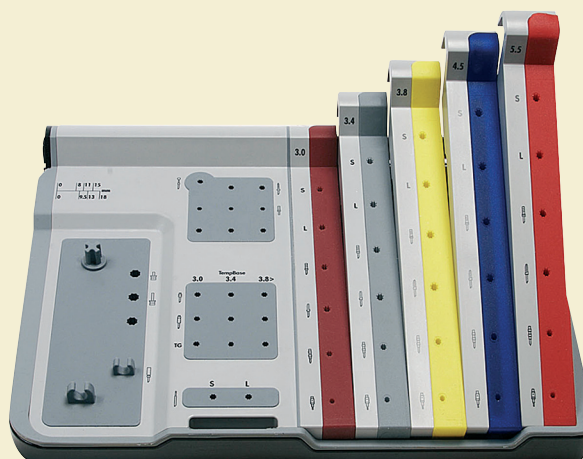
Use only water with a bioburden ≤ 10 CFU/ml and an endotoxin burden ≤ 0.25 IU/ml (e.g. water for cleaning or freshly prepared purified or ultrapurified water in accordance with the pharmacopoeia).



The internal padded insert is for protection during shipping only and must be removed before using the tray for the first time. The padded insert must never be sterilized.

All trays must be cleaned, disinfected and sterilized before using them for the first time and then after every use and every time they are contaminated. If greater contamination can be avoided (used instruments not returned to tray, no visible contamination on the tray), it is not necessary to clean and disinfect the trays. In this case the used instruments must be cleaned and disinfected separately and the loaded trays sterilized. However, thorough cleaning and disinfection is absolutely essential for effective sterilization.

Please also follow the relevant instructions in the manual on sterilization and instrument care.



1. Pretreatment

Large or visible impurities must be removed from the trays immediately after use (no more than two hours later).

Remove all instruments from the trays (separate cleaning and disinfection as directed by the manual for sterilization and instrument care).

Use running water (rinse thoroughly for at least one minute) or a disinfectant solution (rinse thoroughly three times). Use only a soft brush or a clean soft cloth, which is used for this purpose only, for manual removal of impurities, never metal brushes or steel wool.

Disassemble the trays completely.

2. Cleaning

Immerse the disassembled trays in a freshly prepared cleaning bath of the specified concentration for the period specified by the manufacturer.

Clean the surfaces with a soft brush until there is no visible contamination. Clean the holes separately with a fine brush. Clean the bottom of the modules thoroughly and also the parts between the hard and soft plastic parts.

After cleaning rinse all parts thoroughly with water at least three times. Move the parts back and forth.

3. Disinfection

Immerse the disassembled tray into a freshly prepared disinfectant bath of the specified concentration for the period specified by the manufacturer.

4. Rinsing and drying

After disinfection rinse all parts thoroughly with water as specified by the disinfectant manufacturer. Move the parts back and forth.

Dry all parts with lint-free disposable cloths (do not use recycled cloths). Use oil-free compressed air to dry holes.

5. Maintenance and assembly

Reassemble the trays. Do not use instrument oil or damaged trays.

6. Preparation for sterilization

Place the separately cleaned and disinfected instruments back into the trays. Please pack the trays in disposable sterilization packs (single or double packs) and/or sterilization containers that conform to the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607
- Suitable for steam sterilization (temperatures up to at least 137 °C (279 °F), adequate steam permeability)
- Adequate protection of trays and sterilization packages from mechanical damage
- Regular maintenance in accordance with the manufacturer's specifications (sterilization containers)

7. Sterilization

See instructions for sterilization and instrument care, section 6

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