



Sterilization & Disinfection Recommendations

Always follow the **Sterilization and High Level Disinfection Recommendations** included in the product's package insert, if applicable. The following recommendations are to be used as general guidelines. Follow the specific sterilization or disinfection procedures that have been validated by your institution. Always carefully examine the physical integrity of the product after processing. Do not use if cracking or crazing is seen, or if parts fit together improperly after processing.

Reusable Plastics & Silicone Rubber Products

Pre-Washing:

A thorough pre-washing of products is necessary to remove foreign and/or organic contaminants. Use a low alkaline soap (pH 8.5 or less) to preserve maximum useful life.

Sterilization:

Steam Autoclave:

Sterilize according to validated parameters.
Do not exceed 135°C (275°F).

Do not steam autoclave polycarbonate products.

Gamma Radiation:

Irradiate according to validated parameters. Some discoloration may occur.

Do not irradiate polyethylene products.

Ethylene Oxide:

Sterilize according to validated parameters. Do not exceed 55°C (131°F). Allow ample aeration time in a well-ventilated area to dissipate the absorbed gas.

Gas Plasma:

Sterilize according to validated parameters.

High Level Disinfection:

Pasteurization:

Pasteurize at 70°C +/- 3°C (153°F - 163°F) for a minimum of 30 minutes.

Chemical Disinfectants:

Recommended Chemical: 2-4% Activated Glutaraldehyde

Disinfect according to validated parameters. Follow the chemical manufacturer's recommendation for temperature and soak time.

Chemical disinfection should be followed by sterile water rinse. Exposure time should be based on the manufacturer's indication for use as a high-level disinfectant or sterilant.

Do not use alcohol or chemicals containing dimethyl ammonium chloride.

Disposable — Single Patient Use Products

Instrumentation Industries, Inc. disposable products are designed for single-patient use. Processing is recommended for most Single Patient Use products prior to usage. **Do not steam autoclave!**

Sterilization:

STERRAD 100S: (Polystyrene Butadiene only)

Full short sterilization cycle.
Hydrogen peroxide gas plasma, 55 minutes,
45°C - 55°C (113°F - 131°F).

High Level Disinfection:

Pasteurization:

Pasteurize at 70°C +/- 3°C (153°F - 163°F) for a minimum of 30 minutes.

Cidex® OPA

Prepare Cidex® OPA solution.

Totally submerge device in the disinfectant. Immerse device completely, eliminating air pockets, in CIDEX® OPA Solution for a minimum of 12 minutes at 20°C (68°F) to destroy all pathogenic microorganisms. Remove device from the solution and rinse thoroughly as per these rinsing instructions:

- Following removal from CIDEX® OPA Solution, thoroughly rinse the product by immersing it completely in a large volume (e.g. 2 gallons) of water. Sterile water rinse is recommended unless potable water is acceptable.
- Keep the device totally immersed for a minimum of 1 minute in duration.
- Manually flush all devices with large volumes (not less than 100 mL) of rinse water.
- Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
- Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove CIDEX OPA Solution residues. Residues may cause serious side effects.
- Dry using sterile, lint-free cloths.

Endotracheal Tube Changers

Endotracheal Tube Changers are designed for Single Patient Use only. Recommended High Level Disinfection methods are Pasteurization at 70°C +/- 3°C (153°F - 163°F) for a minimum of 30 minutes, or Chemical Disinfection. Sterilization can be performed in 100% ethylene oxide at 54°C (129°F) for 60 minutes. Sterilized tubes must be allowed to aerate for no less than 12 hours to dissipate any residual gas.

Steam autoclave, gas plasma and gamma radiation are not recommended processing methods.

Reusable Neoprene Products

Test Lungs:

Clean

Wipe the exterior with a soft cloth, water and a mild detergent or liquid soap. Rinse exterior (**Do not allow water to enter the bag**). Allow to air dry. **Do not clean with alcohol.**

Reusable Breathing Bags:

Clean

Wash with mild detergents or natural liquid soap followed by a thorough rinse prior to processing.

Sterilization

Steam:

Steam sterilize with temperature not exceeding 132°C (270°F).

Caution: Drying vacuums should be avoided.

Ethylene Oxide:

Gas sterilize by using an Ethylene Oxide mixture at 52°C - 57°C (126°F - 135°F). Follow the sterilizer manufacturer's recommendations for rubber articles. Allow ample aeration time in a well-ventilated area to dissipate the absorbed gas. Consult the sterilizer manufacturer's recommendations for specific aeration periods.

Drying

If a mechanical dryer is used to dry the products following disinfection or sterilization, a bio clean dryer with a HEPA filter is recommended to prevent recontamination while drying. Do not exceed 60°C (140°F) and remove the product as soon as all moisture has evaporated. Exposures to elevated temperatures when the product is dry will significantly shorten product life.

High Level Disinfection

Pasteurization:

Pasteurize at 71°C - 77°C (160°F - 171°F) for minimum of 30 minutes. System should have a mechanism for removing all air pockets before initiating the cycle.

Caution: Plasma Pasteurization will accelerate deterioration.

Chemical Disinfectants:

High level disinfection can be achieved using most cold sterilants. Follow the chemical manufacturer's recommendations for temperature and soak time and remove all air pockets. Chemical disinfection should be followed by a sterile water rinse.

Single Patient Use Neoprene Products

Single Patient Use Breathing Bags:

Clean

Wipe the exterior with a soft cloth, water and a mild detergent or liquid soap. Rinse exterior (do not allow water to enter the bag). Allow to air dry. **Do not clean with alcohol.**

Gauges & Metal Products

Clean these products by wiping the outside with a disinfectant on a soft cloth.

Do not immerse, disassemble, use bleach, or sterilize.

Instrumentation Industries, Inc. Metal products include all Brackets, Flexible Support Arms, Instant Flow Valves, and Manual Jet Ventilators.

Reusable Ventilator Tubing

Reusable Tubing: *KC Series — KC-P Series — KC-N Series — KC-3 Series*

Clean

Ventilator Tubing should be cleaned with a mild detergent followed by a sterile water rinse prior to processing.

Sterilization

Steam:

Steam Autoclave at: 134°C (273°F) — 96kPa (14psi) — 15 minutes.

Ethylene Oxide:

Sterilize according to validated parameters. Do not exceed 55°C (131°F). Allow ample aeration time in a well-ventilated area to dissipate the absorbed gas.

Gamma Radiation:

Irradiate according to validated parameters.

Do not use: Phenol (>5%), Ketones, Formaldehyde, Chlorinated Hydrocarbons, Aromatic Hydrocarbons or Inorganic Acids. These solutions may cause cracking or disintegration of the tubing. Do not autoclave if medications containing Quaternary Ammonium compounds, chlorinated or aromatic hydrocarbons have been used.

Tubes are rated for 50 cycles, but actual cycle life depends on end user handling precautions.

High Level Disinfection

Pasteurization:

Pasteurize at 70°C (158°F) for 30 minutes.

Chemical Disinfectants:

High level disinfection can be achieved using most cold sterilants. Follow the chemical manufacturer's recommendations for temperature and soak time and remove all air pockets. Chemical disinfection should be followed by a sterile water rinse. Mild cleansers may also be used.

Single Patient Use Ventilator Tubing

Single Patient Use Tubing: *KC-5 Series — KC-5P Series — KC-5N Series*

Clean

Ventilator Tubing should be cleaned with a mild detergent followed by a sterile water rinse prior to processing.

Sterilization

Ethylene Oxide:

Sterilize according to validated parameters. Do not exceed 55°C (131°F). Allow ample aeration time in a well-ventilated area to dissipate the absorbed gas.

Gamma Radiation:

Irradiate according to validated parameters.

Do not use: Phenol (>5%), Ketones, Formaldehyde, Chlorinated Hydrocarbons, Aromatic Hydrocarbons or Inorganic Acids. These solutions may cause cracking or disintegration of the tubing.

High Level Disinfection

Pasteurization:

Pasteurize at 70°C (158°F) for 30 minutes.

Chemical Disinfectants:

High level disinfection can be achieved using most cold sterilants. Follow the chemical manufacturer's recommendations for temperature and soak time and remove all air pockets. Chemical disinfection should be followed by a sterile water rinse. Mild cleansers or hydrogen peroxide solution may also be used.

Other Cleaning Recommendations

The following recommendations are to be used as general guidelines. Always carefully examine the physical integrity of the product after cleaning. **Do not use if damage is seen, or if parts fit together improperly after cleaning.**

Acrylic Products

Instrumentation Industries, Inc. Acrylic products include **Mask/Filter Storage Boxes**. Clean these products by wiping the exterior with a soft cloth, water and a mild detergent or liquid soap.

Do not use abrasive cleaners.

Home Use Cleaning Recommendations

Wash products in a mild liquid dish detergent. Products should be thoroughly scrubbed in order to remove all contaminants. Rinse well; ensure all remaining detergent is removed. Soak products for 20 minutes in a fresh vinegar solution that is 1 part vinegar and 3 parts water. (EXAMPLE: ½ cup vinegar and 1 ½ cup water).

Thoroughly rinse products with sterile water. Allow to air-dry on a clean towel. Do not wipe or dry with towel.