
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 components 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/Single Patient Reuse Products

Instrumentation Industries, Inc. **Disposable/Single Patient Use** products are intended to be discarded after one use on one single patient.

Single Patient Reuse products are intended to be used to repeatedly administer medications to one single patient while installed in a breathing circuit.

Disposable/Single Patient Use/Single Patient Reuse products include those made of polystyrene butadiene, acrylonitrile butadiene styrene (ABS), acrylic co-polymer, and high-density polyethylene.

As these products are packaged as **'Not Sterile'**, processing is recommended for most **Disposable/Single Patient Use/Single Patient Reuse** products prior to usage. Always follow the processing recommendation shown in the product's instruction sheet, if provided. Suggested processing methods for **Disposable/Single Patient Use/Single Patient Reuse** products not having an instruction sheet are shown below:

Sterilization:

STERRAD 100S: (Polystyrene Butadiene only)

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

Do not steam autoclave Disposable/Single Patient Use/Single Patient Reuse devices.

High Level Disinfection:

Pasteurization:

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

CIDEX® OPA: (Not a valid method for RTC 26-C Inline Aerosol Adapter)

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.

Continued on pg. 2

Continued from pg. 1:

- 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.

Sterilization:

Ethylene Oxide:

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.

High Level Disinfection:

Pasteurization:

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

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.

High Level Disinfection:

Pasteurization:

Pasteurize at **71°C - 77°C (160°F - 171°F)** for a 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.

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.

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.**

Gauges & Metal Products

Instrumentation Industries, Inc. **Metal** products include all **Brackets, Flexible Support Arms, Instant Flow Valves, and Manual Jet Ventilators**. Clean these products by wiping the outside with a disinfectant on a soft cloth.

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

Reusable Ventilator 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.

High Level Disinfection:

Pasteurization:

Pasteurize at **70°C (158°F)** for a minimum of **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.

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.

Single Patient Use Ventilator 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.

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.

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

Other Cleaning Recommendations

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.

Home Use Cleaning Recommendations

Reusable Products only. Cleaning should be performed by responsible care giver.

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 1½ cups water) Thoroughly rinse products with sterile water. Allow to air-dry on a clean towel.

Do not wipe or dry with towel.