

Potable Water Rinse

For all other devices a sterile water rinse is recommended when practicable, otherwise a high quality potable tap water rinse is acceptable. A high quality potable water is one that meets Federal Clean Water Standards at the point of use.

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with *Pseudomonads* and *atypical* (fast growing) *Mycobacteria* often present in potable water supplies. A device (e.g. colonoscope) that is not completely dried provides an ideal situation for rapid colonization of bacteria. Additionally, *Mycobacteria* are highly resistant to drying. Therefore, rapid drying will avoid possible colonization but may not result in a device free from *atypical Mycobacteria*. Although these bacteria are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms. A final rinse using a 70% isopropyl alcohol solution is useful to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

d. Reusage

Cetycide-G Use Solution has demonstrated efficacy in the presence of 2% organic soil contamination and a simulated amount of microbiological burden during reuse. This solution may be used and reused within the limitations indicated above for up to 28 days after preparation. Do not use prepared solution beyond 28 days. Use the 3M™ Comply™ Cold SteriLog™ 2.1% Glutaraldehyde Monitors reagent test strip to determine that the minimum effective concentration of glutaraldehyde (MEC) of 2.1% is present.

4. Monitoring of Germicide to Ensure Specifications are Met

During the usage of Cetycide-G Use Solution, as a high level disinfectant and/or sterilant, it is recommended that a thermometer and timer be utilized to ensure that the optimum usage conditions are met. In addition, it is recommended that the Cetycide-G Use Solution be tested with the 3M™ Comply™ Cold SteriLog™ 2.1% Glutaraldehyde Monitors prior to each use. This is to insure that the appropriate concentration of glutaraldehyde is present and to guard against an unexpected dilution which may lower the effectiveness of the solution below its MEC. The pH of the activated solution may also be periodically checked to verify that the pH of the solution is between 6.5 and 7.8.

5. Post-Processing Handling and Storage of Reusable Devices

Disinfected and/or sterilized reusable devices are either to be immediately used or stored in a manner to minimize recontamination. Refer to the reusable device-equipment manufacturer's labeling for additional storage and/or handling instructions.

F. Storage Conditions and Expiration Date

1. Prior to preparation, Cetycide-G Concentrate should be stored in its original container at room temperature 15°-30°C (59°- 86° F).

Once the Cetycide-G Use Solution has been prepared, it may be stored in the closed containers in which the immersion for high level disinfection or sterilization is to take place, (C-Tub or other appropriate instrument tray). Closed containers should be stored in a well ventilated, low traffic area at room temperature.

2. The expiration date of Cetycide-G will be found on the bottle and the immediate box.
3. The use period for prepared Cetycide-G Use Solution is for no longer than 28 days following preparation. It should not be used if the MEC falls below a level of 2.1% glutaraldehyde as indicated by the 3M™ Comply™ Cold SteriLog™ 2.1% Glutaraldehyde Monitors, regardless of the number of days of actual use.

G. Emergency and Technical Product Information

Emergency, safety, or technical information about Cetycide-G Use Solution can be obtained from Cetylite Industries, Inc. at 1-800-257-7740.

H. User Proficiency

The user should be adequately trained in the decontamination and disinfection or sterilization of medical devices and the handling of toxic substances such as liquid chemical germicides. Additional information about Cetycide-G Use Solution can be obtained from Cetylite Industries, Inc. at 1-800-257-7740.

I. Disposal Information

Germicide Disposal

Dispose of glutaraldehyde solutions in accordance with local, state, and federal regulations. Where neutralization of glutaraldehyde solution with glycine is required prior to disposal, use Cetylite's "Hyde-Out™" Aldehyde Neutralizer," Item No. 0128.

Container Disposal

Do not re-use empty container. Remove the topmost cap and triple rinse bottle. Dispose of entire container in a sanitary landfill or by incineration if allowed by state and local authorities.

J. Order Information

Cetylite #	Description
0122	Cetycide-G Concentrate 32 oz Bottle (Includes Diluent).
0106	C-Tub Instrument Tray
0128	Hyde-Out™ Aldehyde Neutralizer 32 oz



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Made in USA

Cetycide-G[®]

CONCENTRATE

FOR STERILIZATION AND HIGH LEVEL DISINFECTION

A. Indications for Use

1. Germicide Level of Activity

Cetycide-G is an effective liquid chemical sterilant and a high level disinfectant when used according to the **Directions for Use**.

Sterilant: Cetycide-G is a sterilant when mixed and used according to its Directions for Use for a maximum of 28 days at 20°C with an immersion time of at least 10 hours at its minimum effective concentration (MEC) of 2.1 % glutaraldehyde.

High Level Disinfectant: Cetycide-G is a high level disinfectant when mixed and used according to its Directions for Use for a maximum of 28 days at 20°C with an immersion time of at least 40 minutes at its minimum effective concentration (MEC) of 2.1% glutaraldehyde.

2. Reuse Period

Cetycide-G can be reused for a period not to exceed 28 days provided the required conditions of glutaraldehyde concentration, pH, and temperature exist based upon monitoring described in Directions for Use. **DO NOT rely solely on days in use. Use the 3M™ Comply™ Cold SteriLog™ 2.1% Glutaraldehyde Monitors to determine that the minimum effective concentration (MEC) of 2.1% glutaraldehyde is present.** (See Directions for Use-Section E4: Monitoring of Germicide to Ensure Specifications are Met.)

3. General Information on Selection and Use of Germicides for Medical Device Reprocessing

Choose a germicide with the level of microbicidal activity that is appropriate for the reusable medical device. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following process:

First, for patient contacting devices, determine whether the reusable device to be reprocessed is a critical or a semi-critical device.

- A **critical device** presents a high risk of infection if not sterile. Critical devices routinely penetrate the skin or mucous membranes during use or are otherwise used in normally sterile tissue of the body.
- A **semi-critical device** makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body.

Second, determine the level of germicidal activity that is needed for the reusable device.

Critical Device - Sterilization required (e.g.: products that enter sterile tissue or the vascular system, such as laparoscopes and microsurgical instruments).

Semi-critical Device - Sterilization recommended whenever practical, otherwise High Level Disinfection acceptable (e.g.: GI endoscopes, anesthesia equipment for the airway, diaphragm-fitting rings, etc.).

Third, select a germicide that is labeled for the appropriate germicidal level and is compatible with the reusable device. Follow directions for the germicide.

4. Material Compatibility

Cetylclide-G Use Solution is a glutaraldehyde solution. Such solutions have a long history of compatible use with medical instruments made from a variety of materials without corrosive or other apparent damaging effects. They have been found to be compatible with the following materials:

METALS

- Chrome Plated Metal
- Nickel Plated Metal
- Carbon Steel
- Stainless Steel
- Aluminum

ELASTOMERS

- Black Rubber
- Red Rubber
- Silicone Rubber
- Polyurethane

PLASTICS

acrylonitrile-butadiene-styrene (ABS)
polyvinyl chloride (PVC)
polystyrene
polyethylene
polypropylene
polysulfone
polymethylmethacrylate (acrylic)
polyethylene terephthalate (polyester)

Check the labeling of the reusable device for any additional instructions. Cetylclide-G Use Solution is not recommended for use on non-anodized aluminum or for the disinfection of one piece molded, solvent-bonded or sonic-welded polycarbonate equipment due to possible stress cracking after repeated treatments.

5. Precleaning Agent Compatibility

Detergents that are either highly acidic or alkaline are contraindicated as precleaning agents since improper rinsing could affect the efficacy of the Cetylclide-G Use Solution by altering its pH.

B. Contraindications

1. Sterilant Usage

Routine biological monitoring is not feasible with Cetylclide-G Use Solution. Therefore, Cetylclide-G Use Solution should **NOT** be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g., heat, ethylene oxide or peroxide gas plasma.

Cetylclide-G Use Solution should **NOT** be used for sterilization of critical devices intended for single use (e.g., catheters)

C. Warnings

HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER

Keep out of Reach of Children.

1. **Corrosive.** Causes irreversible eye damage. Causes skin burns. Harmful if inhaled. May be fatal if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Causes asthmatic signs and symptoms in some hyper-active individuals. Do not get in eyes, on skin or on clothing. Avoid breathing vapor. Do not swallow. Wear goggles, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing, and wash before reuse.

2. **HARMFUL IF SWALLOWED.** If ingested, do not induce vomiting. Obtain medical attention immediately.

D. Precautions

1. Use rubber or nitrile gloves, eye protection, face mask and chemical apron when cleaning and disinfecting/sterilizing devices.
2. Use in well ventilated area in closed containers.
3. Contaminated, reusable devices **MUST BE THOROUGHLY CLEANED** prior to high level disinfection or sterilization, since residual contamination will decrease the effectiveness of the germicide.
4. The user must follow the Directions for Use since any modifications will affect the safety and effectiveness of the germicide.
5. To optimize the effective reprocessing of reusable devices, the user must follow a validated reprocessing procedure for any device disinfected or sterilized in Cetylclide-G Use Solution.

E. Directions for Use

1. Preparation of the Use Solution

(See the How-To-Prepare Sheet for diagrams)

Step 1: With both caps closed, tilt the bottle forward to fill the measuring chamber.

Step 2: Tilt the bottle back using angular pour-back scale to adjust to desired level (e.g. 1 qt.)

Step 3: Remove the Pour Cap and pour the measured dose into the C-Tub or other receptacle.

For 1 quart: Add 15 ml of Cetylclide-G Diluent Concentrate (yellow liquid) to 1 quart of water in a C-Tub Instrument Tray or other appropriate container. Then add 63 ml. of Cetylclide-G Concentrate (green liquid) and mix.

For 1/2 gallon: Add 30 ml of Cetylclide-G Diluent Concentrate (yellow liquid) to 1/2 gallon of water in a C-Tub Instrument Tray or other appropriate container. Then add 126 ml. of Cetylclide-G Concentrate (green liquid) and mix.

For 1 gallon: Add 60 ml of Cetylclide-G Diluent Concentrate (yellow liquid) to 1 gallon of water in a C-Tub Instrument Tray or other appropriate container. (Fill the measuring chamber to the 30 ml line twice.) Then add 252 ml. of Cetylclide-G Concentrate (green liquid) and mix. (Fill the measuring chamber to the 126 ml line twice.)

Record the mixing date on the provided green Use Dilution Label and affix to the container. The glutaraldehyde concentration of the Cetylclide-G Use Solution when freshly mixed is 3.2%, and its pH is in the range of 6.5-7.8. The minimum effective concentration (MEC) of glutaraldehyde is 2.1%, and the Use Solution should not be used if the level of glutaraldehyde falls below the MEC during the re-use period. Monitor the concentration with the reagent test strip as set out in step 4 below. The pH should remain between 6.5-7.8.

2. Cleaning/Decontamination

Clean instruments thoroughly. Rinse free of all soap before immersion. Do not use either highly acidic or alkaline detergents as precleaning agents.

Blood and other body fluids must be thoroughly cleaned from surfaces, lumens, and objects before application of the disinfectant or sterilant.

For complete high-level disinfection or sterilization of medical instruments, thoroughly, clean, rinse and dry objects prior to immersion in Cetylclide-G Use Solution. Clean and rinse the lumens of hollow instruments before filling with Cetylclide-G Use Solution. Refer to the reusable device manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

3. Usage

a. Sterilization (C-Tub or other Instrument Tray)

Immerse medical device completely in Cetylclide-G Use Solution for a minimum of 10 hours at 20°C to eliminate all microorganisms including Clostridium sporogenes and Bacillus subtilis spores. Remove devices from the solution using sterile technique and rinse thoroughly with sterile water following the rinsing instructions below.

b. High Level Disinfection (C-Tub or other Instrument Tray)

Immerse medical device completely in Cetylclide-G Use Solution for a minimum of 40 minutes at 20°C to destroy pathogenic microorganisms except large quantities of bacterial endospores but including Mycobacterium tuberculosis (Var. bovis). Remove devices from the solution and rinse thoroughly following the rinsing instructions below.

c. Rinsing Instructions

Following immersion in Cetylclide-G Use Solution, thoroughly rinse the instrument by immersing it completely in three separate copious volumes of water (sterile water if taken from sterilant). Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose as it will be contaminated with glutaraldehyde.

Refer to the reusable device manufacturer's labeling for additional rinsing instructions.

Sterile Water Rinse

The following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:

1. Devices intended for use in normally sterile areas of the body;
2. Devices intended for use in known immunocompromised patients, or potentially immunocompromised patients based on institutional procedures (e.g., high risk population served) and;
3. When practicable, bronchoscopes, due to a risk of atypical Mycobacteria contamination from potable water supply.