2) The expiration date of the unactivated **COECIDE XL PLUS** Solution will be found on the bottom of the immediate container.

3) The use period for activated **COECIDE XL PLUS** Solution is for no longer than 28 days following activation or as indicated by a 1.8% glutaraldehyde test indicator. Once activated, the solution requires no further dilution prior to its usage.

G) EMERGENCY AND TECHNICAL PRODUCT INFORMATION

Emergency, safety, or technical information about **COECIDE XL PLUS** Solution can be obtained from GC America Inc. Customer Service Department at 1-800-323-7063, or by contacting your local GC America Inc. sales representative.

H) USER PROFICIENCY

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. 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 **COECIDE XL PLUS** Solution can be obtained from GC America Inc. Customer Service Department at 1-800-323-7063, or by contacting your local GC America Inc. sales representative.

I) DISPOSAL INFORMATION

Germicide Disposal

Discard residual solution in accordance with federal, state and local regulations.

Container Disposal

- **One Gallon (3.8 L) Size Container**

  Do not reuse empty container. Wrap container and put in trash.

J) HOW SUPPLIED

Reorder	Description	Case Containers
550128	One Gallon (3.8 L) Container	4 x Gallons (4 x 3.8 L)/case

References supplied upon request.

Manufactured for:

GC AMERICA INC.
ALSIP, IL 60803
1-800-323-7063

70-3331-7

COECIDE XL PLUS
LONG-LIFE ACTIVATED DIALDEHYDE SOLUTION
(GLUTARALDEHYDE 3.4%)

A) INDICATIONS FOR USE

1) Germicide Level of Activity

COECIDE XL PLUS Long-Life Activated Dialdehyde Solution is a liquid chemical sterilant and high- level disinfectant, when used according to the **Directions for Use**.

Sterilant: COECIDE XL PLUS Solution is a sterilant when used or reused, according to **Directions for Use**, at full strength for a maximum of 28 days at 25°C with an immersion time of at least **10 hours**.

High-Level Disinfectant: COECIDE XL PLUS Solution is a high-level disinfectant when used or reused, according to **Directions for Use**, at full strength for a maximum of 28 days at 25°C with an immersion time of at least **90 minutes**.

2) Reuse Period

COECIDE XL PLUS Solution has also demonstrated efficacy in the presence of 2% organic soil contamination and a simulated amount of microbiological burden during reuse.

COECIDE XL PLUS Solution 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. **Efficacy of this product during its use-life must be verified by a 1.8% glutaraldehyde test indicator to determine that at least the minimum effective concentration (MEC) of 1.8% glutaraldehyde is present.**

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 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 when practical, otherwise, High-Level Disinfection is 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) Microbicidal Activity

The following table indicates the spectrum of activity as demonstrated by testing of **COECIDE XL PLUS** Solution*:

BACTERIA		FUNGI	VIRUSES	
SPORES	VEGETATIVE ORGANISMS		NON-ENVELOPED	ENVELOPED
Bacillus subtilis	Staphylococcus aureus	Trichophyton mentagrophytes	Poliovirus Types 1 & 2	Cytomegalovirus
Clostridium sporogenes	Salmonella choleraesuis		Rhinovirus Type 14	Influenza virus Type A_2HK
	Pseudomonas aeruginosa		Adenovirus Type 2	HIV-1 (AIDS Virus)
	Mycobacterium tuberculosis		Vaccinia	Herpes simplex Types 1 & 2
			Coxsackievirus B5a	

*Testing was done after 28 days of simulated reuse using prescribed testing methods.

5) Material Compatibility

COECIDE XL PLUS is compatible with the following reusable devices and materials: Respiratory therapy equipment, anesthesia equipment, rubber, most stainless steel instruments, plastic, most dental instruments (not including dental handpieces), many types of metals, such as stainless steel, carbon steel, and aluminum, and plated metals such as nickel plating or chrome plating.

For a listing of specific device manufacturers that have reported device compatibility with **COECIDE XL PLUS**, see Table 1 below.

Table 1. Manufacturers Reporting Device Compatibility with **COECIDE XL PLUS**

Company	Instrumentation
Acoustic Imaging	Transducers
Advanced Technology Lab	Ultrasound Scanheads
Hewlett Packard	Omniplane TEE Probe
Instrumentation Industries	Respiratory Therapy Equipment

Please refer to labeling of the reusable device for additional instructions, or call the reusable device manufacturer directly.

PLEASE NOTE: COECIDE XL PLUS is incompatible with the following specific reusable devices: Acuson V510B transesophageal transducers, high-frequency cables, coagulating forceps, resectoscope instruments, and devices that have the potential for electrosurgical malfunctioning.

6) Precleaning Agent Compatibility

COECIDE XL PLUS Solution is compatible with enzymatic detergents which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acidic or alkaline are contraindicated as precleaning agents since improper rinsing could affect the efficacy of the **COECIDE XL PLUS** Solution by altering its pH.

B) CONTRAINDICATIONS

1) Sterilant Usage

Routine biological monitoring is not feasible with **COECIDE XL PLUS** Solution, and therefore, **COECIDE XL PLUS** 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.

COECIDE XL PLUS Solution should not be used for sterilization of critical devices intended for single use (e.g.: catheters).

2) High-Level Disinfectant Usage

COECIDE XL PLUS Solution should **NOT** be used to high-level disinfect a semi-critical device when sterilization is practical.

3) Endoscope Usage

COECIDE XL PLUS Long-Life Activated Dialdehyde Solution is not the method of choice for steriliization of rigid endoscopes which the device manufacturer indicates are compatible with steam sterilization. In general, glutaraldehyde solutions that do not contain surfacants are more appropriate for flexible endoscopes, because glutaraldehyde solutions containing surfactants (e.g.: **COECIDE XL** Solution or **COECIDE XL PLUS** Solution) are more difficult to rinse from the devices. However these surfactant-containing disinfectants may be used for reprocessing of flexible endoscopes **if a validated protocol for rinsing and leak testing is employed.**

C) WARNINGS

COECIDE XL PLUS LONG-LIFE ACTIVATED DIALDEHYDE SOLUTION IS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Keep Out of Reach of Children
Contains Glutaraldehyde

1) **Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin, or on clothing.**
2) **Avoid contamination of food.**
3) **Use in well-ventilated area in closed containers.**

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, get medical attention.

Harmful if swallowed. Drink large quantities of water and call a physician immediately.

Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

Emergency, safety, or technical information about **COECIDE XL PLUS** Solution can be obtained from GC America Inc. Customer Service Department at 1-800-323-7063, or by contacting your local GC America Inc. sales representative.

D) PRECAUTIONS

1) Protective gloves (butyl rubber, nitrile rubber, polyethylene or double-gloved latex), eye protection, face masks, and liquid-proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices and equipment.

2) Contaminated, reusable devices **MUST BE THOROUGHLY CLEANED** prior to disinfection or sterilization, because residual contamination will decrease effectiveness of the germicide.

3) The user **MUST** adhere to the **Directions for Use**, because any modification will affect the safety and effectiveness of the germicide.

4) The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using **COECIDE XL PLUS** Solution.

5) The use of **COECIDE XL PLUS** Solution in automated endoscope washers must be part of a validated reprocessing procedure provided by the washer manufacturer. Contact the manufacturer of the endoscope washer for instructions on the maximum number of reprocessing cycles which may be used before refilling with fresh **COECIDE XL PLUS** Solution. Use a 1.8% glutaraldehyde test indicator to monitor glutaraldehyde concentration before each cycle to detect unexpected dilution.

E) DIRECTIONS FOR USE

1) Activation

Activate the **COECIDE XL PLUS** Solution by adding the entire contents of the *Activator Plus* vial which is attached to the **COECIDE XL PLUS** Solution container. Shake well. Activated solution immediately changes color to bluish-green, thereby indicating solution is ready to use. **COECIDE XL PLUS** Solution is intended for use in manual (bucket and tray) systems made from polypropylene, ABS, polyethylene, glass-filled polypropylene or specially molded polycarbonate plastics. Record the date of activation (mixing date) and expiration date on the **COECIDE XL PLUS** Solution container label in the space provided, in a log book, or on a label affixed to any secondary container used for the activated solution.

2) Cleaning/Decontamination

Blood and other body fluids must be thoroughly cleaned from surfaces, lumens, and objects before application of the disinfectant or sterilant. Blood and other body fluids should be autoclaved and disposed of according to all applicable federal, state and local regulations for infectious waste disposal.

For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in **COECIDE XL PLUS** Solution.

Cleanse and rinse the lumens of hollow instruments before filling with **COECIDE XL PLUS** Solution. **Refer to the reusable device manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of their equipment.**

3) Usage

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

a) Sterilization (Bucket/Tray Manual System)

Immerse medical equipment/device completely in **COECIDE XL PLUS** Solution for a minimum of **10 hours at 25°C** to eliminate all microorganisms including **Clostridium sporogenes** and **Bacillus subtilis** spores. Remove equipment from the solution using sterile technique and **rinse thoroughly** with **sterile water** following the rinsing instructions below.

b) High-Level Disinfection (Bucket/Tray Manual System)

Immerse medical equipment/device completely in **COECIDE XL PLUS** Solution for a minimum of **90 minutes at 25°C** to destroy all pathogenic microorganisms, except for large numbers of bacterial endospores, but including **Mycobacterium tuberculosis** (Quantitative TB Method). Remove devices and equipment from the solution and rinse thoroughly following the rinsing instructions below.

c) Rinsing Instructions

Following immersion in **COECIDE XL PLUS** Solution, thoroughly rinse the equipment or medical device by immersing it completely in three separate copious volumes of water. Each rinse should be a minimum of one minute in duration unless otherwise noted by the device or equipment 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/equipment 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.

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 **Pseudomonas** 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

COECIDE XL PLUS Solution has also 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 activation. **Do not use activated solution beyond 28 days. Efficacy of this product during its use-life must be verified by a 1.8% glutaraldehyde test indicator to determine that the minimum effective concentration (MEC) of 1.8% is present.**

4) Monitoring of Germicide to Ensure Specifications are Met

During the usage of **COECIDE XL PLUS** 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 **COECIDE XL PLUS** Solution be tested with a 1.8% glutaraldehyde test indicator prior to each usage. This is to ensure that the appropriate concentration of glutaraldehyde is present and to guard against a 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 8.5.

5) Post-Processing Handling and Storage of Reusable Devices

Sterilized or disinfected reusable devices are either to be immediately used or stored in a manner to minimize recontamination. Note that only terminal sterilization (sterilization in a suitable wrap) provides maximum assurance against 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 activation, **COECIDE XL PLUS** Solution should be stored in its original sealed container at room temperature.

Once the **COECIDE XL PLUS** Solution has been activated, it should be stored in the original container until transferred to the containers in which the immersion for disinfection or sterilization is to take place. Containers should be stored in a well-ventilated, low traffic area at room temperature.