



MediVators<sup>®</sup> Inc.

## Rapicide™ High-Level Disinfectant and Sterilant

Trade Name and Synonyms:	Rapicide™ High-Level Disinfectant and Sterilant	HAZARDOUS MATERIALS
Chemical Family:	Di-aldehydes	Identification System
Chemical Name and Synonyms:	Glutaraldehyde or 1,5 Pentanedial-2%	(NIOSH)
CAS No.:	111-80-8	3 Health
		0 Flammability
		0 Reactivity
		B Personal Protection

### A. INDICATIONS FOR USE

#### 1. Germicidal Level of Activity

*Rapicide™ High-Level Disinfectant and Sterilant* is a liquid chemical sterilant and a high-level disinfectant when used according to **Directions for Use**.

##### **Sterilant**

*Rapicide™ High-Level Disinfectant and Sterilant* is a sterilant when used or reused, in a legally marketed Automated Endoscope Reprocessor according to Directions for Use, at a minimum recommended concentration (MRC) of 1.5% glutaraldehyde at 35°C (95°F), not to exceed 28 days, with a minimum contact or immersion time of at least 7 hours and 40 minutes.

##### **High-Level Disinfectant**

*Rapicide™ High-Level Disinfectant and Sterilant* is a high-level disinfectant when used or reused, in a legally marketed Automated Endoscope Reprocessor according to Directions for Use, at a minimum recommended concentration (MRC) of 1.5% glutaraldehyde at 35°C (95°F), not to exceed 28 days, with a minimum contact or immersion time of at least 5 minutes.

#### 2. Reuse Period

*Rapicide™ High-Level Disinfectant and Sterilant*, at a minimum recommended concentration (MRC) of 1.5% glutaraldehyde, has demonstrated efficacy in the presence of organic matter and microbiological burden during reuse. The solution can be reused as long as the minimum recommended concentration (MRC) of glutaraldehyde is 1.5% w/v or greater. **Maintain the solution at 35°C over the 28-day reuse period.** In no case should the solution be reused longer than 28 days. **DO NOT RELY SOLELY ON DAYS IN USE.** The concentration of this product during its use-life must be verified by utilizing 3M Comply, Cold SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983MM, chemical indicator strips to determine that at least the minimum recommended concentration (MRC) of 1.5% glutaraldehyde is present. The pH of the solution is to be between 6.0 and 7.0.

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

Choose a germicide with the level of microbial 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 contact devices, determine whether the reusable device to be reprocessed is a critical, semi-critical, or non-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, 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 demonstrated by the testing of *Rapicide™ High-Level Disinfectant and Sterilant* (Testing was done after 28 days of simulated reuse using prescribed testing methods and at 1.5% glutaraldehyde, pH 6.1).

Bacteria		Fungi	Viruses	
Spores	Vegetative Organisms	Trichophyton mentagrophytes	Non-enveloped	Enveloped
Bacillus subtilis	Staphylococcus aureus	Candida albicans	Poliovirus Type 1	Herpes simplex Type 1
Clostridium sporogenes	Salmonella cholerasuis	Aspergillus niger	Adenovirus Type 2	Herpes simplex Type 2
	Pseudomonas aeruginosa			Influenza virus Type A
	Mycobacterium bovis			HIV-1 Type 1

#### 5. Material Compatibility

*Rapicide™ High-Level Disinfectant and Sterilant* is compatible with the following reusable devices and materials: flexible endoscopes, rubber, plastic, many types of metals, such as stainless steel, carbon steel, aluminum, and plated metals such as chrome plating.

*Rapicide™ High-Level Disinfectant and Sterilant* is recommended for use with medical devices from the materials shown following. These devices may be damaged if cleaned with a high alkaline detergent, poorly rinsed after disinfection, stored wet, or dried at temperatures exceeding 105°F.

Metals	Plastics	Elastomers
416 Stainless steel (1)	Polyethylene (2)	Neoprene (1)
316 Stainless steel (1)	Polyvinyl Chloride (1)	Red Natural Rubber (1)
303 Stainless steel (1)	Teflon (1)	Silicone Rubber (2)
Anodized black aluminum (1)	Polyurethane (1)	
Chrome plate (1)	Polysulfone (1)	
	Polyester (1)	
	Polycarbonate (1)	
	Acrylonitrile-butadiene-styrene (1)	
	Nylon (2)	
	Polypropylene (2)	

Note:

(1) Satisfactory test results after 532 hours of soaking at 35°C and 20 cycles of alternate contact or immersion in *Rapicide™ High-Level Disinfectant and Sterilant*.

(2) Tinting observed after 532 hours of soaking at 35°C and 20 cycles of alternate contact or immersion in *Rapicide™ High-Level Disinfectant and Sterilant*.

532 hours soaking at 35°C represents over 6000 high-level disinfectant 5 minute exposure cycles.

Please contact the reusable device or Automated Endoscope Reprocessor manufacturer for compatibility with *Rapicide™ High-Level Disinfectant and Sterilant*.

6. Pre-Cleaning Agent Compatibility

*Rapicide™ High-Level Disinfectant and Sterilant* is compatible with enzymatic detergents which are mild in pH, low foaming, and easily rinsed from equipment.

Detergents that are either highly acid or alkaline are contraindicated as pre-cleaning agents since improper rinsing could affect the efficacy of *Rapicide™ High-Level Disinfectant and Sterilant* by altering its pH.

B. CONTRAINDICATIONS

1. Sterilant Usage: Routine biological monitoring is not feasible with *Rapicide™ High-Level Disinfectant and Sterilant*, and therefore *Rapicide™ High-Level Disinfectant and Sterilant* 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 gas plasma.

2. High-Level Disinfectant Usage: *Rapicide™ High-Level Disinfectant and Sterilant* should NOT be used to high-level disinfect a semi-critical device when sterilization is practical.

3. Endoscope Usage: *Rapicide™ High-Level Disinfectant and Sterilant* is not the method of choice for sterilization of rigid endoscopes that the device manufacturer indicates are compatible with steam sterilization. *Rapicide™ High-Level Disinfectant and Sterilant* may be used for flexible endoscope reprocessing if a validated protocol for automated rinsing and leak testing is employed. Contact the reusable instrument manufacturer if there are doubts about the compatibility of *Rapicide™ High-Level Disinfectant and Sterilant* and the instrument.

C. WARNINGS

*Rapicide™ High-Level Disinfectant and Sterilant* is hazardous to humans and domestic animals.

**DANGER: Keep Out of Reach of Children.**

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 areas in an Automated Endoscope Reprocessor with an effective vapor containment system to manage vapors.

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 *Rapicide™ High-Level Disinfectant and Sterilant* can be obtained by calling MediVators, Inc. 1-651-405-1661.

D. PRECAUTIONS

1. Nitrile gloves, eye protection, face masks, and liquid-proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices.

2. The user is cautioned to minimize exposure to vapors at elevated temperature by using *Rapicide™ High-Level Disinfectant and Sterilant* in an Automated Endoscope Reprocessor with an effective vapor containment system and placed in a well-ventilated area.

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

4. The user **MUST** adhere to the **Directions for Use** since any modification will affect the safety and effectiveness of the germicide.

5. The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using *Rapicide™ High-Level Disinfectant and Sterilant*.

6. The use of *Rapicide™ High-Level Disinfectant and Sterilant* in Automated Endoscope Reprocessors must be part of a validated reprocessing procedure supplied by the Automated Endoscope Reprocessor manufacturer to ensure that a minimum contact or immersion time of 5 minutes at 35°C is provided for high-level disinfection, and 7 hours and 40 minutes at 35°C for sterilization.

7. Use 3M Comply, Cold SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983MM chemical indicator strips to monitor glutaraldehyde concentration prior to each reprocessing in order to detect unexpected dilution.

#### E. DIRECTIONS FOR USE

Monitor the contact or immersion time, temperature, minimum recommended concentration (MRC) of glutaraldehyde and pH of the *Rapicide™ High-Level Disinfectant and Sterilant* utilizing the Automated Endoscope Reprocessor process controls or manual timing device, thermometer, 3M Comply, Cold SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983MM chemical indicator strips, and a pH test kit. Maintain the solution at 35°C over the reuse period. Monitor the glutaraldehyde concentration prior to each reprocessing using 3M Comply, Cold SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983MM chemical indicator strips. The pH of the solution is to be between 6.0 and 7.0. **The user is cautioned to minimize exposure to vapors at elevated temperature by using *Rapicide™ High-Level Disinfectant and Sterilant* in an Automated Endoscope Reprocessor with an effective vapor containment system that is placed in a well-ventilated area.**

1. **Preparation:** *Rapicide™ High-Level Disinfectant and Sterilant* does not require activation. *Rapicide™ High-Level Disinfectant and Sterilant* is ready-to-use. Record the date of use at the beginning of the reuse period and calculate the expiration date by adding 28 days. Expiration date should be recorded in a log book. Check the concentration of glutaraldehyde prior to each reprocessing with 3M Comply, Cold SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983MM chemical indicator strips and discard the solution when less than 1.5% glutaraldehyde is present. Check the pH to ensure it is between 6.0 and 7.0.

2. **Cleaning/Decontamination:** Blood and other body fluids must be thoroughly cleaned from medical devices before processing in *Rapicide™ High-Level Disinfectant and Sterilant*. Thoroughly clean, rinse and rough dry devices before processing in *Rapicide™ High-Level Disinfectant and Sterilant*. Cleanse and rinse the lumens of hollow instruments before automated reprocessing with *Rapicide™ High-Level Disinfectant and Sterilant*. Refer to the reusable device manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of the equipment.

OBSERVE UNIVERSAL PRECAUTIONS AS DEFINED BY THE CDC FOR MEDICAL INSTRUMENTS OR EQUIPMENT SOILED WITH BLOOD OR BODY FLUIDS.

**Personal Protection:** Nitrile gloves, eye protection, and face masks should be worn when cleaning and disinfecting soiled equipment.

**Cleaning Procedure:** Blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before automated reprocessing with the disinfectant or sterilant. See labeling of the reusable device for additional instructions.

**Disposal of Infectious Wastes:** Blood and other bodily fluids should be disposed of according to approved hospital procedures.

#### 3. Usage

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

a. **Sterilization:** Place pre-cleaned devices into an Automated Endoscope Reprocessor in accordance with the manufacturer's instructions. Select a validated sterilization cycle that provides for a minimum sterilant contact or immersion time of 7 hours and 40 minutes at 35°C (95°F) to eliminate all microorganisms including *Clostridium sporogenes* and *Bacillus subtilis* spores. Select an adequate automated rinse cycle with bacterial-retentive filtered, potable water. See rinsing instructions below for additional information. Monitor the minimum recommended concentration (MRC) of glutaraldehyde with 3M Comply, Cold SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983MM chemical indicator strips prior to each reprocessing

b. **High-Level Disinfection:** Place pre-cleaned devices into an Automated Endoscope Reprocessor in accordance with the manufacturer's instructions. Select a validated high-level disinfection cycle that provides for a minimum disinfectant contact or immersion time of 5 minutes at 35°C (95°F) to destroy all pathogenic microorganisms except for large numbers of bacterial endospores but including *Mycobacterium bovis*. Select an adequate automated rinse cycle with bacterial retentive-filtered or potable water. The quality of the rinse water is dependent on the intended use of the instrument. See rinsing instructions below for additional information. Monitor the minimum recommended concentration (MRC) of glutaraldehyde daily with 3M Comply, Cold SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983MM chemical indicator strips prior to each reprocessing

c. **Rinsing Instructions:** Select a validated automated rinse cycle in accordance with the Automated Endoscope Reprocessor manufacturer's instructions. Ensure that the automated rinse cycle selected will thoroughly rinse the medical device including all channels with copious volumes of bacterial-retentive filtered or potable water equivalent to the device manufacturer's recommendations. Each rinse should be a minimum of three minutes in duration unless otherwise noted by the device manufacturer. Ensure that a fresh supply of water is used for 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.

Bacterial-retentive filtered, potable water rinse: The following devices should be rinsed with bacterial-retentive filtered, potable water.

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 bacterial-retentive filtered, potable water rinse is recommended when practicable, otherwise a high-quality potable water rinse is acceptable. 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 medical device 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 those opportunistic microorganisms. A final rinse using a 70% isopropyl alcohol solution is useful to speed the drying process and reduce the number of any organism present as a result of rinsing with potable water.

d. Reuse

*Rapicide™ High-Level Disinfectant and Sterilant* has also demonstrated efficacy in the presence of organic soil contamination and a simulated amount of microbiological burden during reuse. This ready-to-use solution may be used and reused within the limitations indicated above provided the minimum glutaraldehyde concentration is 1.5% w/v or higher for up to 28 days. **Maintain the solution at 35°C over the 28-day reuse period. Do not use *Rapicide™ High-Level Disinfectant and Sterilant* solution beyond 28 days. Efficacy of this product during its use-life must be verified at least daily by using 3M Comply, Cold SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983MM chemical indicator strips to determine that the minimum recommended concentration (MRC) of 1.5% glutaraldehyde is present. The pH of the solution is to be between 6.0 and 7.0.**

4. Monitoring of Germicide to Ensure Specifications Are Met

During the usage of *Rapicide™ High-Level Disinfectant and Sterilant* as a high-level disinfectant or sterilant, it is recommended that the *Rapicide™ High-Level Disinfectant and Sterilant* be tested with 3M Comply, Cold SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983MM chemical indicator strips prior to each reprocessing. This is to ensure that the appropriate concentration of glutaraldehyde is present and to guard against dilution and polymerization that may lower the effectiveness of the solution below its MRC. The temperature, contact or immersion time, and pH of the solution should also be periodically checked. The pH of the solution is to be between 6.0 and 7.0.

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. 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. Ready-to-use *Rapicide™ High-Level Disinfectant and Sterilant* should be stored in its original sealed container at a controlled room temperature of 15°C to 25°C (59°F to 77°F). Once opened, the contents of container should be immediately used, with any unused portion being discarded.
2. The expiration date of *Rapicide™ High-Level Disinfectant and Sterilant* will be found at the bottom of the container. Do not utilize beyond the expiration date.
3. The use period of *Rapicide™ High-Level Disinfectant and Sterilant* should never exceed 28 days. 3M Comply, Cold SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983MM chemical indicator strips will indicate at any time if the concentration of glutaraldehyde is below the MRC of 1.5%. DO NOT RELY SOLELY ON DAYS OF USE.

G. EMERGENCY AND TECHNICAL PRODUCT INFORMATION

Emergency, safety, or technical information about *Rapicide™ High-Level Disinfectant and Sterilant* can be obtained by calling MediVators, Inc. at 1-800-537-7324 or 1-651-405-1661.

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 *Rapicide™ High-Level Disinfectant and Sterilant* can be obtained from MediVators, Inc. at 1-800-537-7324 or 1-651-405-1661.

I. DISPOSAL INFORMATION

Germicide Disposal

Discard residual solution in drain or according to local, state, and Federal regulations.

Container Disposal

Do not reuse empty container. Rinse thoroughly with water and dispose in trash.

J. HOW SUPPLIED

Order information:

*Rapicide™ High-Level Disinfectant and Sterilant*

4 - 1 gallon bottles per case

Product Code: ML02-0059

Manufactured for:

MediVators, Inc.

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Eagan, MN 55121

1-800-537-7324

1-651-405-1661

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