

Date opened: _____

Discard opened
solution by: _____

DIRECTIONS FOR USE: It is a violation of Federal (USA) Law to use this product in a manner inconsistent with its labeling. Read the DFU prior to using this product.

CLEANING/DECONTAMINATION: Medical devices must be thoroughly cleaned of blood and other body fluids before sterilization or high-level disinfection with RAPICIDE® High-Level Disinfectant & Sterilant. See labeling of the reusable device for additional cleaning and decontamination. Select a medical grade detergent that is low foaming, neutral in pH, and is easily rinsable. Improper rinsing may effect RAPICIDE Disinfectant efficacy.

STERILIZATION: RAPICIDE High-Level Disinfectant & Sterilant is intended to be used for the automated sterilization of heat sensitive critical medical equipment for which alternative sterilization methods are not suitable. Place devices into an Automated Endoscope Reprocessor (AER) in accordance with the manufacturer's instructions. Select a validated sterilization cycle that provides for a minimum concentration of 1.5% Glutaraldehyde. Select an adequate rinse cycle with bacterial-retentive filtered, potable water.

HIGH LEVEL DISINFECTION: RAPICIDE High-Level Disinfectant & Sterilant is intended to be used for the automated high level disinfection of heat sensitive semi-critical medical devices for which sterilization is not practical. Place devices into an AER 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) at a minimum concentration of 1.5% Glutaraldehyde. Select an adequate rinse cycle with bacterial-retentive filtered, potable water.

REUSE PERIOD: RAPICIDE High-Level Disinfectant & Sterilant may be used and reused for 28 days provided the glutaraldehyde concentration remains above 1.5%. Always monitor the glutaraldehyde concentration prior to use. Do not use beyond the expiration date on the product label or the 28 day reuse period even if the concentration is above the minimum concentration. Maintain the solution at 35°C over the 28-day reuse period.

Read DFU and SDS for RAPICIDE High-Level Disinfectant & Sterilant and the Automated Endoscope Reprocessing System prior to use.

MEDIVATORS®

Rapicide®

High-Level Disinfectant & Sterilant

- Ready to Use
- No Activation Required
- 28-Day Maximum Use Life

FOR USE IN REPROCESSING FLEXIBLE FIBEROPTIC AND VIDEO ENDOSCOPES IN LEGALLY MARKETED AUTOMATED REPROCESSORS ONLY

PRECAUTIONARY STATEMENTS:

HAZARD TO HUMANS AND DOMESTIC ANIMALS.

Direct contact is corrosive to exposed tissue, causing eye and skin damage. Do not get in eyes, on skin or clothing, and avoid breathing the fumes. Avoid contamination of food. Wear protective eye covers and Nitrile gloves when handling or pouring.

STATEMENT OF PRACTICAL TREATMENT:

In case of contact, immediately flush eyes or skin with copious amounts of water for a least fifteen (15) minutes. Get medical attention for eye contact. Harmful if swallowed. Drink large quantities of water and call a physician immediately. Note to Physician: Probable mucosal damage may contraindicate gastric lavage.

ACTIVE INGREDIENT:

Glutaraldehyde	2.5%
Inert Ingredients	97.5%
Total	100.0%

NET CONTENTS:

1.0 Gallon
(3.8 Liters)

4 x 1 Gallon bottles per case
U.S. Pat. Reg. No. 4,748,279

KEEP OUT OF REACH OF CHILDREN
DANGER

MEDIVATORS
A Cantel Medical Company

Manufactured in the USA by:

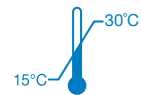
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REF MLO2-0059

USER PROFICIENCY: The user should be adequately trained in the decontamination and disinfection or sterilization of medical devices and handling of toxic substances such as liquid chemical germicides.



STORAGE AND DISPOSAL: Store at controlled room temperature 15°C - 30°C (59°F - 86°F). Once opened, the contents of container should be used within 28 days. Discard residual solution according to local, state, and federal regulations. Do not reuse empty container. Triple rinse with water and dispose in an incinerator or landfill approved for pesticide containers. For additional information regarding the safety and effectiveness of RAPICIDE call 1-800-444-4729 (1-800-328-3340).

PRECAUTIONS:

1. Sterilant Usage: Routine biological monitoring is not feasible with RAPICIDE® High-Level Disinfectant & Sterilant and therefore Rapicide 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 & Sterilant should NOT be used to high-level disinfect a semi-critical device when sterilization is practical.
3. Endoscope Usage: RAPICIDE High-Level Disinfectant & Sterilant is not the method of choice for sterilization of rigid endoscopes that the reusable device manufacturer indicates is compatible with steam sterilization. RAPICIDE High-Level Disinfectant & Sterilant may be used for flexible endoscope reprocessing if a validated protocol for automated rinsing and leak testing is employed. Contact the instrument manufacturer if there are doubts about the compatibility of RAPICIDE High-Level Disinfectant & Sterilant and the instrument.
4. Nitrile gloves, eye protection, face masks and liquid proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices.
5. The user is cautioned to minimize exposure to vapors at elevated temperature by using RAPICIDE High-Level Disinfectant & Sterilant in an AER with an effective vapor containment system and placed in a well-ventilated area.
6. Contaminated reusable devices MUST BE THOROUGHLY CLEANED prior to disinfection or sterilization, since residual contamination will decrease effectiveness of the germicide.
7. The user MUST adhere to the Direction for Use since any modification will affect the safety and effectiveness of the germicide.
8. The reusable device manufacturer should provide the user with a validated reprocessing procedure for the device using Rapicide.
9. The use of RAPICIDE High-Level Disinfectant & Sterilant in Automated Endoscope Reprocessors must be part of a validated reprocessing procedure supplied by the AER manufacturer to ensure that a minimum contact or immersion time is achieved per the directions on this label and the package insert.
10. Use RAPICIDE® Glutaraldehyde Indicator Test Strips, order number MLO2-0120 to monitor glutaraldehyde concentration prior to reprocessing in order to detect unexpected dilution.

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