PM-31

Reg # 46851-2

OmniCide™

Long Life Reusable Activated Dialdehyde

Sterilizing and Disinfecting Solution

Sporicidal, Virucidal†, Fungicidal, Pseudomonacidal, Bactericidal, Tuberculocidal

Recommended for use in hospitals, medical/dental clinics, nursing homes, healthcare institutions and veterinary clinics.

Active Ingredient	
Glutaraldehyde	2.4%
Inert Ingredient	97.6%
TOTAL	100.0%

E.P.A. Registration No. 46851-2
E.P.A. Establishment No. 37765-CA-01
E.P.A. Establishment No. 39754-WI-1
(See shoulder of container for E.P.A. Est. No.)

Note: Contents of attached vial must be added to solution before this product is effective. See "DIRECTIONS FOR USE - ACTIVATE."

† See package insert for specific viruses claimed.

Contents: 1 Quart (946 ml)
Reorder No. OM32/28

INTENDED USE

Sterilization: This solution should be used for the sterilization of heat sensitive medical equipment for which alternative methods of sterilization are not suitable. Medical equipment which should always be sterilized is that which is categorized as critical (e.g., used in procedures in which contact will be made with tissue that is normally considered sterile).

High Level Disinfection: This solution should be used for the high level disinfection of heat sensitive medical equipment for which sterilization is not practical. Medical equipment which should always be subjected to high level disinfection or sterilization is that which will be used in procedures categorized as semi-critical (e.g., used in procedures in which contact will be made with mucous membranes or other body surfaces which are not normally considered sterile).

Intermediate Level Disinfection: This solution should be used for disinfection of medical equipment for which a risk of cross contamination exists. Medical equipment which should always be disinfected is that which is to be used in procedures categorized as non-critical (e.g., used in procedures in which contact will only be made with intact skin).

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Keep Out of Reach of Children.

Direct contact may cause eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing. Wear goggles or face shield and chemical resistant gloves when handling or pouring. Avoid contamination of food. Use in a well ventilated area in closed containers.

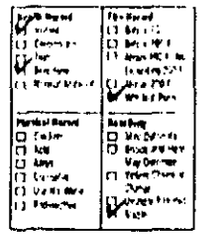
STATEMENT OF PRACTICAL TREATMENT: In case of contact, immediately flush eyes or skin with copious amounts of water for at least 15 minutes. For eyes, get medical attention. Harmful if swallowed. Drink large quantities of water and call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL

Store at controlled room temperature 15°C-30°C (59°-86°F).
Pesticide Disposal: Discard residual solution in drain. Flush thoroughly with water.
Container Disposal: Do not reuse empty container. Wrap container and put in trash.

NFPA HAZARDOUS CHEMICAL CHART



Product Name: OmniCide
Hazardous Chemicals: Glutaraldehyde
Route of Entry:
✔ Inhalation
✔ Ingestion
✔ Skin/Eye Absorption
Personal Protection: Chemical Resistant Gloves, Goggles or Face Shield

COTTRELL, LTD.
7399 SOUTH TUCSON WAY
ENGLEWOOD, CO 80112 USA
1 800 THE EDGE

H816OM322805

DIRECTIONS FOR USE

IT IS VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING

Activation: Activate the OmniCide solution by adding the entire contents of the Activator Bottle (which is attached to the OmniCide solution container) to the container. Place cap on container and shake well. On activation the solution immediately changes color to blue, thereby indicating solution is ready to use. Record the date of activation on the indicated space below, in a log book or a label affixed to any secondary container used for activated solution. *See package insert for additional instructions and information regarding activated solution.*

Cleaning/Decontamination: Blood and other body fluids must be thoroughly cleaned from the 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 OmniCide solution. Cleanse and rinse the lumens of hollow instruments before filling with OmniCide solution. *See package insert for additional cleaning/decontamination instructions.*

Sterilization: Immerse medical equipment/devices completely in OmniCide solution for a minimum of ten hours at 68°F (20°C) to eliminate all microorganisms, including *Clostridium sporogenes* and *Bacillus subtilis* spores. Rem
solution using steril
thoroughly with ste
Insert for complete
information on ster

High Level Disinfec
medical equipment/
OmniCide solution
45 minutes at 68°
pathogenic microor
large numbers of ba
but including Mycob
(Quantitative 3.8 lo

Remove devices fro
solution and rinse th
water or potable wa
water used is depen
use of the instrumen
package insert for co
information on high l

Intermediate Level
medical instruments
in OmniCide for a m
at 68°F (20°C) to d
bacteria, all pathogen
viruses and **99.99%**
strains (Quantitative
represented by *bovis*
for complete instruc
intermediate level di

Refer to package ins
usage/product data.

Note Dates Here:
Activation Date:

Check solution upon a
use with ProChe
Concentration indicato
discarded after 2
ProChek G *Glutara*
Indicator in
Control Number an
Unactivated Sol

DANGER: Keep Out of Reach of Children
See Side Panel for Additional Precautionary Statements

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OmniCide™

Long Life Reusable Activated Dialdehyde

Sterilizing and Disinfecting Solution

Cottrell, Ltd.
7399 South Tucson Way
Englewood, CO 80112 USA
1 800 *THE EDGE*

A. INTENDED USE/DIRECTIONS FOR USE

OmniCide long life activated dialdehyde solution is a liquid chemical sterilant and a high or intermediate level disinfectant when used according to the **DIRECTIONS FOR USE.**

1. **Germicide Level of Activity: OmniCide** can be used at the following germicide levels of activity:

   Sterilant: OmniCide is a sterilant when used or reused, according to the Directions For Use, at or above its Minimum Effective Concentration (MEC) as determined by the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip at 68°F (20°C) with an immersion time of ten hours for a use period not to exceed 28 days.

   High Level Disinfectant: OmniCide is a high level disinfectant when used or reused, according to the **DIRECTIONS FOR USE**, at or above its Minimum Effective Concentration (MEC) as determined by the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip at 68°F (20°C) with an immersion time of 45 minutes for a use period not to exceed 28 days.

   Intermediate Level Disinfectant: OmniCide is an intermediate level disinfectant when used or reused, at or above its Minimum Effective Concentration (MEC) as determined by the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip at 68°F (20°C) with an immersion time of ten minutes according to the **DIRECTIONS FOR USE** in **SECTION E** for a use period not to exceed 28 days.

   A ten minute immersion at 68°F (20°C) will destroy vegetative bacteria including *S. aureus, S. choleraesuis, P. aeruginosa, E. coli,* all pathogenic fungi, representative viruses and 99.99% of *Mycobacterium* strains (Quantitative TB Method) as represented by *bovis*. ***HIV-1* (AIDS virus) is destroyed in 60 seconds with full strength solution

2. **Reuse Period: OmniCide** has demonstrated efficacy in the presence of 5 percent organic soil contamination and a simulated amount of microbiological burden during reuse. **OMNICIDE SOLUTION MAY BE REUSED ONLY WHILE THE MINIMUM EFFECTIVE CONCENTRATION (MEC) AS DETERMINED BY THE PROCHEK G GLUTARALDEHYDE CONCENTRATION INDICATOR TEST STRIP, PH AND TEMPERATURE MEET THE REQUIREMENTS BASED UPON MONITORING AS DESCRIBED IN THE PROCHEK G DIRECTIONS FOR USE.** Efficacy of **OmniCide** solution during its use-life must be verified by the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip to determine that at least the MEC as determined by the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip is present. This product must be discarded

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after 28 days, even if the **ProChek G** Concentration indicates pass.

3. **General Information:** Choose a germicide with th[e] that is appropriate for the reusable medical device. Follow the reusable device labeling and standard i[n] absence of complete instructions, use the followin[g]

   First, for patient contacting devices, determine w[hether] to be processed is a critical, semi-critical, or non

   - **A critical device** routinely penetrates the skin during use or are otherwise used in normally
   - **A semi-critical device** makes contact with m[ucous] but does not ordinarily penetrate sterile areas
   - **A non-critical device** contacts only intact ski[n]

   Second, determine if sterilization, high level or i[ntermediate] disinfection is required.

   Critical device:
   Sterilization is required

   Semi-critical device:
   Although sterilization is recommended whene[ver] disinfection is acceptable (e.g., GI endoscope[s] be used in the airway, diaphragm-fitting rings

   Non-critical device:
   Medical Equipment Surfaces: Intermediate lev[el] is recommended.

   Third, determine the time required to achieve the sterilization required for the specified medical de[vice]

4. The germicidal activity of **OmniCide** was demonstr[ated] solutions* in performance, clinical and simulated u[se] following organisms.

Organisms • OmniCide Sterilization/Disinfection Times

Spores – 10 hours
- *Bacillus subtilis*
- *Clostridium sporogenes*

Vegetative Organisms – 10 minutes
- *Staphylococcus aureus*
- *Salmonella choleraesuis*
- *Pseudomonas aeruginosa*
- *Escherichia coli*

Vegetative Organisms – 45 minutes
- *Mycobacterium bovis*

Fungi – 10 minutes
- *Trichophyton interdigitale*
- *Trichophyton mentagrophytes*

Non-lipid Small Virus† – 10 minutes
- *Polio 2*

Lipid Medium Virus†
- *Herpes simplex (varicella)** *HIV-1 (AIDS virus)** (60 sec.)

* Testing was performed using OmniCide solution which had been diluted to 1.5 percent using 5 percent bovine calf serum

5. **Material Compatibility:** OmniCide solution is recommended for usage with medical devices made from the materials shown below.

- polypropylene
- ABS
- polyethylene*
- polycarbonate
- black oxide steel
- Mylar*
- vinyl and Tygon tubing**
- Nickel plating*
- acrylic bar*
- polyethylene tubing*
- PVC*

*represents four weeks of exposure **represents 13 days of exposure

Following sterilization or disinfection, the sterilized or disinfected medical device should be rinsed according to the **DIRECTIONS FOR USE, RINSING (SECTION E.4)**, and dried according to manufacturer's instructions.

6. **Pre-cleaning Agent Compatibility:** OmniCide is compatible with enzymatic detergents which are neutral 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 effect the efficacy of the OmniCide solution by altering its pH.

B. CONTRAINDICATIONS

1. **Sterilant Usage:** Routine biological monitoring is not possible with **OmniCide** solution and therefore **OmniCide** solution should **NOT** be used to sterilize reusable medical devices that are compatible with other sterilization processes that can be biologically monitored.

   OmniCide solution should not be used for sterilization of critical devices intended for single use (e.g., catheters).

2. **High Level Disinfectant Usage: OmniCide** solution should not be used to high level disinfect a semi-critical device when sterilization is practical.

3. **Endoscope Usage: OmniCide** solution is not the method of choice for sterilization of rigid endoscopes which the device manufacturer indicates are compatible with steam sterilization.

C. WARNINGS

OmniCide 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 copious amounts 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 OmniCide solution can be obtained from Cottrell, Ltd. Hotline at 1-800-*THE EDGE* (843-3343), or by contacting Infotrac at 1-800-535-5053 or by contacting your Cottrell, Ltd. representative.

D. PRECAUTIONS

1. Appropriate hand, eye and face protection, as well as should be worn when cleaning and sterilizing/disinfe and equipment.

   More detailed information regarding the handling of th compatible materials is included in the MSDS sheet a

2. Contaminated, reusable devices **MUST BE THOROUG** disinfection or sterilization, since residual contamina effectiveness of the germicide.

3. The user **MUST** adhere to the **DIRECTIONS FOR USE** will affect the safety and effectiveness of the germici

4. The reusable device manufacturer should provide the reprocessing procedure for that device using OmniC

E. DIRECTIONS FOR USE

1. **Activation**

   Activate the **OmniCide** solution by adding the entire bottle (which is attached to the **OmniCide** solution co Place cap on container and shake well. On activation, changes color to blue, thereby indicating solution is should then be immediately tested with the **ProChek** Concentration Indicator Test Strip upon activation an assure glutaraldehyde concentration is above the ME intended for use in manual (bucket and tray) systems ABS, polyethylene, glass-filled polypropylene or specia plastics. Record the date of activation (mixing date) the **OmniCide** solution container label in the space pr log book or a label affixed to any secondary containe solution. **OmniCide** must be discarded after 28 days, Glutaraldehyde Concentration Indicator Test Strip ind

2. **Cleaning/Decontamination**

   Blood and othe: body fluids must be thoroughly clear lumens, and objects before application of the disinfec and other body fluids should be autoclaved and dispo applicable Federal, State and local regulations for infe

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For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in OmniCide solution. Cleanse and rinse the lumens of hollow instruments before filling with OmniCide solution. Refer to the reusable device manufacturer's labeling for 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)

Prior to immersing medical equipment/devices, test the solution with a ProChek G Glutaraldehyde Concentration Indicator Test Strip to assure that the glutaraldehyde concentration is above its MEC.

Immerse medical equipment/devices completely in OmniCide solution for a minimum of ten hours at 68°F (20°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)

Prior to immersing medical equipment/devices, test the solution with a ProChek G Glutaraldehyde Concentration Indicator Test Strip to assure that the glutaraldehyde concentration is above its MEC.

Immerse medical equipment/devices completely in OmniCide solution for a minimum of 45 minutes at 68°F (20°C) to destroy all pathogenic microorganisms, except for large numbers of bacterial endospores, but including *Mycobacterium bovis* (Quantitative TB Method). Remove devices and equipment from the solution and rinse thoroughly following the rinsing instructions below.

c. Intermediate Level Disinfectant

Prior to immersing medical equipment/devices, test the solution with a ProChek G Glutaraldehyde Concentration Indicator Test Strip to assure that the glutaraldehyde concentration is above its MEC.

OmniCide is an intermediate level disinfectant when used or reused, at full strength for a maximum of 28 days or above its Minimum Effective Concentration (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip at 68°F (20°C) with an immersion time of ten minutes for a use period not to exceed 28 days.

4. Rinsing Instructions

Following immersion in OmniCide solution, thoroughly rinse the equipment or medical device by immersing in two gallons of water. Repeat this procedure a second time with a fresh two gallon volume of water.

For endoscopic instruments with lumens, a minimum of 500 ml of water should be flushed through lumens during each separate rinse unless otherwise noted by the device or equipment manufacturer. Use fresh volumes 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 become contaminated with glutaraldehyde.

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

Sterile Water Rinse: Critical devices which are sterilized with OmniCide must be rinsed with sterile water.

Potable Water Rinse: A sterile water rinse is recommended when practical, for all devices. Alternatively, a high quality potable water (one that meets Federal Clean Water Standards at point of use) may be used.

The use of potable water for rinsing, increases the risk of contaminating the device or medical equipment with *pseudomonades* and atypical (fast growing) *mycobacteria* that are often present in potable water supplies. The devices (e.g., colonoscope) need to be completely dried, because any moisture remaining 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. A final rinse using a 70 percent isopropyl alcohol solution should be used to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

F. REUSE

OmniCide solution has demonstrated efficacy in the prese
soil contamination and a simulated amount of microbiolog
The glutaraldehyde concentration of this product during it
by the ProChek G Glutaraldehyde Concentration Indicator
solution is above the Minimum Effective Concentration (M
ProChek G Glutaraldehyde Concentration Indicator Test Stri
used and reused within the limitations indicated above for
activation. OmniCide must be discarded after 28 days, eve
Glutaraldehyde Concentration Indicator Test Strip indicates

G. MONITORING OF GERMICIDE TO ENSURE SPECIFICATIO

It is recommended that the OmniCide solution be tested v
Glutaraldehyde Concentration Indicator Test Strip prior to
insure that the appropriate concentration of glutaraldehyde
against a dilution which may lower the concentration of th
MEC. During the use of OmniCide as a high level disinfect
also highly recommended that a thermometer and timer b
mum conditions are met. The pH of the activated solution
checked to verify that the pH of the solution is between 8.

H. POST-PROCESSING HANDLING AND STORAGE OF REUS

Sterilized or disinfected reusable devices are either to be u
stored in a manner to minimize contamination. Refer to re
manufacturer's labeling for additional storage and/or handl

I. STORAGE CONDITIONS AND EXPIRATION DATE

1. Prior to activation, OmniCide solution should be sto
container at controlled room temperature 59°-86°F (1
2. The expiration date of the unactivated OmniCide sol
activator will be found on the side of the immediate
3. The use period for activated OmniCide is for no long
following activation or as indicated by ProChek G Gl
Concentration Indicator Test Strip. Once activated, th
further dilution prior to its usage.

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J. **SAFETY INFORMATION**

Emergency, safety, or technical information about **OmniCide** solution can be obtained from Cottrell, Ltd. at 1-800-*THE EDGE* (843-3343), Infotrac at 1-800-535-5053, or by contacting your Cottrell, Ltd. representative.

K. **USER TRAINING**

The user should be adequately trained in the decontamination and disinfection or sterilization of medical devices and the handling of liquid chemical germicides. Additional information about **OmniCide** solution can be obtained from Cottrell, Ltd. at 1-800-843-3343, or by contacting your local Cottrell, Ltd. representative.

L. **DISPOSAL INFORMATION**

0.946 L (1 quart), 1.892 L (1/2 gallon) and 3.785 L (1 gallon) size container must be triple rinsed and disposed of in accordance with Federal, State or local regulations

M. **REORDER INFORMATION**

Reorder	Description	Case Contains
OM32/28	1 quart (0.946 L)	4 qts/case
OM128/28	1 gallon (3.785 L)	4 gals/case
PCG660	ProChek G Concentration Indicator Strips	60 strips/canister (6 canisters/case)
PCG615	ProChek G Concentration Indicator Strips	15 strips/canister (16 canisters/case)

ENDOSCOPE REPROCESSING

A. **INTENDED USE/DIRECTIONS FOR USE**

OmniCide is a liquid chemical sterilant and high level disinfectant for flexible endoscopes when used according to the **DIRECTIONS FOR USE (SEE SECTION E).**

1. **Germicide Level of Activity: OmniCide** can be used at the following germicide levels of activity:

   Flexible endoscopes, when expected to penetrate the skin or mucous membranes or are used in otherwise normally sterile tissues of the body during use are critical devices and therefore, are required to be sterile.

   Sterilant: OmniCide is a sterilant for flexible endoscopes when used or reused, according to the DIRECTIONS FOR USE., at full strength for a maximum of 28 days or above its Minimum Effective Concentration (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip at **68°F (20°C) with an immersion time of ten hours** for a use period not to exceed 28 days.

   Flexible endoscopes when expected to come in contact without penetration of mucous membranes are semi-critical devices and therefore may be high level disinfected

   High Level Disinfectant: OmniCide is a high level disinfectant for flexible endoscopes when used or reused, according to the DIRECTIONS FOR USE, at or above its Minimum Effective Concentration (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip at **68°F (20°C) with an immersion time of 45 minutes** according to the **DIRECTIONS FOR USE in SECTION E** for a period not to exceed 28 days.

B. **GENERAL PROCEDURE FOR HIGH LEVEL DISINFECTION OF FLEXIBLE ENDOSCOPES**

(This procedure is recommended in the absence of specific directions from the device manufacturer)

1. **Trained Personnel**

   a. Personnel involved in the reprocessing of endoscopes should have the ability to read, understand, and implement instructions from manufacturer's and regulatory agencies as they relate to endoscopic disinfection

   b. The person(s) to whom the job of reprocessing endoscopes is given should have the opportunity to become completely familiar with the mechanical aspects of the endoscopic equipment.

   c. Training should include familiarization with OSHA r in-house policies on how to appropriately and safel chemical germicides.

   d. Training should also include information on the saf instruments that are contaminated with body fluids should include familiarization with universal precau

2. **Cleaning of flexible endoscopes**

a. **Cleaning at the Examination Room**

   Reflux of body fluids from the patient may occur in channels. Cleaning of endoscopes and accessories promptly after removing the endoscope from the p drying of secretions.

   1. Personnel should donne all personnel protective equipr

   2. Prepare an enzyme detergent (e.g., ProEZ) or one r scope manufacturer.

   3. Gently wipe all debris from the insertion tube with a the like.

   4. Place the distal end of the flexible endoscope into t detergent solution and aspirate through the biopsy/. 5-10 seconds or until the solution is visibly clear. A the detergent solution and air several times. Finish t

   5. Flush or blow out air and water channels in accorda endoscope manufacturer's instructions

   6. Transport the endoscope to the reprocessing area.

b. **Cleaning at the Reprocessing Area**

   1. Attach any necessary water-tight caps to the electric of the umbilicus.

   2. Before proceeding with any further cleaning steps, t endoscope should be leak tested. (Refer to manufac instructions). Follow the manufacturer's instructions appears damaged.

   3. Fill a sink or basin with a freshly made enzyme (e.g detergent solution.

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4. Immerse the endoscope. All channels should be irrigated with copious amounts of detergent and tap water to soften, moisten, and dilute the organic debris. All detachable parts (e.g., hoods and suction valves) should be removed and soaked in the detergent solution. The insertion tube should be washed with detergent solution and rinsed.
5. Use a small soft brush to scrub all detachable parts.
6. Use a brush to clean under the suction valve, air/water valve and biopsy port openings.
7. Brush the entire suction/biopsy system including the body, the insertion tube, and the umbilicus of the endoscope in accordance with the manufacturer's instructions.
8. Accessible channel(s) should be brushed to remove particulate matter, and the detergent solution must be suctioned or pumped through all channels to remove dislodged material. Channel irrigators may be useful for this step. Fill all channels with detergent solution and soak 2-5 minutes in accordance to the ProEZ instructions.

3. **Rinse after cleaning**
   a. Rinse the endoscope and all detachable parts in clean water.
   b. Rinse all channels well with water to remove debris and detergent.
   c. Purge water from all channels and wipe dry the exterior of the endoscope with a soft clean cloth to prevent dilution of the OmniCide disinfectant used in subsequent steps.
4. **Manual Disinfection**
   a. Activate the OmniCide solution by adding the entire content of the Activator bottle which is attached to the OmniCide solution container. Recap the container and shake well. On activation, the solution immediately changes color to blue, thereby indicating the solution is ready. Use ProChek G Glutaraldehyde Concentration Indicator Test Strips after activation to determine that the solution is above the Minimum Effective Concentration (MEC) before use.

      Test the activated OmniCide solution using the ProChek G Glutaraldehyde Concentration Indicator at 68°F (20°C), before each use.
   b. Attach channel irrigators/adapters and cover the biopsy port in accordance with the manufacturer's instructions.

   c. Pour the activated OmniCide into an appropriate sized basin.
   d. Completely immerse the endoscope in the basin of OmniCide. **NOTE:** In order to prevent damage to the endoscope, **DO NOT** soak any other accessory equipment with the endoscope.
   e. Inject the OmniCide solution into all channels of the endoscope until it can be seen exiting the opposite end of each channel. Assure that all channels are filled with disinfectant and that no air pockets remain within the channels.
   f. Cover the disinfectant soaking basin with a tight fitting lid to minimize chemical vapor exposure.
   g. Soak the endoscope for 45 minutes. Use a timer to ensure adequate soaking time.
   h. Before completely removing the endoscope from the disinfectant, flush all channels with air to remove disinfectant.
5. **Rinse After Manual Disinfection**
   a. Rinse 1: Fill a basin with two gallons of water (preferably sterile water). Place the endoscope into the basin and thoroughly rinse the exterior of the scope. Attach channel irrigators/adapters to the endoscope and flush with 500 ml of water through the channel irrigator. Empty basin.
   b. Rinse 2: Fill a basin with two gallons of water (preferably sterile water). Place the endoscope into the basin and thoroughly rinse the exterior of the scope and flush with 500 ml of water through the channel irrigator.
   c. Purge all channels with air.
   d. Flush all channels with 70% alcohol until the alcohol can be seen exiting the opposite end of each channel.
   e. Purge all channels with air.
   f. Remove all adapters and devices.

6. **Storage**
   a. Dry the exterior of the endoscope with a soft (prefe
      DO NOT attach detachable parts to the endoscope
      Storage of endoscopes with the removable parts d
      risk of trapping liquid inside the instrument and fa
      drying of the channels and channel openings. To p
      waterborne organisms, the endoscope and all deta
      thoroughly dried prior to storage.
   b. Hang the endoscope vertically with the distal tip h
      ventilated, dust-free cabinet.

REFERENCES:

1. ASTM F 1518-94, Standard for Cleaning and Disinfection of Flexible Fiberoptic an
   the Examination of the Hollow Viscera, Current edition approved May 15, 1994, Pu
2. Martin, M.A., MD, Reichelderfer, M., APIC guideline for infection prevention and c
   Association for Professionals in Infection Control and Epidemiology, Inc., AJIC, A
   Control, 1994; 22: 19-38
3. Vesley, D. et al., Significant factors in the disinfection and sterilization of flexible
   Journal of Infection Control, December 1992, pg. 297
4. Axon, A.T.R., Bond, B., Botwill, P.M., Cowen, A.E., Fleisher, D.E. and Tandon, R.K.,
   disinfection, Working Party Reports, Blackwell Scientific Publications, 1990, 46 S

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ULTRASOUND TRANSDUCER REPROCESSING
(Endocavity, Endovaginal, Endorectal, Transesophageal, etc)

(Refer to the device manufacturer's instruction for specific procedures)

A. **INTENDED USE/DIRECTIONS FOR USE**

OmniCide activated dialdehyde solution is a liquid chemical sterilant, high level disinfectant and intermediate level disinfectant for ultrasound transducers when used according to the **DIRECTIONS FOR USE.**

1. **Germicide Level of Activity: OmniCide** can be used at the following levels of activity:

   Sterilant: OmniCide is a sterilant for ultrasound transducers when used or reused according to the **DIRECTIONS FOR USE,** at or above its Minimum Effective Concentration (MEC) as determined by the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip at **68°F(20°) with an immersion time of ten hours** for a use period not to exceed 28 days.

   High Level Disinfectant: OmniCide is a high level disinfectant for ultrasound transducers when used or reused, according to the **DIRECTIONS FOR USE,** at or above its Minimum Effective Concentration (MEC) as determined by **ProChek G** Glutaraldehyde Concentration Test Strip at **68°F(20°) with an immersion time of 45 minutes** according to the **DIRECTIONS FOR USE** in **SECTION E** for a use period not to exceed 28 days.

   Intermediate Level Disinfectant: OmniCide is an intermediate level disinfectant when used or reused according to the **DIRECTIONS FOR USE,** at or above its Minimum Effective Concentration (MEC) as determined by the **ProChek G** Glutaraldehyde Concentration Indicator Strip at **68°F(20°C) with an immersion time of 10 minutes** according to the **DIRECTIONS FOR USE** in **SECTION E** for a use period not to exceed 28 days

B. GENERAL PROCEDURE FOR HIGH LEVEL DISINFECTION OF ULTRASOUND TRANSDUCERS (Endocavity, Endovaginal, Endorectal, Transesophageal, etc.)

(Refer to the device manufacturer's instruction for specific procedures)

1. Trained Personnel

   a. Personnel involved in the reprocessing of ultrasound transducers should have the ability to read, understand, and implement instructions from manufacturers and regulatory agencies as they relate to transducer disinfection.

   b. The person(s) to whom the job of reprocessing ultrasound transducers is given should have the opportunity to become completely familiar with the mechanical aspects of the ultrasound equipment.

   c. Training should include familiarization with OSHA regulations and in-house policies on how to appropriately and safely handle liquid chemical germicides.

   d. Training should also include information on the safe handling of instruments that are contaminated with body fluids after use. This should include familiarization with universal precautions.

2. **Cleaning of Transducers**

   Cleaning of transducers and accessories should be performed promptly after patient use to prevent drying of secretions.

   a. Personnel should donne all personnel protective equipment.

   b. Prepare an enzyme detergent (e.g., Pro EZ) or one recommended by the transducer manufacturer.

   c. Gently wipe all debris from transducer surfaces with a moistened gauze or the like.

   d. Immerse the distal end of the transducer into the water and enzyme detergent solution for 2-5 minutes or as recommended by the device manufacturer.

      NOTE: Refer to manufacturer's instructions for recommended immersion depth.

   e. Rinse all surfaces with water and dry by wiping with a soft clean cloth.

3. **Manual Disinfection**

   Caution: OmniCide may discolor the exterior of some transducers, however, the acoustic or scanning performance is not impaired. Check with the device manufacturer for specific recommendations before proceeding.

   a. Activate the **OmniCide** long life activated dialdehyde by adding the entire content of the Activator bottle which is attached to the **OmniCide** solution container. Recap the container and shake well. On activation, the solution immediately changes color to blue, thereby indicating the solution is ready. Use **ProChek G** Glutaraldehyde Concentration Indicator Test Strips after activation to determine that the solution is above the Minimum Effective Concentration (MEC) before use.

      Test the activated **OmniCide** solution using the **ProC** Glutaraldehyde Concentration Indicator at **68°F(20°** each use.

   b. Pour the activated **OmniCide** into an appropriate siz

   c. Immerse the distal end of the transducer into the Om

      Note: Refer to manufacturer's instructions for recon immersion depth

   d. Cover the disinfectant soaking basin to minimize ch vapor exposure.

   e. Soak the transducer for 45 minutes. Use a timer to adequate soaking time.

4. **Rinse After Manual Disinfection**

   a. Rinse 1: Fill a basin with a minimum of 1 gallon of (preferably sterile water). Place the transducer into recommended depth and allow to soak for 5 minute transducer.

   b. Rinse 2: Holding the transducer over the basin, flush water (preferably sterile water) for one minute

   c. Dry the transducer by wiping with a soft (preferably

5. **Storage**

   Refer to manufacturer's recommendation.

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Under the Federal I... Fungicide, and Rode... as amended, for the pesti... registered under EPA Reg. No. 46851-2

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