PM 31 46851-1

OmniCide™ NS

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. 46851-4
E.P.A. Establishment No. 37265-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 Gallon (3.785 liters)
Reorder No. OM128/NS

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

ACCEPTED
199
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 46851-1

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.

H816OM12BNS09

NFPA HAZARDOUS CHEMICAL CHART

Health Hazard ☑ Irritant ☐ Carcinogen ☐ Toxic ☑ Sensitizer ☐ Normal Material	**Fire Hazard** ☐ Below 73° ☐ Below 100°F ☐ Above 100°F, Not Exceeding 200°F ☐ Above 200°F ☑ Will Not Burn
Physical Hazard ☐ Oxidizer ☐ Acid ☐ Alkali ☐ Corrosive ☐ Use No Water ☐ Radioactive	**Reactivity** ☐ May Detonate ☐ Shock and Heat May Detonate ☐ Violent Chemical Change ☐ Unstable If Heated ☑ Stable

Product Name: **OmniCide 14 N.S.**

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*

OMP128/UL Rev. (A)

DIRECTIONS FOR USE

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

Activation: Activate the OmniCide NS solution by adding the entire contents of the Activator bottle (which is attached to the OmniCide NS solution container) to the container. Place cap on container and shake well. On activation the solution immediately changes color to green, 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 NS solution. Cleanse and rinse the lumens of hollow instruments before filling with OmniCide NS solution. Refer to the reusable device manufacturers labeling for instructions on disassembly, cleaning and leak testing of their equipment. *See package insert for additional cleaning/decontamination instructions.*

Sterilization: Immerse medical equipment/devices completely in OmniCide NS 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. *See package insert for complete instructions/information on sterilization.*

High-Level Disinfection: Immerse medical equipment/devices completely in OmniCide NS 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 with sterile water or potable water. The quality of rinse water used is dependent upon the intended use of the instrument/equipment. *See package insert for complete instructions/information on high level disinfection.*

Intermediate Level Disinfection: Immerse medical instruments/equipment completely in OmniCide NS for a minimum of **10 minutes at 68°F (20°C)** to destroy vegetative bacteria and representative viruses. **A nine minute immersion at 68°F (20°C)** will destroy **99.97%** of *Mycobacterium* strains (Quantitative TB Method) as represented by *M. bovis*. **A twelve minute Immersion at 68°F (20°C)** will destroy **99.98%** of *Mycobacterium* strains (Quantitative TB Method) as represented by *M. bovis*. *See package insert for complete instructions/information on intermediate level disinfection.*

Refer to package insert for more detailed usage/product data.

Note Dates Here.	
Activation Date	Expiration Date For Activated Solution

Check solution upon activation and prior to each use with ProCheck G *Glutaraldehyde Concentration Indicators. This product must be discarded after 14 days even if the* ProCheck G *Glutaraldehyde Concentration Indicator indicates pass.*

Control Number and Expiration Date for Unactivated Solution on Shoulder

OmniCide™ NS

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 NS 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 NS** can be used at the following germicide levels of activity:

   Sterilant: OmniCide NS 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 14 days.

   High Level Disinfectant: OmniCide NS 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 14 days.

   Intermediate Level Disinfectant: OmniCide NS 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 14 days.

   A ten minute immersion at 68°F (20°C) will destroy vegetative bacteria including *S. aureus, P. aeruginosa, E. coli*, representative viruses. **A nine minute immersion at 68°F (20°C)** will destroy 99.97% of *Mycobacterium* strains (Quantitative TB Method) as represented by *M. bovis*., **A twelve minute immersion at 68°F (20°C)** will destroy 99.98% of *Mycobacterium strains* (Quantitative TB Method) as represented by *M. bovis*.

2. **Reuse Period: OmniCide NS** has demonstrated efficacy in the presence of 5 percent organic soil contamination and a simulated amount of microbiological burden during reuse. **OMNICIDE NS 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 PROCHEK G DIRECTIONS FOR USE.** Efficacy of **OmniCide NS** 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 after 14 days, even if the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip indicates pass.

3. **General Information:** Choose a germicide with the level of microbial activity that is appropriate for the reusable medical device or equipment surface. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following guidance:

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

   - **A critical device** routinely penetrates the skin or mucous membranes during use or are otherwise used in normally sterile tissues of the body
   - **A semi-critical device** makes contact with mucous membranes but does not ordinarily penetrate sterile areas of the body
   - **A non-critical device** contacts only intact skin during routine use

   Second, determine if sterilization, high level or intermediate level disinfection is required.

   Critical device:
   Sterilization is required.

   Semi-critical device:
   Although sterilization is recommended whenever practical, high level disinfection is acceptable (e.g., GI endoscopes, anesthesia equipment to be used in the airway, diaphragm fitting rings, etc.)

   Non-critical device:
   Medical Equipment Surfaces: Intermediate level disinfection is recommended.

   Third, determine the time required to achieve the level of disinfection or sterilization required for the specified medical device.

4. The germicidal activity of **OmniCide NS** was demonstrated using stressed solutions* in performance, clinical and simulated use testing using the following organisms:

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Organisms • OmniCide NS 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† – 10 minutes
- *Herpes simplex*
- *HIV-1 (AIDS virus)*

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

5. **Material Compatibility:** **OmniCide NS** 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 NS** 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 NS** solution by altering its pH.

B. CONTRAINDICATIONS

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

   OmniCide NS solution should not be used for sterilization of critical devices intended for single use (e.g., catheters).
2. **High Level Disinfectant Usage: OmniCide NS** solution should not be used to high level disinfect a semi-critical device when sterilization is practical.
3. **Endoscope Usage: OmniCide NS** 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 NS 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 NS** 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 liquid-proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices and equipment.

   More detailed information regarding the handling of the products along with compatible materials is included in the MSDS sheet available from Cottrell, Ltd.
2. Contaminated, reusable devices **MUST BE THOROUGHLY CLEANED** prior to disinfection or sterilization, since residual contamination will decrease effectiveness of the germicide.
3. The user **MUST** adhere to the **DIRECTIONS FOR USE** since 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 **OmniCide NS** solution.
5. The use of **OmniCide NS** 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 replacing with fresh **OmniCide NS** solution. Use **ProChek G** Glutaraldehyde Concentration Indicator Test Strips to monitor glutaraldehyde concentration before each cycle to detect unexpected dilution.

E. DIRECTIONS FOR USE

1. **Activation**

   Activate the **OmniCide NS** solution by adding the entire contents of the Activator bottle (which is attached to the **OmniCide NS** solution container) to the container. Place cap on container and shake well. On activation, the solution immediately changes color to green, thereby indicating solution is ready to use. The solution should then be immediately tested with the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip upon activation and prior to each use to assure glutaraldehyde concentration is above the MEC. **OmniCide NS** 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 the expiration date on the **OmniCide NS** solution container label in the space provided, as well as in a log book or a label affixed to any secondary container used for the activated solution. **OmniCide NS** must be discarded after 14 days, even if the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip indicates pass.

2. **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 NS** solution. Cleanse and rinse the lumens of hollow instruments before filling with **OmniCide NS** solution. Refer to the reusable device manufacturer's labeling for instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

3. **Usage**

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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 NS** 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.

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 NS** 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 NS 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** for a use period not to exceed 14 days.

A ten minute immersion at 68°F (20°C) will destroy vegetative bacteria including *S. aureus, P. aeruginosa, E. coli*, representative viruses.

A nine minute immersion at 68°F (20°C) will destroy 99.97% of *Mycobacterium* strains (Quantitative TB Method) as represented by *M. bovis*

A twelve minute immersion at 68°F (20°C) will destroy 99.98% of *Mycobacterium* strains (Quantitative TB Method) as represented by *M. bovis*

4. **Rinsing Instructions**

Following immersion in **OmniCide NS** 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 NS** 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 organisms present as a result of rinsing with potable water.

F. **REUSE**

OmniCide NS solution has demonstrated efficacy in the presence of 5 percent organic soil contamination and a simulated amount of microbiological burden during reuse. The glutaraldehyde concentration of this product during its use-life must be verified by the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip to determine the solution is above the Minimum Effective Concentration (MEC) as determined by the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip is present. This solution may be used and reused within the limitations indicated above for up to 14 days after activation. **OmniCide NS** must be discarded after 14 days, even if the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip indicates pass.

G. **MONITORING OF GERMICIDE TO ENSURE SPECIFICATIONS ARE MET**

It is recommended that the **OmniCide NS** solution be tested with the **ProChek G** Glutaraldehyde Concentration Indicator Test Strip prior to each usage. This is to insure that the appropriate concentration of glutaraldehyde is present and to guard against a dilution which may lower the concentration of the glutaraldehyde below its MEC. During the use of **OmniCide NS** as a high level disinfectant and/or sterilant, it is also highly recommended that a thermometer and timer be used to ensure that optimum conditions are met. The pH of the activated solution may be periodically checked to verify that the pH of the solution is between 8.0 and 9.0.

H. **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 contamination. Refer to reusable device equipment manufacturer's labeling for additional storage and/or handling instructions.

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I. STORAGE CONDITIONS AND EXPIRATION DATE

1. Prior to activation, **OmniCide NS** solution should be stored in its original sealed container at controlled room temperature 59°-86°F (15°-30°C)
2. The expiration date of the unactivated **OmniCide NS** solution and activator will be found on the side of the immediate container
3. The use period for activated **OmniCide NS** is no longer than 14 days following activation or as indicated by **ProChek G** Glutaraldehyde Concentration Indicator Test Strip. Once activated, the solution requires no further dilution prior to its usage

J. SAFETY INFORMATION

Emergency, safety, or technical information about **OmniCide NS** 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 NS** solution can be obtained from Cottrell, Ltd. at 1-800-843-3343, or by contacting your Cottrell, Ltd. representative.

L. DISPOSAL INFORMATION

3.785 L (1 gallon) size container must be triple rinsed and disposed of according to Federal, State or local regulations.

M. REORDER INFORMATION

Reorder	Description	Case Contains
OM128/NS	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 NS activated dialdehyde solution 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 NS** 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 NS is a sterilant 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 ten hours** for a use period not to exceed 14 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 NS 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 use period not to exceed 14 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 manufacturers 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 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 Flexible Endoscopes**

   a. **Cleaning at the Examination Room**

   Reflux of body fluids from the patient may occur in any of the standard channels. Cleaning of endoscopes and accessories should be performed promptly after removing the endoscope from the patient to prevent drying of secretions.

   1. Personnel should donne all personnel protective equipment.
   2. Prepare an enzyme detergent (e.g., **ProEZ**) or one recommended by the scope manufacturer
   3. Gently wipe all debris from the insertion tube with a moistened gauze or the like.
   4. Place the distal end of the flexible endoscope into the water and enzyme detergent solution and aspirate through the biopsy/suction channel for 5-10 seconds or until the solution is visibly clean. Alternate aspiration of the detergent solution and air several times. Finish by suctioning air.
   5. Flush or blow out air and water channels in accordance with the 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 electrical portions of the umbilicus.
   2. Before proceeding with any further cleaning steps, the flexible endoscope should be leak tested. (Refer to manufacturer's leakage test

instructions). Follow the manufacturer's instructions if the instrument appears damaged.

3. Fill a sink or basin with a freshly made enzyme (e.g., **ProEZ**) detergent solution.
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 NS** disinfectant used in subsequent steps.

4. **Manual Disinfection**

a. Activate the **OmniCide NS** solution by adding the entire content of the Activator bottle which is attached to the **OmniCide NS** solution container. Recap the container and shake well. On activation, the solution immediately changes color to green, 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 NS** 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 NS** into an appropriate sized basin.
d. Completely immerse the endoscope in the basin of **OmniCide NS**. **Note:** in order to prevent damage to the endoscope, **DO NOT** soak any other accessory equipment with the endoscope.
e. Inject the **OmniCide NS** 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 (preferably sterile) cloth. **DO NOT** attach detachable parts to the endoscope prior to storage. Storage of endoscopes with the removable parts detached lowers the risk of trapping liquid inside the instrument and facilitates continued drying of the channels and channel openings. To prevent the growth of waterborne organisms, the endoscope and all detached parts should be thoroughly dried prior to storage.
b. Hang the endoscope vertically with the distal tip hanging freely in a well ventilated, dust-free cabinet.

REFERENCES:

1. ASTM F 1518-94, Standard for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera. Current edition approved May 15, 1994. Published July 1994.
2. Martin, M.A., MD, Reichelderfer, M., APIC guideline for infection prevention and control in flexible endoscopy. Association for Professionals in Infection Control and Epidemiology, Inc., AJIC: American Journal of Infection Control, 1994; 22: 19-38.
3. Vesley, D. et al., Significant factors in the disinfection and sterilization of flexible endoscopes. AJIC: American Journal of Infection Control, December 1992, pg. 292.
4. Axon, A.T.R., Bond, B., Bottrill, P.M., Cowen, A.E., Flesher, D.E. and Tandon, R.K., Endoscope disinfection: Working Party Reports. Blackwell Scientific Publications, 1990, 46-50.

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

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

INTENDED USE/DIRECTIONS FOR USE

OmniCide NS 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 NS** can be used at the following levels of activity.

   Sterilant: OmniCide NS 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°C) with an immersion time of ten hours** for a use period not to exceed 14 days

   High Level Disinfectant: OmniCide NS 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°C) with an immersion time of 45 minutes** according to the instructions for use in **SECTION E** for a use period not to exceed 14 days

   Intermediate Level Disinfectant: OmniCide NS 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 **INSTRUCTIONS FOR USE** in **SECTION E** for a use period not to exceed 14 days.

   A ten minute immersion at 68°F (20°C) will destroy vegetative bacteria including *S. aureus, P. aeruginosa, E. coli* representative viruses **A nine minute immersion at 68°F (20°C)** will destroy 99.97% of *Mycobacterium* strains (Quantitative TB Method) as represented by *M. bovis*. **A twelve minute immersion at 68°F (20°C)** will destroy 99.98% of *Mycobacterium strains* (Quantitative TB Method) as represented by *M. bovis*.

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 manufacturer's 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., **ProEZ**) 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 NS 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 NS** solution by adding the entire content of the Activator bottle which is attached to the **OmniCide NS** solution container. Recap the container and shake well. On activation, the solution immediately changes color to green, 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 NS** solution using the **ProChek G** Glutaraldehyde Concentration Indicator at **68°F (20°C),** before each use.

   b. Pour the activated **OmniCide NS** into an appropriate sized basin

   c. Immerse the distal end of the transducer into the **OmniCide NS** solution

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

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

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

6. **Rinse After Manual Disinfection**

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

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

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

7. **Storage**

   Refer to manufacturer's recommendation