

VISIBLE WITH LABEL CLOSED



STATE OF HAWAII  
Department of Agriculture

**ACCEPTED**

LICENSE NO. 9591.68

**MetriCide OPA Plus**  
ortho-Phthalaldehyde Solution  
high level disinfectant for semi-critical medical devices

**INDICATIONS FOR USE**  
MetriCide OPA Plus Solution is a high level disinfectant for reprocessing heat sensitive semi-critical medical devices for which sterilization is not suitable, and when used according to the Directions for Use. MetriCide OPA Plus may be used or reused at or above its Minimum Recommended Concentration (MRC) of 0.2%, as determined by MetriCide OPA Plus Test Strips, in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20°C (68°F), for a reuse period not to exceed 14 days. MetriCide OPA Plus Solution may also be used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 22°C) at or above its Minimum Recommended Concentration (MRC), as determined by MetriCide OPA Plus Test Strips, with an immersion time of at least 5 minutes at a minimum of 25°C (77°F), for a reuse period not to exceed 14 days.

**DIRECTIONS FOR USE**  
Does not require activation before use.  
The user should be adequately trained in the decontamination and disinfection of semi-critical medical devices and the handling of liquid chemical germicides. Additional information about MetriCide OPA Plus Solution can be obtained by contacting your local Metrex sales representative.  
**Cleaning/Decontamination:** Refer to detailed instructions for use found in the following pages.  
**Chemical Indicator:** Always use MetriCide OPA Plus Test Strips to monitor the concentration of ortho-phthalaldehyde (MRC 0.2%) before each use.  
**High Level Disinfection Manual Processing:** High Level Disinfectant at a minimum of 20°C (68°F). Immerse device completely, filling all lumens and admitting air pockets, in MetriCide OPA Plus Solution for a minimum of 12 minutes at 20°C (68°F) or higher to destroy all pathogenic microorganisms. For additional information, refer to detailed instructions for use found in the following pages of this label.  
**Automatic Endoscope Reprocessors (AER)** that can be set to a minimum of 25°C: High Level Disinfectant at a minimum of 25°C (77°F). For use in a legally marketed AER (that can be set to a minimum of 25°C) with a minimum immersion time of 5 minutes. As with all high level disinfectants, it is critical that temperature is monitored when using MetriCide OPA Plus Solution in an AER. For additional information, refer to detailed instructions for use found in the following pages of this label.  
MetriCide OPA Plus Solution can be used for 14 days provided the required conditions for use (storage conditions, concentration of ortho-phthalaldehyde (MRC 0.2%)) are based on monitoring with MetriCide OPA Plus Test Strips.  
For technical information and/or information regarding safety and effectiveness, call (800) 841-1428.  
\*If your AER cannot be set to a minimum of 25°C please follow the time and temperature stated in Indicators for Use for Manual Processing found in the following pages.

**STATEMENT OF PRACTICAL TREATMENT**  
In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eye contact, seek immediate medical attention. In case of adverse reactions from inhalation of vapor, move to fresh air. If breathing is difficult, oxygen may be given by qualified personnel. If symptoms persist, seek medical attention. If swallowed, do not induce vomiting. Drink large quantities of water and call a physician or poison control center immediately. Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

**STORAGE AND DISPOSAL**  
Store original sealed containers at a controlled room temperature of 15 - 30°C (59 - 86°F).  
Solution Disposal: Discard residual and used solution in accordance with federal, state and local regulations.  
Container Disposal: Do not reuse empty containers. Dispose per hospital policy.  
Refer to the following pages of this label for material compatibility information and more detailed usage/product data.

**PRECAUTIONS**  
Rinse devices thoroughly following disinfection or sterilization to remove toxic residues. Contact with MetriCide OPA Plus Solution may stain clothing or environmental surfaces. Wear eye protection, fluid-resistant gowns or aprons, and gloves when handling or pouring. Do not reuse beyond 14 days or sooner as indicated by MetriCide OPA Plus Solution Test Strips.

**WARNINGS**  
Avoid contact with eyes, skin or clothing. Direct contact with eyes may cause irritation. Direct contact with skin may cause temporary stinging. Repeated contact with skin may cause skin sensitization. Wear eye protection, fluid-resistant gowns or aprons, and gloves when handling or pouring. Avoid contamination of food, avoid exposure to vapors as they may be irritating to the respiratory tract and eyes, and may cause stinging sensation in the nose and throat, discharge, coughing, chest discomfort and lightness, difficulty breathing, or headache. Vapors may aggravate pre-existing asthma or bronchitis condition. Use in well-ventilated areas. Between uses, keep in closed containers with tight-fitting lids.  
For contraindications and adverse reactions refer to the information found on the following pages.

Active ingredient	0.20%
ortho-phthalaldehyde	99.80%
Inert ingredients	100.00%
Total	100.00%

Does not require activation before use.

**EMERGENCY INFORMATION**  
For chemical emergencies ONLY, call CHEMTREC at 1-800-424-9300.  
For product or technical information, contact Metrex at 800-841-1428 or visit our web site www.metrex.com.

Marketed by: METREX RESEARCH, 1717 West Collins Avenue, Orange CA 92667

Reorder No. 10-6000 70-6001-3

\*+H9711060001/\*

**MetriCide**  
**OPA Plus**  
ortho-Phthalaldehyde Solution  
high level disinfectant for semi-critical medical devices

SPORICIDAL • FUNGICIDAL • BACTERICIDAL • VIRUCIDAL • TUBERCULOCIDAL • PSEUDOMONICIDAL

Date opened: \_\_\_\_\_  
Expiration date for opened solution (75 days after date above): \_\_\_\_\_

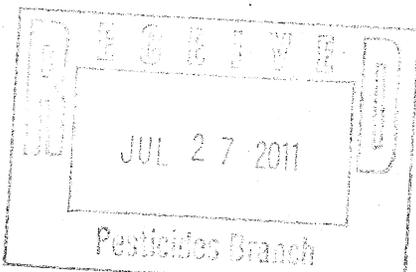
KEEP OUT OF REACH OF CHILDREN  
**DANGER!** See attached labeling information for additional precautionary statements.

NET CONTENTS  
1 U.S. GALLON (3.785 L)

**Metrex**  
Protecting People

↑  
FLAP

↑  
base



Star instruction  
use here.

Reseal Area

**METRICIDE OPA PLUS (ortho-Phthalaldehyde Solution)**  
high level disinfectant for semi-critical medical devices

**INSTRUCTIONS FOR USE**

**Indications for Use:** Metricide OPA Plus Solution is a high level disinfectant for reprocessing heat sensitive semi-critical medical devices for which sterilization is not suitable, and when used according to the Directions for Use. Metricide OPA Plus may be used or reused at or above its Minimum Recommended Concentration (MRC) of 0.3%, as determined by Metricide OPA Plus Test Strips, in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20°C (68°F), for a reuse period not to exceed 14 days. Metricide OPA Plus may also be used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 25°C) at or above its Minimum Recommended Concentration (MRC), as determined by Metricide OPA Plus Test Strips, with an immersion time of at least 5 minutes at a minimum of 25°C (77°F), for a reuse period not to exceed 14 days.

Metricide OPA Plus Solution is intended for use in manual (bucket and tray) systems made from polypropylene, polyethylene, acrylonitrile butadiene styrene (ABS), glass-filled polypropylene and/or polycarbonate plastics. Metricide OPA Plus Solution may also be used in automated endoscope reprocessors according to the manufacturer's instructions and should be monitored with Metricide OPA Plus Test Strips. See DIRECTIONS FOR USE - Reusage for Disinfection.

The semi-critical medical devices reprocessed in Metricide OPA Plus Solution must first be cleaned according to a validated cleaning protocol or standard, such as the ASTM F 1518 US Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera.

**Manual Processing:** High Level Disinfectant at a minimum of 20°C (68°F). Metricide OPA Plus Solution is a high level disinfectant when used or reused, according to the Directions for Use, at or above its Minimum Recommended Concentration (MRC) as determined by Metricide OPA Plus Test Strips, with an immersion time of at least 12 minutes for a reuse period not to exceed 14 days. Remove the device from the solution and rinse thoroughly with sterile water or potable tap water. Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water, at least 5 liters each, to remove Metricide OPA Plus Solution residues. Residues may cause serious side effects. SEE WARNINGS, THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED. THE VOLUME OF WATER USED IN EACH RINSE CYCLE SHOULD BE AT LEAST 9 LITERS. The type

of rinse water used is dependent upon the intended use of the device.

Automatic Endoscope Reprocessors that can be set to a minimum of 25°C; High Level Disinfectant at a minimum of 25°C (77°F). Metricide OPA Plus Solution is a high level disinfectant when used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 25°C) according to the Directions for Use, at or above its Minimum Recommended Concentration (MRC) as determined by Metricide OPA Plus Test Strips, with an immersion time of at least 5 minutes for a reuse period not to exceed 14 days.

**Note:** If your AER cannot be set to a minimum of 25°C please follow the time and temperature stated in Indications for Use for Manual Processing. Minimum Recommended Concentration (MRC): 0.3%.

**Reuse Period for Disinfection:** Metricide OPA Plus Solution has demonstrated disinfection efficacy in the presence of 5% organic soil contamination and microbiological burden during reuse. Metricide OPA Plus Solution may be reused for up to a maximum of 14 days, provided the required conditions of ortho-phthalaldehyde concentration and temperature exist based upon monitoring described in the Directions for Use. DO NOT rely solely on days in use. Concentration of this product during its reuse life must be verified by the Metricide OPA Plus Test Strip prior to each use to determine that the concentration of ortho-phthalaldehyde is above the MRC of 0.3%. The product must be discarded after 14 days, even if the Metricide OPA Plus Test Strip indicates a concentration above the MRC.

**General Information on Selection and Use of Germicides for Medical Device Reprocessing:** Choose a germicide with the level of antimicrobial activity that is appropriate for the reusable device. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following process:

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

**Critical device:** Presents a high risk of infection if not sterile. Routinely penetrates the skin or mucous membranes during use or are otherwise used in normally sterile tissue of the body.

**Semi-critical device:** Makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body.

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

**Critical device (e.g., cardiac catheters, scalpels, surgical instruments):** Sterilization is required.

Hinge Area

BASE LABEL

<p>Semi-critical reusable device (e.g., endoscopes): Sterilization is required whenever feasible; where not feasible, high level disinfection is the minimum acceptable process.</p> <p>Third, select a germicide that is labeled for the appropriate germicidal level and is compatible with the reusable device. Follow directions for the germicide.</p> <p>Microbicidal Activity: The following table indicates the spectrum of activity as demonstrated by testing of MetriCide OPA Plus Solution using prescribed test methods.</p> <p><b>MICROORGANISM</b></p> <p><b>VEGETATIVE ORGANISMS</b></p> <p><i>Staphylococcus aureus</i>  <i>Salmonella choleraesuis</i>  <i>Pseudomonas aeruginosa</i>  <i>Mycobacterium bovis</i></p> <p><b>FUNGI</b></p> <p><i>Trichophyton mentagrophytes</i></p> <p><b>VIRUSES</b></p> <p><b>NON-ENVELOPED</b></p> <p>Poliiovirus Type 1  Rhinovirus Type 42  Hepatitis A (AER)</p> <p><b>ENVELOPED</b></p> <p>Influenza virus Type A [Hong Kong]  HM-1  Herpes simplex Type 1  Duck Hepatitis B  Avian Influenza A</p> <p>To qualify MetriCide OPA Plus Solution as a high level disinfectant, the reused solution passed the AOAC Sporidical Activity Test in 32 hours at 20°C and in 32 hours at 25°C.</p> <p><b>Material Compatibility:</b> MetriCide OPA Plus Solution has been tested and found to be compatible with the materials shown below. Materials were exposed to 91 days (744 hours) of continuous contact with MetriCide OPA Plus Solution with no effect unless otherwise noted.</p> <p><b>METALS</b></p> <p>Chrome plated steel  Anodized aluminum  Brass  Carbon steel</p>	<p>Chrome plated brass</p> <p><b>PLASTICS</b></p> <p>Polymethacrylate (Acrylic)  Nylon  Polyethylene terephthalate (Polyester)  Polystyrene  Polyvinylchloride (PVC)  Acrylonitrile/butadiene/styrene (ABS)  Polyamide</p> <p><b>ELASTOMERS</b></p> <p>Polychloroprene (Neoprene)  Kraton G<sup>®</sup>  Polyurethane  Silicone rubber  Natural rubber latex</p> <p><b>ADHESIVES</b></p> <p>EPO-TEK 301 Epoxy<sup>®</sup>  EPO-TEK 353ND Epoxy</p> <p><sup>1</sup>Shows signs of surface discoloration.  <sup>2</sup>Stainless steel 304 showed slight discoloration and some corrosion.  <sup>3</sup>Shows degradation and discoloration.</p> <p>Olympus and Pirtax endoscopes are compatible with MetriCide OPA Plus Solution. Use MetriCide OPA Plus Solution only in AER's that have been validated for use with OPA-based disinfectants.</p> <p>If questions arise regarding the compatibility of a device with MetriCide OPA Plus Solution, contact the device manufacturer.</p> <p><b>Cleaning Agent Compatibility:</b> MetriCide OPA Plus Solution is compatible with enzymatic detergents that are mild in pH, low foaming, and easily rinsed from equipment (e.g., such as Empower<sup>®</sup> Dual Enzymatic Detergent). Detergents that are either highly acidic or alkaline are not recommended as cleaning agents.</p> <p><b>CONTRAINDICATIONS</b></p> <p>1. MetriCide OPA Plus Solution should not be utilized to process any urological instrumentation used to treat patients with a history of bladder cancer.</p> <p>In rare instances, solutions containing ortho-Phthalaldehyde have been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.</p> <p>2. MetriCide OPA Plus Solution should not be utilized to process</p>	<p>Tungsten carbide<sup>1</sup></p> <p>Polysiloxane  Polycarbonate  Polystyrene  Polypropylene  Acetal  PTFE</p>
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instrumentation for patients with known sensitivity to MetriCide OPA Plus Solution or any of its components.

3. MetriCide OPA Plus Solution should not be used to sterilize heat sensitive medical devices. When sterilization by a biologically monitorable process is not feasible, high level disinfection of rigid endoscopes is recommended by the Centers for Disease Control and Prevention (CDC) and the Association for Professionals in Infection Control and Epidemiology (APIC).

#### ADVERSE REACTIONS

Adverse events associated with exposure to and use of MetriCide OPA Plus include, but may not be limited to skin irritation, eye irritation, allergic reaction/angioedema, skin sensitivity, headache, respiratory tract irritation including stinging sensation in the nose and throat, discharge, coughing, chest discomfort and lightheadedness, and difficulty breathing.

#### WARNINGS

1. May elicit an allergic reaction. Possible allergic reactions have been reported in rare instances. It is important that health care workers use the product in a well-ventilated room and wear proper personal protective equipment. (See PRECAUTIONS).
2. Avoid contact with eyes, skin or clothing. (See PRECAUTIONS - for important information on how to protect eyes, skin and clothing.) Direct contact with eyes may cause irritation. Direct contact with skin may cause temporary staining. Repeated contact with skin may cause skin sensitization. In case of eye contact, immediately flush eyes with large quantities of water for at least 15 minutes. Seek medical attention. In case of skin contact, immediately wash with water. Refer to the MSDS for additional information. Do not form sprays, mists or aerosols of this product.
3. Avoid contamination of food. Ingestion may cause irritation or chemical burns of the mouth, throat, esophagus and stomach. If swallowed, DO NOT INDUCE VOMITING. Drink large quantities of water and call a physician or poison control center immediately. Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.
4. Avoid exposure to ortho-phthalaldehyde vapors, as they may be irritating to the respiratory tract and eyes. May cause stinging sensation in the nose and throat, discharge, coughing, chest discomfort and lightheadedness, difficulty breathing, wheezing, tightening of throat, urticaria (hives), rash, loss of smell, tingling of mouth or lips, dry mouth or headache. May aggravate a preexisting asthma or bronchitis condition. In case of

adverse reactions from inhalation of vapor, move to fresh air. If breathing is difficult, oxygen may be given by qualified personnel. If symptoms persist, seek medical attention.

5. The use of MetriCide OPA Plus Solution with semi-critical devices must be part of a validated rinsing procedure as provided by the device manufacturer. See DIRECTIONS FOR USE Rinsing Instructions - for important information on rinsing.

6. ALWAYS follow the Directions For Use Rinsing Instructions (Part B) and the SPECIAL INSTRUCTIONS for transesophageal echocardiography (TEE) probes in Part C EXACTLY or residues of MetriCide OPA Plus Solution may remain on the device. Failure to follow rinsing instructions exactly has resulted in reports of chemical burns, irritation, and staining of the mouth, throat, esophagus and stomach.

#### PRECAUTIONS

Follow OSHA Bloodborne Pathogens Universal Precautions when handling and cleaning soiled devices.

When disinfecting devices, use gloves of appropriate type and length, eye protection and fluid-resistant gowns. When using latex rubber gloves, the user should double glove and/or change single gloves frequently, e.g., after 12 minutes of exposure. For those individuals who are sensitive to latex or other components in latex gloves, 100% synthetic copolymer gloves, nitrile rubber gloves, or butyl rubber gloves may be used.

Note: Contact with MetriCide OPA Plus Solution may stain exposed skin or clothing.

Use MetriCide OPA Plus Solution in a well-ventilated area. Between uses, keep in closed containers with tight-fitting lids.

1. If adequate ventilation is not provided by the existing air conditioning system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices that contain filter media that absorb ortho-phthalaldehyde from the air.

2. Contaminated reusable devices MUST BE THOROUGHLY CLEANED prior to disinfection, since residual contamination with soil or lubricants will decrease the effectiveness of the germicides.

3. The user MUST adhere to the Directions for Use, as non-adherence may affect the safety and effectiveness of the germicides.

4. Do not use MetriCide OPA Plus Solution on critical medical devices that are intended for use in a sterile area of the body (e.g., cataract surgical instruments).

5. The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using MetriCide OPA Plus Solution.
6. The use of MetriCide OPA Plus Solution in automated endoscope reprocessors must be part of a validated reprocessing procedure. The contact conditions must be 25°C for 5 minutes. (See note following the Indications for Use section).
7. Use MetriCide OPA Plus Test Strips to detect ortho-phthalaldehyde concentration before each cycle to detect the MRC. Follow the Directions For Use provided with the MetriCide OPA Plus Test Strips.

**DIRECTIONS FOR USE**

**Cleaning/Decontamination:** Blood, other body fluids, and lubricants must be thoroughly cleaned from the surfaces and lumens of semi-critical medical devices before reprocessing in the disinfectant. Blood and other body fluids should be disposed of according to all applicable regulations for infectious waste disposal.

Refer to the reusable device manufacturer's labeling for instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

Before immersion in MetriCide OPA Plus Solution, thoroughly clean devices, including all lumens, using a cleaning protocol or standard, such as the ASTM F 1518 "Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera."

Thoroughly rinse and rough dry all surfaces and lumens of cleaned devices.

**Usage: NO ACTIVATION IS REQUIRED.**

Record the date the container was opened on the container label, or in a log book. After opening, the solution remaining in the container may be stored for up to 75 days (provided the 75 days does not extend past the expiration date on the container) until used.

Record the date the solution was poured out of the original container into a secondary container in a log book (separate from the one mentioned above), or on a label affixed to the secondary container. The solution in the secondary container can be used for a period up to 14 days. The product must be discarded after 14 days even if the MetriCide OPA Plus Test Strip indicates a concentration above the MRC.

A. High Level Disinfection

1. **Manual Processing:** Immerse device completely, tilting all lumens and eliminating air pockets, in MetriCide OPA Plus Solution for a minimum of 12 minutes at 20°C (68°F) or higher to destroy all pathogenic microorganisms. Remove device from the solution and rinse thoroughly following the rinsing instructions below.
2. **Automatic Endoscope Reprocessors (AER)** that can be set to a minimum of 25°C (See note following the Indications for Use section): High Level Disinfectant at a minimum of 25°C (77°F). For use in a legally marketed AER (that can be set to a minimum of 25°C) with a minimum immersion time of 5 minutes. As with all high level disinfectants, it is critical that temperature is monitored when using MetriCide OPA Plus Solution in an AER at 25°C. See section "Monitoring of Germicide."

**B. Rinsing Instructions**

**1. RINSING PROCEDURE**

**a) Manual Processing:**

- Following removal from MetriCide OPA Plus Solution, thoroughly rinse the semi-critical medical device by immersing it completely in a large volume (e.g., 9 liters) of water. Use sterile water unless potable water is acceptable. See item 2 or 3 below.
- Keep the device totally immersed for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer.
- Manually flush all lumens with large volumes (not less than 100 ml) of rinse water unless otherwise noted by the device manufacturer.
- Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
- Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water, at least 9 liters each rinse, to remove MetriCide OPA Plus Solution residues. Residues may cause serious side effects. SEE WARNINGS. THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED. THE VOLUME OF WATER USED IN EACH RINSE CYCLE SHOULD BE AT LEAST 9 LITERS.
- Refer to the reusable semi-critical medical device manufacturer's labeling for additional rinsing instructions.

**b) Automated Reprocessing:**

- Select a rinse cycle on an automatic endoscope reprocessor that has been validated for use with OPA-based disinfectants.
- Ensure that the automated rinse cycle selected will thoroughly rinse the semi-critical medical device including all lumens with large volumes of sterile or potable water equivalent to the reusable device manufacturer's recommendations.
- Verify that each rinse is a minimum of 1 minute in duration unless the reusable device manufacturer specifies a longer time. Ensure that a fresh volume of water is used for each rinse. Do not reuse the water for rinsing or any other purpose.
- Refer to the reusable device manufacturer's labeling for additional rinsing instructions.

**2. STERILE WATER RINSE:** The following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:

- Devices intended for use in normally sterile areas of the body.
- Devices intended for use in known immunocompromised patients, or potentially immunocompromised patients based on institutional procedures (e.g., high risk population served).
- When practical, bronchoscopes, due to a risk of contamination from potable water supply. Although microorganisms in this type of water system are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms.

**3. POTABLE WATER RINSE:** For all other devices, a sterile water rinse is recommended when practical. Otherwise, potable tap water rinse is acceptable.

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with microorganisms, which may be present in potable water supplies.

Water treatment systems, such as softeners or deionizers, may add microorganisms to the treated water to the extent that microbial content of the water at the point of use could exceed that of the pretreated drinking water. To ensure proper water quality, adherence to maintenance of the water treatment system(s) is recommended.

The use of a bacterial retentive (0.2 micron) filter system may eliminate or greatly reduce the amount of these waterborne bacteria from the potable water source. Contact the manufacturer of the filter or UV

system for instructions on preventative maintenance and periodic replacement of the filter to avoid colonization or formation of biofilms in the filter.

A device that is not completely dried provides an ideal situation for rapid colonization of bacteria. As these waterborne bacteria are highly resistant to drying, rapid drying will avoid possible colonization but may not result in a device free from these bacteria. A final rinse using a 70% isopropyl alcohol solution can be used to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

**C. Special Instructions for Transesophageal Echocardiography (TEE) probe reprocessing:** As with all devices, carefully follow all probe manufacturer recommendations such as use of a sterile protective sheath when performing TEE. Soaking for a minimum of 12 minutes in MetriCide OPA Plus Solution is required for high level disinfection (HLD). Excessive soaking of the probes (e.g., longer than an hour) during HLD and/or not rinsing three times with a fresh quantity of water each time as described in Part B, may result in residual MetriCide OPA Plus Solution remaining on the device, the use of which may cause staining, irritation or chemical burns of the mouth, throat, esophagus and stomach.

**D. Reuseage for Disinfection:** MetriCide OPA Plus Solution has demonstrated efficacy in the presence of organic soil contamination and microbiological burden during reuse. The ortho-phthalaldehyde concentration of MetriCide OPA Plus Solution during its use-life must be verified by the MetriCide OPA Plus Test Strips prior to each use, to determine that the MRC of 0.2% is present. MetriCide OPA Plus Solution may be used and reused within the limitations indicated above for up to a maximum of 14 days. MetriCide OPA Plus Solution must be discarded after 14 days, even if the MetriCide OPA Plus Test Strip indicates a concentration above the MRC.

**MONITORING OF GERMICIDE:** During reuse, it is recommended that the MetriCide OPA Plus Solution be tested with MetriCide OPA Plus Test Strips prior to each use. This is to ensure that the Minimum Recommended Concentration (MRC) of ortho-phthalaldehyde is present.

During the usage of MetriCide OPA Plus Solution as a high level disinfectant, it is recommended that a thermometer and timer be utilized to ensure that the optimum conditions are met.

**Monitoring Temperature in Automatic Endoscope Reprocessor that can be set to a minimum of 25°C:** As with all high level disinfectants, temperature monitoring is critical for use of MetriCide OPA Plus Solution at a minimum of 25°C for 5 minutes in an AER.

Visually inspect the solution during the reuse life for the presence of precipitates, which may result from the use of hard water. Discard solution if precipitation occurs.

**POST-PROCESSING HANDLING AND STORAGE OF REUSABLE DEVICES:**  
Disinfected reusable devices are either to be immediately used, or stored in a manner to minimize recontamination. Refer to the reusable device manufacturer's labeling for additional storage and/or handling instructions.

**STORAGE CONDITIONS AND EXPIRATION DATE**

1. MetriCide OPA Plus Solution should be stored in its original sealed container at controlled room temperature 15 - 30°C (59 - 86°F) in a well-ventilated, low-traffic area.
2. Once opened, the unused portion of the solution may be stored in the original container for up to 75 days until used.
3. The expiration date of the MetriCide OPA Plus Solution is found on the immediate container.

**EMERGENCY AND TECHNICAL PRODUCT INFORMATION**

For further hazard information please refer to the Material Safety Data Sheet. Emergency, safety, or technical information about MetriCide OPA Plus Solution can be obtained from Metrex Research at 1-800-841-1428, by contacting your local Metrex sales representative, or visit our website at [www.metrex.com](http://www.metrex.com). For chemical emergencies ONLY, call CHEMTREC at 1-800-424-9300.

**USER TRAINING**

The user should be adequately trained in the decontamination and disinfection of semi-critical medical devices and the handling of liquid chemical germicides. Additional information about MetriCide OPA Plus Solution can be obtained by contacting your local Metrex sales representative.

**SOLUTION AND CONTAINER DISPOSAL INFORMATION**

**Solution Disposal:** Discard residual and used solution in accordance with federal, state and local regulations.  
**Container Disposal:** Do not reuse empty container. Dispose per hospital policy.

**ACTIVE INGREDIENT**

ortho-Phthalaldehyde.....	0.80 %
Inert Ingredients .....	99.40 %
Water	
Dipotassium hydrogen phosphate	
Potassium dihydrogen phosphate	
Benzotriazole	
Citric acid	
D&C Green Dye #5	
N-(hydroxyethyl)-ethylenediaminetriacetic acid (HEDTA)	
Total.....	100.00 %

Does not require activation before use.

**HOW SUPPLIED**

REORDER	DESCRIPTION	CASE CONTAINERS
10-8000	MetriCide OPA Plus Solution One Gallon (3.8 l)	4 x 1 Gallons (4 x 3.8 l/case)

REORDER	DESCRIPTION	CASE CONTAINERS
10-802	MetriCide OPA Plus Solution Test Strips Concentration Indicator	100 Test Strips/bottle; 2 bottles/case

Marketed By:  
METREX RESEARCH  
1717 Weber College Avenue  
Orange, CA 92667  
1-800-841-1428

