4. The user MUST adhere to the Directions for Use since any modification will affect the safety and effectiveness of the germicide.
5. The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using McKesson OPA/28.
6. The use of McKesson OPA/28 High-Level Disinfectant in automated reprocessors must be part of a validated reprocessing procedure supplied by the automated reprocessor manufacturer to ensure a minimum contact or immersion time of 5 minutes at a minimum of 77°F (25°C).
7. Use McKesson OPA/28 Test Strips as a chemical indicator to ensure the concentration of OPA in the solution is at or above 0.35% prior to each reprocessing cycle in order to detect unexpected dilution. Follow the directions for use provided with the McKesson OPA/28 Test Strips.

STORAGE CONDITIONS AND EXPIRATION DATE

1. Store McKesson OPA/28 in its original sealed container at controlled room temperature of 59°F - 77°F (15°C - 25°C) in a well ventilated area.
2. Once opened, the unused portion of the solution may be stored in its original container for up to 75 days until used.
3. The expiration date of McKesson OPA/28 may be found on the bottle label of the immediate container. DO NOT use product from an unopened or opened bottle after the labeled expiration date.
4. The reuse period of McKesson OPA/28 should never exceed 28 days.

EMERGENCY AND TECHNICAL PRODUCT INFORMATION

For further hazard information please refer to the Material Safety Data Sheet. For technical questions about McKesson OPA/28, call 1-800-722-1529. For 24-hour emergency and safety information about McKesson OPA/28, call CHEMTREC at 1-703-527-3887 or 1-800-424-9300.

USER TRAINING AND PROFICIENCY

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. The user should be adequately trained in the decontamination and disinfection of medical devices and the handling of toxic substances such as liquid chemical germicides. Additional information about McKesson OPA/28 High-Level Disinfectant can be obtained by calling 1-800-722-1529.

DISPOSAL INFORMATION

Discard any remaining solution according to local, state and federal regulations. Glycine (free base) may be used as a neutralizer for McKesson OPA/28 Solution prior to disposal, if required. A minimum of 25 grams of glycine (free base) should be used to neutralize one gallon of solution. The minimum recommended neutralization time is one hour. Discard residual solution into drain. Flush drain thoroughly with water.

Do not reuse empty containers. Triple rinse with water and dispose of per facility policy. For 24-hour emergencies and additional information, call CHEMTREC at 1-703-527-3887 or 1-800-424-9300.

HOW SUPPLIED

McKesson OPA/28 High-Level Disinfectant
1 Gallon (3.8 L) Bottle, 4 Bottles Per Case
MFR # 73-OPA28

McKesson OPA/28 High-Level Disinfectant Test Strips
50 Strips Per Bottle, 2 Bottles Per Case
MFR # 73-OPA28B

***NOTE:** McKesson OPA/28 High-Level Disinfectant has been validated in MEDIVATORS® reprocessors to use 2 rinses, 30 seconds each.

Distributed By McKesson Medical-Surgical Inc.
Richmond, VA 23228
LI-6745-0813 50098-124/B
Made in USA

McKESSON

OPA/28

HIGH-LEVEL DISINFECTANT

KEEP OUT OF REACH OF CHILDREN

DANGER

READ DIRECTIONS FOR USE AND MSDS FOR McKESSON OPA/28. READ DEVICE MANUFACTURERS REPROCESSING INSTRUCTIONS AND AUTOMATED ENDOSCOPE REPROCESSING SYSTEM DIRECTIONS FOR USE.

MFR # **73-OPA28**

DIRECTIONS FOR USE

An *ortho*-Phthalaldehyde (OPA) Solution High-Level Disinfectant for semi-critical medical devices.

Active Ingredient
ortho-Phthalaldehyde (OPA) 0.575%

Inactive Ingredients **99.425%**
Buffers
Surfactants
Antifoaming agent
Solvent
Deionized water
Total **100.0%**

Does not require activation before use.

CONDITIONS FOR USE

Indications for Use: McKesson OPA/28 is a High-level Disinfectant solution for reprocessing of heat sensitive semi-critical medical devices for which sterilization is not suitable. McKesson OPA/28 may be used at or above the minimum recommended concentration (MRC) of 0.35% OPA as determined by McKesson OPA/28 Test Strips in manual device reprocessing with an immersion time of at least 10 minutes at a minimum temperature of 68°F (20°C) for a reuse period not to exceed 28 days. McKesson OPA/28 may also be used in compatible legally marketed automatic endoscope reprocessors at or above its MRC as determined by McKesson OPA/28 Test Strips with an immersion time of at least 5 minutes at a minimum of 77°F (25°C) for a reuse period not to exceed 28 days.

Devices to be reprocessed must first be thoroughly cleaned according to device manufacturer's recommendations for decontamination. The cleaning process should follow an established cleaning protocol consistent with professional society guidelines and/or a standard such as the ASTM F1518 "Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of Hollow Viscera."

Reuse Period for Disinfection: McKesson OPA/28 may be reused according to the directions for use for up to 28 days provided that prior to each use the concentration of OPA in the solution is verified using McKesson OPA/28 Test Strips to be above the MRC of 0.35%. The test strips must be used prior to each use. DO NOT rely solely on days in use. DO NOT use beyond the 28 day reuse period or the labeled expiration date even if the concentration is above the MRC. Maintain the solution at room temperature during the 28-day reuse period. This product must be discarded after 28 days, even if the test strips indicate a concentration above the 0.35% OPA.

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

a) For patient contact devices, determine whether the reusable device to be reprocessed is a critical or a semi-critical device.
   - A critical device presents a high risk of infection if not sterile. Critical devices routinely penetrate the mucous membranes during use or are otherwise used in normally sterile tissue of the body.
   - A semi-critical device makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body.

b) Determine if sterilization or high-level disinfection is required.
   - Sterilization is required for **critical devices** (e.g., products that enter sterile tissue or the vascular system, such as laparoscopes, and microsurgical instruments).
   - For **semi-critical devices** sterilization is recommended whenever feasible, otherwise high-level disinfection is the minimum acceptable process.

c) Select a germicide that is labeled for the appropriate disinfection level and is compatible with the reusable device. Follow directions for that germicide.

DIRECTIONS FOR USE

A. <u>Cleaning/Decontamination:</u> 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. Follow OSHA Bloodborne Pathogens Universal Precautions when handling and cleaning soiled devices. 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 McKesson OPA/28 Solution thoroughly clean devices, including all lumens, using an established cleaning protocol consistent with professional society guidelines and/or a standard such as the ASTM F1518 "Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera." Thoroughly rinse and dry all surfaces and lumens of cleaned devices.

B. <u>Preparation and Usage:</u> McKesson OPA/28 is supplied ready-to-use and does not require activation.

   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 (providing 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 or on a label affixed to the secondary container. The solution in the secondary container can be used for a period up to 28 days provided that prior to each use the concentration of *ortho*-Phthalaldehyde (OPA) in the solution is verified using McKesson OPA/28 Test Strips to be above the MRC of 0.35%. Maintain the solution at room temperature during the 28-day reuse period. This product must be discarded after 28 days, even if the test strips indicate a concentration above the 0.35% OPA.

C. <u>High-Level Disinfection Procedure</u>

   1. **Manual Reprocessing:** Place pre-cleaned medical device into compatible tray. Immerse device completely, filling all lumens, with McKesson OPA/28 Solution at or above 0.35% OPA for a minimum of 10 minutes at room temperature (minimum 68°F (20°C)). Monitor the MRC of the solution with McKesson OPA/28 Test Strips prior to each reprocessing

cycle. Remove the device from the solution and rinse thoroughly according to device manufacturer's rinsing instructions. In the absence of manufacturer's rinsing instructions, follow the rinsing instructions and procedure in section D.1.

2. **Automated Reprocessing:** Place device into a legally marketed reprocessor that can be set to a minimum of 77°F (25°C). Load the reprocessor with McKesson OPA/28 Solution and select a high-level disinfection cycle that provides for a minimum disinfectant immersion or contact time of 5 minutes at a minimum temperature of 77°F (25°C). Select an automated rinsing cycle that provides thorough rinsing equivalent to the device manufacturer's rinsing instructions and consistent with the automated processing rinsing instructions provided below.*

D. Rinsing Instructions and Procedure

1. **Manual Reprocessing**
   - Following removal from McKesson OPA/28, thoroughly rinse the semi-critical device by immersing it in a large volume of water (e.g., 8 liters). Use rinse water that is consistent with the directions provided below (see section 3).
   - Keep the device entirely submersed 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 from the water and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing for any other purpose.
   - Repeat the procedure for rinsing manual devices TWO additional times for a total of THREE (3) RINSES with large volumes of fresh water to remove McKesson OPA/28 HLD residues. Proper rinsing of devices is required, see warnings and precautions. Three (3) separate large volume water immersion rinses are required unless otherwise specified by device manufacturer's instructions.
   - Refer to the reusable medical device manufacturer's labeling for additional rinsing instructions.
2. **Automated Reprocessing**
   - Select a rinse cycle on an automatic reprocessor that has been validated for use with OPA-based disinfectants. Perform automated rinsing in accordance with the reprocessor manufacturer's instructions.
   - Ensure that the automated rinse cycle selected will thoroughly rinse the medical device including all channels with large volumes of rinse water equivalent to the device manufacturer's recommendations.
   - Each rinse should be a minimum of 1 minute in duration, unless otherwise specified by device manufacturer's instructions. Ensure that a fresh volume of rinse water that is consistent with the directions provided below is used for each rinse. Do not reuse the water for rinsing or any other purpose.
   - Refer to the reusable medical device manufacturer's labeling for additional rinsing instructions.
3. **Rinse Water**

   Sterile Water Rinse: When practical and feasible, the following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:
   - Devices that may contact 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 opportunistic microorganisms present in potable water.

Bacterial-retentive Filtered or Potable Rinse Water: When rinsing with sterile rinse water is not practical or feasible, then rinsing with bacterial-retentive (0.2 micron) filtered rinse water is recommended. If rinsing with bacterial-retentive filtered rinse water is not practical or feasible, then 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.

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.

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.

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.

E. Reusage for Disinfection: McKesson OPA/28 has demonstrated efficacy in the presence of organic soil contamination and simulated amount of microbiological burden during reuse. This ready-to-use solution may be used and reused according to the directions for use provided the concentration of OPA in solution is 0.35% or greater for 28 days. Prior to each use the concentration of OPA in the solution must be verified using McKesson OPA/28 Test Strips to be above the MRC of 0.35%. DO NOT rely solely on days in use. DO NOT use beyond the 28 day reuse period or the labeled expiration date even if the concentration is above the MRC. Maintain the solution at room temperature during the 28-day reuse period. This product must be discarded after 28 days, even if the test strips indicate a concentration above the 0.35% OPA.

F. Monitoring of Germicide: Users are directed to test the solution with McKesson OPA/28 Test Strips prior to each use throughout the entire reuse period. This is to ensure that the concentration of OPA in the solution remains above 0.35% throughout the reuse period.

During manual disinfection with McKesson OPA/28 it is recommended that a thermometer and timer be utilized to ensure that the specified use conditions are met. For automated reprocessing ensure that the automated reprocessor is capable of monitoring the cycle to ensure a contact time of 5 minutes at a minimum of 77°F (25°C) is achieved. Do not use an automated reprocessor if it cannot monitor time and temperature parameters appropriately. Refer to the reprocessor manufacturer's labeling for germicide monitoring instructions.

G. Special Instructions for Transesophageal Echocardiography (TEE) probe reprocessing: As with all devices, carefully follow all probe manufacturer recommendations. Soaking for a minimum of 10 minutes in McKesson OPA/28 Solution at a minimum of 68°F (20°C) is required for high-level disinfection. Excessive soaking of the probes during disinfection and/or not rinsing three times with a fresh quantity of water each time as described in the rinsing instructions may result in residual solution remaining on the device, the use of which may cause staining, irritation or chemical burns of the mouth, throat, esophagus and stomach.

H. 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/equipment manufacturer's labeling for additional storage and/or handling instructions.

MICROBICIDAL ACTIVITY
The following table indicates the range of activity as demonstrated by testing of McKesson OPA/28 High-Level Disinfectant using prescribed test methods.

MICROORGANISM
BACTERIAL ENDOSPORES
Bacillus subtilis
Clostridium sporogenes
VEGETATIVE ORGANISMS
Staphylococcus aureus
Salmonella choleraesuis
Pseudomonas aeruginosa
Mycobacterium terrae
Mycobacterium bovis
FUNGI
Trichophyton mentagrophytes
VIRUSES
Poliovirus Type 1
Poliovirus Type 2
Herpes Simplex Virus

MATERIAL COMPATIBILITY
McKesson OPA/28 has been tested and is found to be compatible with the materials shown below.

Metals
Stainless Steels (17-7, 302, 303, 304, 316, 430)
Galvanized Steel
Mild Steel
Inconnel
Hastelloy C
Nickel Plated Brass
Naval Brass 464
Copper
Bare Aluminum (2024, 6061)
Anodized Aluminum (2024, 6061, 1100)
Elastomers/Adhesives
Buna-N
EPDM
Viton (type HK)
Silicone rubber
Neoprene (Polychloroprene)
Nitrile Rubber
Santoprene
Epoxy
Ceramics/Adhesive
Ceramic
Devcon Adhesive
Plastics
Polyethylene
HDPE
Polypropylene
PVC (white, gray)
CPVC
Polysulfone
Polycarbonate
Acrylic
ABS
Delrin (Acetal)
Polystyrene
Nylon
Teflon (PTFE)
PCTG
PVDF

McKesson OPA/28 is compatible with the materials commonly used in the construction of medical endoscopes.

If questions arise regarding the compatibility of a device with McKesson OPA/28 Solution, contact the device manufacturer.

CLEANING AGENT COMPATIBILITY
McKesson OPA/28 is compatible with detergents which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acidic or alkaline are not recommended as cleaning agents.

CONTRAINDICATIONS
1. McKesson OPA/28 should NOT be used to reprocess any urological instrumentation to be utilized for cystoscopy or other urological procedures for patients with a history of bladder cancer. In rare instances similar *ortho*-Phthalaldehyde (OPA) based disinfectants have been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.
2. McKesson OPA/28 should NOT be used to reprocess any instrumentation for patients with known sensitivity to similar OPA disinfectant solutions.
3. McKesson OPA/28 should NOT be used to sterilize reusable heat-sensitive medical devices and should not be used to reprocess critical devices. McKesson OPA/28 should NOT be used to high-level disinfect semi-critical devices if sterilization using other available methods that can be biologically monitored is practical.

WARNINGS
DANGER: KEEP OUT OF REACH OF CHILDREN.

1. McKesson OPA/28 must be used in a well-ventilated area and in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air handling system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices which contain filter media which absorb *ortho*-Phthalaldehyde (OPA) from the air.
2. May elicit an allergic reaction. Possible allergic reactions have been reported in rare instances with similar OPA disinfectant products. Ensure that all users wear proper personal protective equipment (See PRECAUTIONS) and that McKesson OPA/28 is used in a well-ventilated area.
3. 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.
4. Avoid ingestion or 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 immediately. Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.
5. Avoid exposure to 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 tightness, difficulty with 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.
6. Use of McKesson OPA/28 must include a rinsing procedure that is consistent with the rinsing instructions provided by the device manufacturer. See Directions for Use - Rinsing Instructions and Procedure for important information on rinsing.

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

1. Wear nitrile gloves of appropriate length, eye protection, face masks, and fluid resistant gowns when disinfecting devices with McKesson OPA/28.

   NOTE: Contact with McKesson OPA/28 may stain exposed skin, clothing or environmental surfaces.
2. Minimize exposure to vapors by using McKesson OPA/28 in well-ventilated areas or by using in automated reprocessors with an effective vapor containment system. Use the product in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air handling system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices which contain filter media which absorb *ortho*-Phthalaldehyde (OPA) from the air.
3. Contaminated reusable devices MUST BE THOROUGHLY CLEANED prior to disinfection, since residual contamination will decrease effectiveness of the germicide.