Reorder No: 20390

Cidex® OPA
ortho-Pthalaldehyde Solution
high level disinfectant
Active ingredient
ortho-pthalaldehyde ........... 0.55%
Inactive ingredients .......... 99.45%
Total ......................... 100.00%

Does not require activation before use.

INDICATIONS FOR USE

Cidex® OPA Solution is a high level disinfectant for reprocessing heat sensitive medical devices when used according to the Directions for Use.

Cidex OPA Solution is intended for use in manual (bucket and tray) systems made from polypropylene, acrylic/EPDM, plastic/EPDM, or PEI/PEI. Cidex OPA Solution may also be used in automated endoscope reprocessors according to the manufacturer's instructions and should be monitored with Cidex OPA Solution Test Strips. See DIRECTIONS FOR USE – Reagents for Disinfection.

Medical devices reprocessed in Cidex OPA Solution must first be cleaned according to a validated cleaning protocol or standard, such as the ASTME 1518. “US Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera.”

Germicide Level of Activity: Cidex OPA Solution can be used at the following germicide level of activity:

High Level Disinfectant: Cidex OPA Solution is a high level disinfectant for semi-critical devices when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) of 0.3% as determined by the Cidex OPA Solution Test Strips, at 20°C (68°F) with an immersion time of at least 12 minutes for a reuse period not to exceed 14 days.

Reuse Period for Disinfection: Cidex OPA Solution has demonstrated disinfection efficacy in the presence of 5% organic soil contamination and microbiological burden during reuse. Cidex OPA Solution may be reused for a period not to exceed 14 days provided the required conditions of ortho-pthalaldehyde 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 Cidex OPA Solution Test Strip as the concentration of ortho-pthalaldehyde is above the MEC of 0.3%. The product must be discarded after 14 days, even if the Cidex OPA Solution Test Strip indicates a concentration above the MEC.

General Information on Selection and Use of Germicides for Medical Device Reprocessing: Choose a germicide with the level of microbial 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., laparoscopes and microsurgical instruments): Sterilization is required.

Semi-critical reusable device (e.g., endoscopes): Sterilization is required unless feasible; where not feasible, high level disinfection is the minimum acceptable process.

Third, select a germicide that is labeled for the appropriate germicide level and is compatible with the reusable device. Follow directions for the germicide.

Microbial Activity: The following table indicates the spectrum of activity as demonstrated by testing of Cidex OPA Solution using prescribed test methods.

<table>
<thead>
<tr>
<th>MICROORGANISM</th>
<th>VEGETATIVE ORGANISMS</th>
<th>BACTERIA</th>
<th>FUNGI</th>
<th>VIRUSES</th>
<th>END-ENVELOPED</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEZONECoccus aureus</td>
<td>S. epidermidis</td>
<td>S. marcescens</td>
<td>S. saprophyticus</td>
<td>S. dysgalactiae</td>
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<td>STEZONECoccus pneumoniae</td>
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<tr>
<td>STEZONECoccus \text{var.}</td>
<td>S. epidermidis</td>
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<td>S. epidermidis</td>
</tr>
</tbody>
</table>

Material Compatibility: Cidex OPA Solution has been tested and found to be compatible with the materials shown below.

<table>
<thead>
<tr>
<th>METALS</th>
<th>PLASTICS</th>
<th>ELASTOMERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum</td>
<td>Polymethylmethacrylate</td>
<td>Polyurethane, Silicone rubber</td>
</tr>
<tr>
<td>Stainless steel</td>
<td>Polyethylene terephthalate, Polytetrafluoroethylene (PTFE)</td>
<td>Polyurethane, Silicone rubber</td>
</tr>
<tr>
<td>Nickel plate</td>
<td>Polycarbonate, Polypropylene, Polyethylene</td>
<td>Polyurethane, Silicone rubber</td>
</tr>
<tr>
<td>Nickel / Cobalt alloy</td>
<td>Polycarbonate, Polypropylene, Polyethylene</td>
<td>Polyurethane, Silicone rubber</td>
</tr>
<tr>
<td>Titanium</td>
<td>PTFE, Polyethylene</td>
<td>Polyurethane, Silicone rubber</td>
</tr>
<tr>
<td>Tungsten carbide</td>
<td>PTFE, Polyethylene</td>
<td>Polyurethane, Silicone rubber</td>
</tr>
<tr>
<td>Stainless steel</td>
<td>Polymethylmethacrylate, Acetate</td>
<td>Polyurethane, Silicone rubber</td>
</tr>
</tbody>
</table>
ADHESIVES®
Cyanacrylate
EPO-TEK 301 Epoxy®
EPO-TEK 353 Epoxy

1. Exposed to 38 days (24 hour) of continuous contact with CIDEX OPA Solution with no effect unless otherwise noted.
2. Shows signs of surface decomposition at 7 days or greater.
3. Most gauze instantly shows no effect. Gauze may exhibit slight degradation at 7 days or greater. Stainless steel lab dishes run at 14 days immersion.
4. Tested with 30 cycles of CIDEX OPA Solution. Surface breakdown noted after 150 cycles 0.5-hour total contact.
5. Exposed 7 days of continuous contact with CIDEX OPA Solution with no effect unless otherwise noted.
6. Some grades of stainless steel exhibit discoloration.
7. Some metal coated parts may exhibit rusting.
8. Some metal in close proximity to metal may exhibit degradation.

CIDEX OPA Solution is not appropriate or reliable for high-level disinfection of Fuhrman endoscopes. Olympus and Pentax endoscopes are compatible with CIDEX OPA Solution.

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

Precleaning Agent Compatibility: CIDEX OPA Solution is compatible with enzymatic detergents which are neutral to mildly alkaline (6-8) in pH, low foaming, and easily rinsed from equipment (e.g., ENZOL® Enzymatic Detergent). Detergents that are either highly acidic or alkaline are not recommended as precleaning agents.

CONTRAINDICATIONS
CIDEX OPA 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 Center for Disease Control and Prevention (CDC) and the Association for Practitioners in Infection Control and Epidemiology (APIC).

WARNINGS

1. 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 stinging. 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.

2. 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 immediately. Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

3. Avoid exposure to ortho-phthalaldehyde vapors, as they may be irritating to the respiratory tract and eyes. May cause burning sensation in the nose and throat, discharge, coughing, chest discomfort and tightness, difficulty with breathing or headache. May aggravate a pre-existing 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.

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

PRECAUTIONS

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

1. 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 CIDEX OPA Solution may stain exposed skin or clothing.

2. Use CIDEX OPA Solution in a well ventilated area and in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air conditioning system, use in local exhaust hoods, or in enclosed fume hoods/ventilated ventilation devices which contain filter media which absorb ortho-phthalaldehyde from the air.

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

4. The user MUST adhere to the Directions for Use, as modification to the Directions for Use may 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 CIDEX OPA Solution.

6. The use of CIDEX OPA Solution in automated endoscope processors must be part of a validated reprocessing procedure. Use CIDEX OPA Solution Test Strips to detect ortho-phthalaldehyde concentration before each cycle to detect the MEC. Follow the Directions For Use provided with the CIDEX OPA Solution Test Strips.

DIRECTIONS FOR USE

Cleaning/Decontamination: Blood, other body fluids, and lubricants must be thoroughly cleaned from the surfaces and lumens of medical devices before reprocessing in the disinfectant. Blood and other body fluids should be autoclaved and disposed of according to all applicable federal, state and local 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 CIDEX OPA 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 can be used for up to 30 days (providing the 30 days does not extend past the expiration date on the container).

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 not to exceed 14 days. The product must be discarded after 14 days even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC.

A. High Level Disinfection

Immerse device completely, filling all lumens and eliminating air pockets, in CIDEX OPA Solution for a minimum of 12 minutes at 20°C (68°F) or higher to destroy all pathogenic microorganisms, including Mycobacterium burns, Pseudomonas aeruginosa, pathogenic fungi, and viruses (Polio virus Type 1; Adenovirus Type 2; Herpes simplex Types 1, 2; HIV-1; Influenza Type A [Hong Kong]; Vaccinia; Coronavirus; Coxsackievirus Type B-3; Cytomegalovirus; Rhinovirus Type 42).

Remove device from the solution and rinse thoroughly following the rinsing instructions below.

B. Rinsing Instructions

1. Rinsing Procedure

a) All Devices: Following immersion in CIDEX OPA Solution, thoroughly rinse the device by immersing it completely in a large volume (e.g., 2 gallons) of water. See below.

Repeat this procedure twice with a volume of fresh rinse water.

Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device or equipment manufacturer.

b) Endoscopic Instruments with Lumens: A minimum of 500 mL of water should be flushed through all lumens during each separate rinse, unless otherwise noted by the endoscope manufacturer.

Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose as it will be contaminated with ortho-phthalaldehyde.

Refer to the reusable medical 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 immuno-compromised patients, or potentially immuno-compromised 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 immuno-compromised 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 bacteria 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. Reuse for Disinfection

CIDEX OPA Solution has demonstrated efficacy in the presence of organic soil contamination and microbiological burden during reuse. The ortho-phthalaldehyde concentration of CIDEX OPA Solution during its use-life must be verified by the CIDEX OPA Solution Test Strips to determine that the MEC of 0.33% is present. CIDEX OPA Solution may be used and reused within the limitations indicated above for up to 14 days. CIDEX OPA Solution must be discarded after 14 days, even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC.

1. Monitoring of Germicide:

During reuse, it is recommended that the CIDEX OPA Solution be tested with the CIDEX OPA Solution Test Strips prior to each usage. This is to ensure that the appropriate concentration of ortho-phthalaldehyde is present.

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

2. 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. CIDEX OPA 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 30 days until used.

3. The expiration date of the CIDEX OPA Solution is found on the immediate container.

EMERGENCY AND TECHNICAL PRODUCT INFORMATION

Emergency, safety, or technical information about CIDEX OPA Solution can be obtained from Advanced Sterilization Products at (800) 783-7723, or by contacting your local Advanced Sterilization Products sales representative.

USER TRAINING

The user should be adequately trained in the decontamination and disinfection of medical devices and the handling of liquid chemical germicides. Additional information about CIDEX OPA Solution can be obtained by contacting your local Advanced Sterilization Products sales representative.

GERMICIDE/CONTAINER DISPOSAL INFORMATION

Germicide Disposal: Check state and local disposal regulations. Glycine (free base) may be used as a neutralizer for CIDEX OPA Solution prior to disposal. A minimum of 25 grams of glycine (free base) should be used to neutralize one gallon of CIDEX OPA Solution. The minimum recommended neutralization time is one hour. Discard residual solution into drain. Flush drain thoroughly with water.

Container Disposal: Do not reuse empty container. Rinse and wrap container then put in trash.

HOW SUPPLIED

<table>
<thead>
<tr>
<th>Reorder</th>
<th>Description</th>
<th>Case Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>20390</td>
<td>One Gallon (3.785L) Container</td>
<td>4 gals (4 x 3.785L)/case</td>
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<tr>
<td>20392</td>
<td>CIDEX OPA Solution Test Strips</td>
<td>60 strips/btl; 2 btl/cs/case</td>
</tr>
<tr>
<td>20393</td>
<td>CIDEX OPA Solution Test Strips</td>
<td>15 strips/btl; 2 btl/cs/case</td>
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ADVANCED STERILIZATION PRODUCTS®

A SCHICK JOHNSON COMPANY
Division of Ethicon, Inc.

33 Technology Drive, Irvine, CA 92618-5824
- ASP 1999

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