INTENDED USE: CIDE® OPA Solution is a high level disinfectant for reprocessing heat sensitive reusable semi-critical medical devices, for which sterilization is not feasible, and when used according to the Directions for Use.

Manual Processing: High Level Disinfectant at a minimum of 20°C (68°F), CIDE® OPA Solution 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 CIDE® OPA Solution Test Strips, with an immersion time of at least 12 minutes for a reuse period not to exceed 14 days.

Automatic Endoscope Reprocessors that can be set to a minimum of 25°C (77°F), CIDE® OPA Solution is a high level disinfectant when used or reused in a legally marketed automated endoscope reprocessor (that can be set to a minimum of 25°C) according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by CIDE® OPA Solution Test Strips, with an immersion time of at least 5 minutes for a reuse period not to exceed 7 days.

Effective concentration: 1. CIDE® OPA Solution should not be utilized to process any urological instrumentation used to treat patients with a history of bladder cancer. In rare instances CIDE® OPA Solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.

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

MEASURES & PLASTICS

Aluminum
Polystyrene (Neoprene)

Carbon steel

Polyethylene terephthalate

Brass

Polycarbonate

Titanium

Stainless steel

Nickel plated brass

Ortho-planished

Nickel silver alloy

Vanadium steel

Metallics

Plastics

MATERIALS Compatibility: CIDE® OPA Solution has been tested and found to be compatible with the materials shown below.

CONTRAINDICATIONS

1. CIDE® OPA Solution should not be utilized to process any urological instrumentation used to treat patients with a history of bladder cancer. In rare instances CIDE® OPA Solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.

2. CIDE® OPA Solution should not be utilized to process instrumentation for patients with known sensitivity to CIDE® OPA Solution or its ingredients.

3. CIDE® 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 Centers for Disease Control and Prevention (CDC) and the Association for Professionals in Infection Control and Epidemiology (APIC).

WARNINGs

1. May elicit an allergic reaction. Possible allergic reactions have been reported in rare instances. In such instances health care workers were not using the product in a well-ventilated room or not wearing proper respiratory 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 eyes 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. 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, which may be severe. Do NOT INJECT VOMITING. Drink large quantities of water and call a physician immediately. Probable mucosal damage from oral exposure may lead to damage of the gastric lumen.

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, difficulty breathing, coughing, chest discomfort and tightness. May aggravate pre-existing asthma or bronchitis conditions. In case of adverse reactions from inhalation of vapor, move to fresh air if possible. Call 911 or other emergency number, and seek medical attention.

5. The use of CIDE® OPA Solution with semi-critical devices that are intended for use in a sterile area of the body (e.g. cataract surgical instruments).

6. User must adhere to the Directions for Use, as modifications to the Directions for Use may affect the safety and effectiveness of the product.

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

8. The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using CIDE® OPA Solution.

PRECAUTIONS

1. When disinfecting devices, use gloves of appropriate type and length, eye protection and fluid-resistant gowns.

2. Use CIDE® 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 ductless fume hoods/portable 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 and/or lubricants will decrease the effectiveness of the germicide.

4. The user must adhere to the Directions for Use, as modifications to the Directions for Use may affect the safety and effectiveness of the product.

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

6. The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using CIDE® OPA Solution.
7. The use of CIDEX OPA Solution in automated endoscope reprocessors must be part of a validated reprocessing process. The contact conditions must be 25°C for 5 minutes. (See note following the Indications for Use section).

8. Use CIDEX OPA Solution Test Strips to detect orthophthalaldehyde 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 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 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, in blue ink. After the last rinse is performed, the rinse 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 (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 CIDEX OPA Solution Test Strip indicates a concentration above the MEC.

**A. High Level Disinfection**

1. **Manual Processing:** 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. Remove device from the solution and rinse thoroughly following the rinsing instructions below.

2. **Automatic Endoscope Reprocessor 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 critical temperature is monitored when using CIDEX OPA Solution in an AER at 25°C. See section D.1 Monitoring of Germicide.

**B. Rinsing Instructions**

1. **RINSING PROCEDURE**
   a) **Manual Processing:**
      - Following removal from CIDEX OPA Solution, thoroughly rinse the semicritical medical device by immersing it completely in a large volume (e.g. 2 gallons) 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 to remove CIDEX OPA Solution residues. This will prevent serious side effects. SEE WARNINGS. THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSIONS REQUIRED.
      - Refer to the reusable semicritical medical device manufacturer’s labeling for additional rinsing instructions.
   b) **Automated Processing:**
      - Select a rinse cycle on an automatic endoscope reprocessor that has been validated for use with CIDEX OPA Solution.
      - Ensure that the automated rinse cycle selected will thoroughly rinse the semicritical 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 one minute in duration unless the reusable device manufacturer specifies a longer time. Ensure that a fresh 100 mL volume of rinse 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 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 immunocompromised patients 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 that 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 ionizers, may effectively treat the 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 minimize the amount of these waterborne bacteria from the potable water source. Contact the manufacturer of the filter or UV system for their 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% 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 CIDEX OPA Solution is required for high level disinfection (HLD). Excessive soaking of the sheath (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 CIDEX OPA Solution remaining on the device, the use of which may cause staining, irritation or chemical burns of the mouth, throat, esophagus and stomach.

D. Reusability 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 prior to each use, to determine that the MEC of 0.3% is present. CIDEX OPA Solution may be used and reused within the limitations indicated above for up to a maximum of 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 CIDEX OPA Solution Test Strips prior to each use. This is to ensure that the Minimum Effective Concentration (MEC) of ortho-phthalaldehyde is present.

2. **Temperature Control:** Initially, 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.

3. **Monitoring Temperature in Automatic Endoscope Reprocessor:** That can be set to a minimum of 25°C (77°F) with all high level disinfectants, temperature monitoring is critical for use of CIDEX OPA Solution at a minimum of 25°C for 5 minutes in an AER. If you cannot monitor temperature appropriately in your machine, contact ASP at (888) 783-7723 for further instructions.

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.

**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 75 days until used.

**EMERGENCY AND TECHNICAL PRODUCT INFORMATION**

For further hazard information please refer to the Material Safety Data Sheet. Emergency, safety, or technical information about CIDEX OPA Solution can be obtained from Advanced Sterilization Products at (888) 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 semi-critical 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.

**DISINFECTANT/CONTAINER DISPOSAL INFORMATION**

**Disinfectant Disposal:** Check state and local disposal regulations. Glycine (free base) may be used as a neutralizer for CIDEX OPA Solution prior to disposal, if required. 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 dispose per hospital policy.

**HOW SUPPLIED**

<table>
<thead>
<tr>
<th>Reorder</th>
<th>Description</th>
<th>Case Contains</th>
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<tbody>
<tr>
<td>20390</td>
<td>One Gallon (3.78L)</td>
<td>4 gal (4 x 3.78L)/case Container</td>
</tr>
<tr>
<td>20392</td>
<td>CIDEX OPA Solution</td>
<td>60 strips/bling, 2 bits/case Test Strips</td>
</tr>
<tr>
<td>20390</td>
<td>CIDEX OPA Solution</td>
<td>15 strips/bling, 2 bits/case Test Strips</td>
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**MARKETED BY:**

Advanced Sterilization Products* *jordan-jordan company*
Division of Ethicon, Inc.
33 TECHNOLOGY DRIVE, IRVINE, CA 92618-9824

For technical information and/or information regarding safety and effectiveness, call 1-888-783-7723

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