Expect Service

Radiation Products Design Inc

INSTRUCTIONS

RPD INFORMATION

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Email	sales@rpdinc.com
Phone	763-497-2071 or 800-497-2071
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RPD PRODUCT INFORMATION

RPD is an authorized distributor

Item Number	Description
466-401	Cidex OPA, 1 gal

CIDEX® OPA

Reorder No. 20390

ortho-Phthalaldehyde Solution high level disinfectant for semi-critical medical devices

Active Ingredient: *ortho*-Phthalaldehyde 0.55%
Inert Ingredients 99.45%
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.

INSTRUCTIONS FOR USE

Intended Use: CIDEX® 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. CIDEX OPA Solution is intended for use in manual (bucket and tray) systems made from polypropylene, acrylonitrile-butadiene-styrene (ABS), polyethylene, glass-filled polypropylene and/or polycarbonate plastics. 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 – Reusage for Disinfection.

The semi-critical medical devices reprocessed in CIDEX OPA 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."

Indications for Use: CIDEX OPA 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.

Manual Processing: High Level Disinfectant at a minimum of 20°C (68°F). CIDEX 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 CIDEX 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: High Level Disinfectant at a minimum of 25°C (77°F). CIDEX OPA 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 Effective Concentration (MEC) as determined by CIDEX OPA Solution 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, Manual Processing.

Minimum Effective Concentration (MEC): 0.3%.

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 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 CIDEX OPA Solution Test Strip prior to each use to determine that the concentration of *ortho*-phthalaldehyde 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 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.*

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

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

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

MICROORGANISM
VEGETATIVE ORGANISMS
- *Staphylococcus aureus*
- *Salmonella choleraesuis*
- *Pseudomonas aeruginosa*
- *Mycobacterium bovis*

FUNGI
- *Trichophyton mentagrophytes*

VIRUSES
NON-ENVELOPED
- Poliovirus Type 1
- Rhinovirus Type 42
- Adenovirus Type 2
- Vaccinia (Wyeth)
- Coxsackievirus Type B-3

ENVELOPED
- Coronavirus
- Cytomegalovirus
- Influenza Virus [Hong Kong]
- HIV-1
- Herpes simplex Types 1,2

To qualify CIDEX OPA Solution as a high level disinfectant, the reused solution passed the AOAC Sporicidal Activity Test in 32 hours at 20°C and in 32 hours at 25°C.

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

METALS[1]
Aluminum
Anodized aluminum[2]
Brass
Carbon steel
Chrome plated brass[2]
Chrome plated steel[2]
Copper
Nickel plated brass[2]
Nickel silver alloy[2]
Stainless steel[3]
Titanium
Tungsten carbide[2]
Vanadium steel[4]

PLASTICS[5]
Polymethylmethacrylate (Acrylic)
Nylon
Polyethylene terephthalate (Polyester)
Polystyrene
Polyvinylchloride (PVC)[6]
Acrylonitrile/butadiene/styrene (ABS)
Polysulfone
Polycarbonate[7]
Polyethylene
Polypropylene
Acetal
PTFE
Polyamide

ELASTOMERS[5]
Polychloroprene (Neoprene)
Kraton G
Polyurethane
Silicone rubber[6]
Natural Rubber Latex

ADHESIVES[5]
Cyanoacrylate[8]
EPO-TEK 301 Epoxy[8]
EPO-TEK 353 Epoxy

1. Exposed to 31 days (744 hours) of continuous contact with CIDEX OPA Solution with no effect unless otherwise noted.
2. Shows signs of surface discoloration at 7 days or greater.
3. Most grades tested show no effect. Others may exhibit slight discoloration at 7 days or greater. Stainless steel 440 shows rust at 14 days immersion.
4. Treated with 500 cycles of CIDEX OPA Solution. Surface breakdown noted after 150 cycles (25 hour total contact).
5. Exposed 7 days of continuous contact with CIDEX OPA Solution with no effect unless otherwise noted.
6. Some grades or applications exhibit discoloration.
7. Some sonic welded parts may exhibit crazing.
8. Some loss in shear strength but show no signs of severe degradation.

Olympus, Pentax, and Fujinon endoscopes are compatible with CIDEX OPA Solution.

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

Cleaning Agent Compatibility: CIDEX OPA Solution is compatible with enzymatic detergents which are mild 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 cleaning agents.

CONTRAINDICATIONS

1. CIDEX OPA Solution should not be utilized to process any urological instrumentation used to treat patients with a history of bladder cancer. In rare instances CIDEX OPA Solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.
2. CIDEX OPA Solution should not be utilized to process instrumentation for patients with known sensitivity to CIDEX OPA Solution or any of its components.
3. 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 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 the majority of these instances health care workers were not using the product in a well-ventilated room or not wearing 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 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 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 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.
5. The use of CIDEX OPA 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 CIDEX OPA 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.

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 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 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. Do not use CIDEX 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 CIDEX OPA Solution.
7. The use of CIDEX OPA 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).
8. 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 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, 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 (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 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 semi-critical 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. Residues may cause serious side effects. SEE WARNINGS. THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED.
      - Refer to the reusable semi-critical 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 this product.

- 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 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 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 CIDEX OPA 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 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. Reusage 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.

   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.

   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 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.

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 75 days until used.
3. The expiration date of the CIDEX OPA 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 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

Reorder	Description	Case Contains
20390	One Gallon (3.785L) Container	4 gals (4 x 3.785L)/case
20392	CIDEX OPA Solution Test Strips	60 strips/btl; 2 btls/case
20393	CIDEX OPA Solution Test Strips	15 strips/btl; 2 btls/case

How to Obtain the Instructions for Use

You can obtain the **Instructions for Use** by the following methods:

- WEB SITE: The **Instructions for Use** are available on www.e-ifu.com
- FAX-ON-DEMAND SYSTEM: Dial 888-783-7723 and follow the prompts.

Marketed By:

ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.

a Johnson & Johnson company

33 Technology Drive, Irvine, CA 92618

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

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