

A) Indications for Use

Sterilant: CIDEX® Activated Dialdehyde Solution is indicated for use as a sterilant when used or reused, according to Directions for Use, for up to a maximum of 14 days at 25°C with an immersion time of at least 10 hours.

1) High Level Disinfectant:

CIDEX Solution is indicated for use as a high level disinfectant when used or reused, according to Directions for Use, for up to a maximum of 14 days at 25°C with an immersion time of at least 45 minutes (Reuse section below).

2) Reuse Period

CIDEX Solution has also demonstrated efficacy in the presence of up to 5% organic soil contamination and a simulated amount of microbiological burden during reuse. CIDEX Solution can be reused for up to a maximum of 14 days provided the required conditions of glutaraldehyde concentration, pH, and temperature exist based upon monitoring described in Directions for Use within this insert. DO NOT rely solely on days in use. Efficacy of this product during its use-life must be verified by the CIDEX Solution Test Strips to determine that the solution is above the minimum effective concentration (MEC) of 1.5% glutaraldehyde¹. Test the solution prior to each use. Use only CIDEX Solution Test Strips as they have been specifically designed to monitor CIDEX Solution MEC. Individual hospital results on the number of days of reuse will vary. Reuse of CIDEX Solution for up to a maximum of 14 days was determined through a standardized regulatory protocol and an analytical test procedure¹.

3) General Information on Selection and Use of Disinfectants for Medical Device Reprocessing

Choose a disinfectant with the level of antimicrobial activity that is appropriate for the reusable medical device. Follow the reusable medical device labeling and standard institutional practices. The following may be used as a guideline:

(a) Determine whether the reusable device to be reprocessed is a critical, semi-critical, or non-critical medical device.

A **critical medical device** presents a high risk of infection if not sterile. Critical devices routinely penetrate the skin or mucous membranes during use, enter the vascular system, or are otherwise used in normally sterile tissue of the body

A **semi-critical medical device** makes contact with mucous membranes but does not usually penetrate normally sterile areas of the body.

A **non-critical medical device** contacts only intact skin during routine use.

(b) Determine the level of activity that is needed for the reusable medical device.

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

Semi-critical Medical Device Sterilization is recommended whenever practical, otherwise High Level Disinfection is acceptable (e.g.: GI endoscopes, anesthesia equipment for the airway, diaphragm-fitting rings, etc.)

(c) Select a disinfectant that is labeled for the appropriate disinfectant level and is compatible with the reusable medical device. Follow directions for the disinfectant.

4. Microbial Activity

The following table indicates the spectrum of activity as demonstrated by testing of CIDEX Solution™

SPORES	BACTERIA		FUNGI		VIRUSES	
	VEGETATIVE ORGANISMS			NON-ENVELOPED	ENVELOPED	
Bacillus subtilis	Staphylococcus aureus	Trichophyton mentagrophytes	Pollivirus Type 1		Coronavirus	
Clostridium sporogenes	Salmonella choleraesuis		Rhinovirus Type 14		Cytomegalovirus	
	Pseudomonas aeruginosa		Adenovirus Type 2		Influenza virus Type A (WSN/33)	
	Mycobacterium tuberculosis		Vaccinia		HIV-1 (AIDS Virus)	
					Herpes simplex Type 1,2	

**Testing was done after 14 days of simulated reuse using the U.S. EPA Reuse Protocol (see section G2 Reference Information).

5) Material Compatibility

CIDEX Solution is recommended for use with medical devices made from the materials shown below. Care must be taken with medical devices such as anesthesia and respiratory therapy tubing, dental mirrors and burners. These devices may be damaged when cleaned with a highly alkaline detergent, poorly rinsed after disinfection, stored wet or dried at temperatures exceeding 40°C.

METALS Chrome plate ¹ Copper ¹ Monel ¹ Nickel plate ¹ Nickel silver alloy ¹ Platinum ¹ Silver Solder ¹ Tungsten ¹ 70-30 Solder ¹ Aluminum ² Gold Plate ² Silver Plate ² Anodized aluminum ³ Brass ⁵ Carbon Steel ⁷ Stainless Steel ⁷	PLASTICS Polysulfone ¹ Teflon ¹ Polyethylene terephthalate (Polyester) ¹ Polymethylmethacrylate (Acrylic) ¹ Polystyrene ¹ Polyvinylchloride (PVC) ¹ Polycarbonate ¹ Acrylonitrile-butadiene-styrene (ABS) ⁷ Nylon ¹ Polyethylene ⁷ Polypropylene ¹	ELASTOMERS Polychloroprene (Neoprene) ¹ Polyurethane ¹ Black natural rubber ⁷ Red natural rubber ⁷ Silicone rubber (Silastic) ⁷
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NOTE:

1 Represents 8 hours of continuous contact with CIDEX Solution.

2 Represents 10 hours of total contact with CIDEX Solution over 20 disinfection cycles.

3 Represents 20 hours of total contact with CIDEX Solution over 20 disinfection cycles.

4 Represents 40 hours of total contact with CIDEX Solution over 40 disinfection cycles.

5 Represents 144 hours of continuous contact with CIDEX Solution.

6 Represents 283 hours of total contact with CIDEX Solution over 20 sterilization cycles.

7 Represents 336 hours or greater of continuous contact with CIDEX Solution.

6) Cleaning Agent Compatibility

Detergents that are either highly acidic or alkaline are contraindicated as cleaning agents since improper rinsing could affect the efficacy of the CIDEX Solution by altering its pH.

Rinse devices completely prior to immersion in CIDEX Solution.

B) Contraindications

• CIDEX Solution should NOT be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g.: heat, ethylene oxide, or hydrogen peroxide gas plasma.

• CIDEX Solution should not be used for sterilization of critical devices intended for single use (e.g.: catheters, cannulae used for intraocular lens replacement and other types of single use devices).

• CIDEX Solution should NOT be used to achieve high level disinfection of a semi-critical device when sterilization is practical.

• CIDEX Activated Dialdehyde Solution should not be used for sterilization of rigid endoscopes which device manufacturers indicate are compatible with sterilization processes that can be biologically monitored (e.g. steam, dry heat, ethylene oxide, hydrogen peroxide gas plasma).

C) Warnings

CIDEX ACTIVATED DIALDEHYDE SOLUTION IS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS
Keep out of reach of children

CAUTION

Contains Glutaraldehyde

Harmful by inhalation and if swallowed.
Irritating to respiratory system and skin.
Risk of serious damage to eyes.
May cause sensitization by inhalation and skin contact.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

HARMFUL

Use only in well-ventilated areas (refer to the Material Safety Data Sheets for additional information).

Avoid release to the environment.

1) Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing.

2) Avoid contamination of food.

3) Refer to Special Instructions/Safety Data Sheet.

Skin Contact: Brief contact may cause itching with mild to moderate local redness. Prolonged contact may result in staining of the skin. Contact may aggravate existing dermatitis. Repeated skin contact may cause a cumulative dermatitis, may cause skin sensitization in a small proportion of individuals and present as an allergic contact dermatitis. This usually results from contact with the liquid but occasionally there may be a reaction to glutaraldehyde vapor.

Eye Contact: If not rinsed properly, liquid will cause conjunctivitis, seen as redness and swelling of the conjunctiva. Severe corneal injury may develop which could permanently impair vision if prompt first aid and medical treatment are not obtained. Vapor may cause stinging sensations in the eye with excess tear production, blinking and possibly a slight redness of the conjunctiva.

Inhalation: May cause sensitization by inhalation. Vapor is irritating to the respiratory tract, causing stinging sensations in the nose and throat. May cause bleeding from the nose, coughing, chest discomfort and tightness, difficulty with breathing and headache. Inhalation of vapor may cause asthma-like symptoms (chest discomfort and tightness, difficulty with breathing). Glutaraldehyde has been reported to cause occupational asthma and may aggravate existing asthma and inflammatory or fibrotic pulmonary disease. Heating the solution may result in more severe irritant effects.

Ingestion: May cause irritation or chemical burns of the mouth, throat, oesophagus and stomach. There may be discomfort or pain in the mouth, throat, chest and abdomen, nausea, vomiting, diarrhea.

FIRST-AID MEASURES:

Skin: Immediately remove contaminated clothing and shoes. Wash skin thoroughly with soap and water. Obtain medical attention. Wash clothing before re-use. Discard contaminated leather articles such as shoes and belt.

Eyes: Immediately flush eyes with water and continue washing for at least 15 minutes. DO NOT remove contact lenses during washing procedure. Obtain medical attention without delay, preferably from an ophthalmologist.

Inhalation: Remove to fresh air. Give artificial respiration if not breathing. If breathing is difficult, oxygen may be given by qualified personnel. Obtain medical attention.

Ingestion: Do not induce vomiting. Wash mouth out thoroughly with water. Drink copious amounts of a demulcent (liquid which soothes irritation) such as milk. Obtain medical attention without delay.

Note to Physician: Probable mucosal damage from oral exposure may contraindicate use of gastric lavage.

For further Hazard information please refer to the Material Safety Data Sheet. See Section G below.

D) Precautions

1) Use gloves of appropriate type and length, eye protection, face-mask and fluid-resistant gowns or aprons. When using latex rubber gloves, the user should double glove and/or change single gloves frequently, e.g. after 10 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. The use of neoprene or polyvinyl chloride (vinyl) gloves is not recommended, as glutaraldehyde may be rapidly absorbed by these materials.

2) Contaminated, cleaned medical devices **MUST BE THOROUGHLY RINSED** prior to immersion in CIDEX Solution, since residual contamination will decrease effectiveness of the disinfectant.

3) The user MUST adhere to the **Directions for Use** (Section E of this insert) since any modification will affect the safety and effectiveness of the disinfectant.

4) The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using CIDEX Solution.

5) The use of CIDEX Solution in Automated Endoscope Reprocessors (AER) **must be part of a validated reprocessing procedure provided by the reprocessor manufacturer.** Monitor Glutaraldehyde¹ concentration to ensure that it is above the MEC. Test the solution prior to each use. CIDEX Solution Test Strips must be used for this purpose.

6) Use CIDEX Solution in a well-ventilated area in closed containers with tight fitting lids. Use in local exhaust hoods or in ductless fume hoods/portable ventilation equipment, which contain filter media that absorb glutaraldehyde from the air, if adequate ventilation is not provided by the existing air conditioning system.

E) Directions for Use

Do not dilute.

CIDEX Solution can be used in Automated Endoscope Reprocessors (AER) where approved by the manufacturer of the AER. CIDEX Solution is intended for use in manual (bucket and tray) systems (see D6 above) made from polypropylene, acrylonitrilebutadiene-styrene (ABS), polyethylene, glass-filled polypropylene or specially molded polycarbonate plastics.

1) Activation

Activate the CIDEX Solution by adding the entire contents of the Activator Vial, which is attached to the CIDEX Solution container. Shake well. Activated solution immediately changes color to green only indicating that the activator has been added to the solution. Record the date of activation (mixing date) and expiration date on the container label in the space provided, in a logbook or a label affixed to any secondary container used for the activated solution. Test the activated solution prior to use with CIDEX Solution Test Strips.

2) Cleaning

Faeces, mucus, tissues, blood and other body fluids must be thoroughly cleaned from surfaces and lumens of devices before processing in CIDEX Solution. Blood and other body fluids should be disposed of according to all applicable regulations for infectious waste disposal.

Thoroughly clean, rinse and rough dry devices before immersing in CIDEX Solution. Clean and rinse the lumens of hollow instruments before filling with CIDEX Solution.

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

3) Usage

(a) Test the solution to ensure that the glutaraldehyde¹ concentration is above its MEC. Test the solution prior to each use. CIDEX Solution Test Strips must be used for this purpose. Although test strips from other manufacturers may give a color reaction with CIDEX Solution, their use has not been validated with this product. Only CIDEX Solution Test Strips can be used with CIDEX Solution as they monitor the MEC of 1.5%.

(b) Immerse cleaned and rough dried medical devices completely in the CIDEX Solution, filling all lumens. Check with the medical device manufacturer to ensure that the device is capable of being completely submerged in liquid before being placed in CIDEX Solution.

(c) Leave medical devices completely immersed for the required time at the appropriate temperature (see section A, Indications for Use).

(d) At the end of the required time remove medical devices from the solution using aseptic technique.

(e) Rinse thoroughly with the appropriate quality of water (sterile or potable) following the rinsing instructions below.

(f) Re-use CIDEX Solution in accordance with the conditions in this insert (see section A 2, Reuse Period)

4) Rinsing Instructions

Following removal from CIDEX Solution, thoroughly rinse the medical device by immersing it completely in three separate copious volumes of water. Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose as it will be contaminated with glutaraldehyde.

Water should be flushed through all lumens during each separate rinse, unless otherwise noted by the endoscope manufacturer.

Refer to the reusable medical device manufacturer's labeling for additional instructions. Check with the applicable AER manufacturer to ensure that these minimum rinsing requirements are met.

(a) Sterile Water Rinse

The following are examples of medical devices that should be rinsed with sterile water, using aseptic technique when rinsing and handling:

1. Medical devices intended for use in normally sterile areas of the body;

2. Medical devices intended for use in known immunocompromised patients,

or potentially immunocompromised patients based on hospital procedures and;

3. Bronchoscopes, if feasible, due to a risk of atypical Mycobacteria contamination from potable water supply.

(b) Potable Water Rinse

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the medical device with waterborne organisms e.g., pseudomonads, atypical mycobacteria etc.

A medical device (e.g., colonoscope) that is not completely dried provides an ideal environment for rapid colonization of bacteria. Additionally, mycobacteria are highly resistant to drying; therefore, rapid drying will avoid possible colonization but may not result in a medical device free from atypical mycobacteria. Although these bacteria are not normally pathogenic in patients with healthy immune systems, patients infected with HIV (Human Immunodeficiency Virus) patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms. A final rinse using a 70% isopropyl alcohol solution is useful to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water. Potable water should be monitored on a regular basis and its microbiological quality controlled.

The use of a bacterial retentive (0.2 micron) filter system may eliminate or greatly reduce the amount of these water-borne bacteria from the potable water source. Contact the manufacturer of the filter for instructions on preventive maintenance and periodic replacement of the filter to avoid colonization or formation of biofilms in the filter.

5) Monitoring of Disinfectant to Ensure Specifications Are Met

During the use of CIDEX Solution it is recommended that a thermometer and timer be used to ensure that the optimum usage conditions are met. In addition, it is necessary to test CIDEX Solution with the CIDEX Solution Test Strips. Test the solution prior to each use. This is to ensure that the glutaraldehyde¹ concentration is above its minimum effective concentration. The pH of the activated solution may also be periodically checked to verify that the pH of the solution is between 8.2-8.9. Method of determining pH requires a specific methodology (see G2 Reference Information).

6) Post-Processing Handling and Storage of Reusable Medical Devices

Processed medical devices are either to be immediately used or stored in a manner to minimize recontamination. Note that only terminal sterilization (sterilization in a suitable wrap) provides maximum assurance against recontamination. Refer to the medical device manufacturer's labeling for additional storage and/or handling instructions.

Once the CIDEX Solution has been activated, it should be stored in the original container until transferred to the closed containers in which the immersion is to take place.

Containers should be stored in a well-ventilated, low traffic area at controlled room temperature.

F) Storage Conditions and Expiration Date

1) Prior to activation, CIDEX Solution should be stored in its original sealed container at controlled room temperature 15°-30°C (59-86°F). In common with other chemicals it is good practice to store this product out of direct sunlight.

2) The expiration dates of the unactivated CIDEX Solution and activator will be found on the container.

3) The use period for activated CIDEX Solution is for up to a maximum of 14 days following activation or, as indicated by the CIDEX Solution Test Strips.

G) Additional Safety and Technical Product Information

1 Safety Information

Safety information about CIDEX Solution (such as the MSDS) can be obtained from:

Advanced Sterilization Products at (888) 783-7723, or by contacting your local Advanced Sterilization Products sales representative.

For further Hazard information please refer to the Material Safety Data Sheet.

2 Reference Information

¹Glutaraldehyde Titration Method
U.S. EPA Reuse Protocol
Test method for pH in CIDEX
Favero M, Bond W. Chemical disinfection of medical surgical material. In: S.S. Block, ed. Disinfection, sterilization and preservation, 5th ed. Williams and Wilkins, 2000. Chapter 43

H) User Proficiency

The user should be adequately trained in the decontamination and reprocessing of medical devices and the handling of toxic substances such as liquid chemical sterilants/high level disinfectants.

I) Disposal Information

CIDEX Solution Disposal
Discard residual solution in drain or per hospital policy. Flush thoroughly with water.

Container Disposal
Do not reuse empty container. Rinse with water, and dispose per hospital policy.

J) How Supplied

Reorder	Description	Case Contains
2245	0.946 L (One Quart) Container	4 x 0.946 L (4 qts)/box; 4 boxes/case 16 x 0.946 L (16 qts)/case
2250	3.785 L (One Gallon) Container	4 x 3.875 L (4 gals)/case
2920	CIDEX® Solution Test Strips	60 strips/btl; 2 btl/case
2927	CIDEX® Solution Test Strips	15 strips/btl; 2 btl/case

References supplied upon request

¹See section G2 Reference Information.

MARKETED BY:

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Cidex®
Activated Dialdehyde Solution
(GLUTARALDEHYDE 2.4%)

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