Dear Valued Customer,

Thank you for your interest in CIDEX® Solutions. Regarding your questions on disposal in California let me provide you with the following information:

SB 2035 was enrolled on the 8th of September 2000. This law went into effect January 1, 2001 and states that: ***'Treatment does not include the combination of glutaraldehyde or ortho-phthalaldehyde, which is used by medical facilities to disinfect medical devices, with formulations containing glycine as the sole active chemical, if the process is carried out onsite."***

What this means:
Customers using Glutaraldehyde solutions or CIDEX® OPA Solution can treat the solution with Glycine prior to disposal WITHOUT a treatment permit from the State.

To treat one gallon of CIDEX® OPA Solution, add 25 grams of Glycine and wait 1 hour prior to disposal.

To treat one gallon of CIDEX® Activated Dialdehyde Solution or CIDEXPLUS® Solution, add 25 grams of Glycine and wait 5 minutes prior to disposal.

Thank you for contacting Advanced Sterilization Products. If you should have additional questions, please call ASP Professional Services at (888)-783-7723.

Sincerely,

33 Technology Drive, Irvine, CA 92618 · Tel: 949.581.5799 · Fax: 949.581.5997
ADVANCED STERILIZATION PRODUCTS
Division of Ethicon, Inc.
a Johnson & Johnson company

Warming CIDEX® Solutions

May 18, 2011

Dear Valued Customer,

Advanced Sterilization Products (ASP) occasionally receives questions from customers related to the reprocessing temperature of CIDEX® Solutions. All CIDEX® Solutions including CIDEX® OPA, CIDEXPLUS® 28 Day Solution and CIDEX® Activated Dialdehyde must be used in accordance with their respective Instructions for Use (IFU), and these IFUs indicate a minimum temperature requirement for high-level disinfection. Whether reprocessing devices manually in a basin or reprocessing using a legally marketed Automatic Endoscope Reprocessor, the temperature of the disinfectant solution must meet or exceed the minimum requirement listed in the solution's IFU.

ASP is aware that regulatory and accrediting organizations have increased their scrutiny of CIDEX® Solution temperatures, and often now request objective evidence that reprocessing temperatures meet requirements. In many cases, the ambient temperature of a reprocessing area is sufficient to ensure the minimum reprocessing temperature is maintained during disinfection. In some cases, however, a reprocessing area may not be sufficiently warm to ensure a basin of CIDEX® Solution is above the required temperature, and in this case the CIDEX® Solution **should not be used** until the temperature is sufficient. Customers must make certain that the solution is warmed to the appropriate temperature before the reprocessing begins, and should have reasonable confidence that the minimum temperature is maintained or exceeded throughout the soaking time.

While ensuring the disinfectant solution temperature meets the minimum requirements is essential, ASP does not endorse any particular system to warm CIDEX® Solutions should they not meet the temperature requirement. ASP strongly recommends that our customers develop and discuss their internal practices for heating disinfectant solutions in cooperation with their Industrial Hygiene, Facilities and risk management personnel. Should a warmer be used with CIDEX® Solutions, heat only to meet or to marginally exceed the minimum required temperature. **DO NOT OVERHEAT CIDEX® Solutions**, as overheating may increase vapors of the solution in the work environment. Solution temperature should be regularly monitored when heating CIDEX® Solutions.

Our customers may select from numerous heating systems on the market today that may be used to safely and gently warm CIDEX® Solutions for manual reprocessing. ASP has performed limited testing on several such commercially available heating systems and has provided the information below to serve as an example only. In this example, a UL certified heating mat, impervious to water, is used to gently heat a basin of CIDEX® Solution.

Pictured:

CIDEX® Solution Tray w/ Cozy Warming Pad & Rack
Part Number: GM-1
Contact: 312.226.2473

Note: Do not use a heating mat on a countertop or surface that is heat sensitive or the surface may discolor or change shape. **Temperatures below the mat may reach 65 °C.**

33 Technology Drive, Irvine, CA 92618 Tel: (800) 595-0200 Fax: (949) 581-5997
ADVANCED STERILIZATION PRODUCTS
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a Johnson & Johnson company

When heating a basin of CIDEX® Solution, it is important to ensure that the temperature is stable so that the minimum temperature is reliably met while not overheating the solution. Temperature control may be attained by using a temperature controller.

A temperature controller may be used to measure the temperature of the CIDEX® Solution and to apply the appropriate amount of power to the heater to maintain a specified temperature. In this scenario, the controller is first plugged into an outlet near the heating mat, the heating mat is then connected to the output of the controller, and finally the controller's temperature probe is placed into the CIDIEX® Solution. The tray's lid may then be sealed over top of the cord, and the temperature may be adjusted to the value appropriate for manual reprocessing. It is highly recommended that the temperature of the CIDEX® Solution be measured with a calibrated thermometer prior to each disinfection cycle, and that this temperature value be logged with the result of the CIDEX® Solution Test Strip used to verify the Minimum Effective Concentration.

Pictured (Available from Amazon.com):

HC-810M: Finnex Digital Temperature Heater Controller
(ASIN: B002TMTA7G)

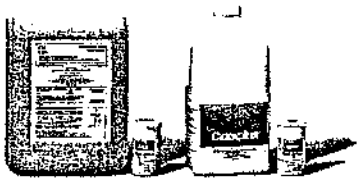
While ASP does not endorse Cozy Products or Finnex, we are providing this information as an example of a heating system that may be used to gently warm CIDEX® Solutions in a basin above their minimum temperatures. If you have any questions please call ASP Customer Care Center at 1-888-783-7723.

Sincerely,

Tracey Grenkoski
US Group Product Director, High-Level Disinfection

ASP
CIDEX®

HOW TO USE CIDEX® ACTIVATED DIALDEHYDE SOLUTION AND CIDEXPLUS® 28-DAY SOLUTION



For over 45 years, CIDEX® Solutions have been safely used by healthcare professionals for the high-level disinfection and sterilization of delicate heat-sensitive instruments because of their efficacy, materials compatibility, economy and ease of use.

Please read and follow the Instructions for Use (IFU) prior to using CIDEX® Solutions for important information, including contraindications, warnings and proper directions for use.

For technical information on CIDEX® Solutions, contact your local Advanced Sterilization Products sales representative or call ASP Customer Support at +1-888-783-7723.

ADVANCED STERILIZATION PRODUCTS
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* CIDEX® Sporicidal label reuse claims are based on an EPA protocol which challenges the solution three times per day in manual systems. Many healthcare workers challenge CIDEX® Solutions more than three times per day or use CIDEX® Solutions in soak washers. These practices cause dilution of the solution to levels below the MEC prior to its stated use life.

 AD-08742-01-US_B

1. Personal Protective Equipment

- Personal protective equipment must always be worn when handling contaminated instruments and equipment. Personal protective equipment includes disposable nitrile gloves, eye protection, face mask, and fluid-repellent gown. Once personal protective equipment is donned, you are ready to begin the disinfection/sterilization process.

2. Clean Instruments

- Contaminated instruments must be thoroughly cleaned prior to disinfection or sterilization since residual organic matter will decrease the effectiveness of the CIDEX® Solutions.
- To remove debris, thoroughly clean all instrument surfaces and the lumens of hollow instruments (e.g., endoscopes) with a mild protein-dissolving detergent such as ENZOL® Enzymatic Detergent Solution. CIDEX® Solutions are compatible with enzymatic detergents (e.g., ENZOL® Detergent Solution) which are mild in pH, low foaming, and easily rinsed from instruments. Detergents that are either highly acid or alkaline are contraindicated as cleaning agents since improper rinsing could affect the efficacy of the CIDEX® Solutions by altering their pH.
- Following cleaning, rinse instrument surfaces and lumens with large amounts of fresh water to remove residual detergent. Remove excess moisture from instrument prior to disinfecting or sterilizing. This will help prevent water from rapidly diluting the CIDEX® Solution below its minimum effective concentration (MEC).
- Refer to instrument manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing.

3. Activate solution

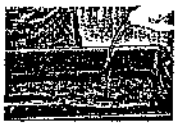
- Once the instruments have been properly cleaned, you are now ready to begin using the CIDEX® Solution. Prepare CIDEX® Solution for use by first adding the entire contents of the activator vial to the solution in the container. Shake well. Activated solution immediately changes color to green, only indicating that the activator has been added to the solution.
- Do not use activated solution beyond stated 14- or 28-day reuse life. NOTE: The activator contains a rust inhibitor. Do not add any other agent.
- Record the date of activation (mixing date) and expiration date in the space provided on the CIDEX® Solution container label, in a log book, or on a label affixed to the CIDEX® Solution tray or any secondary container. Log books are available through your local Advanced Sterilization Products sales representative.

4. Testing

- It is important to note that CIDEX® Solutions may expire prior to the reuse date stated on the label.* Do not rely solely on days in use. To determine if the correct MEC of the CIDEX® Solution is still present, CIDEX® Solutions must be tested prior to each use with the appropriate CIDEX® Solution Test Strip.
- It is recommended that CIDEX® Solutions be tested before each usage with appropriate CIDEX® Test Strips to verify that solution is above MEC. CIDEX® Solutions must be discarded after 14 or 28 days even if CIDEX® Test Strips indicate a concentration above the Minimum Effective Concentration (MEC).

5. Disinfection / Sterilization

- Immerse clean, dry instruments completely in the CIDEX® Solution. Fill all lumens of hollow instruments. To reduce exposure to glutaraldehyde vapors which can be irritating, cover the CIDEX® Solution tray or bucket with a secure lid. Soak instruments for the amount of time required for disinfection or sterilization. Please read and follow the Instructions for Use for complete instructions/information on soak times and temperature for disinfection and sterilization.
- Use CIDEX® Solutions in a well-ventilated area and in closed containers with tight-fitting lids. Failure to use CIDEX® Solutions without proper ventilation or engineering controls may result in an allergic reaction, urticaria (hives), or a rash. Use of CIDEX® Solutions without proper ventilation may also result in irritation to the respiratory tract and eyes, stinging sensation in the nose and throat or difficulty breathing.



6. Rinse Instruments

- For devices that have been sterilized: Remove instruments from solution using sterile technique and rinse thoroughly with sterile water. Please read and follow the Instructions for Use for complete rinsing instructions/information.
- Following disinfection, aseptically remove instruments from the solution and rinse instruments thoroughly, flushing the channels with potable or sterile water.
- Be sure to repeat this procedure twice, for a total of three rinses. Each rinse should be a minimum of one minute in duration, and a large volume of fresh water (e.g., two gallons) must be used for each rinse.
  Note: Please refer to the Instructions for Use for information on rinsing during processing in an automatic endoscope reprocessor.

7. Dry

- Once the instruments have been properly high-level disinfected or sterilized, dry the instruments. Disinfected or sterilized equipment should be used immediately or stored in a manner to minimize recontamination.
- Please read and follow the Instructions for Use for complete instructions/ information on drying flexible endoscopes when using potable water for rinsing, e.g., the use of alcohol for thorough drying. Refer to the instrument manufacturer's labeling for additional storage and/or handling instructions.

8. Disposal

- In compliance with the United States Environmental Protection Agency requirements, CIDEX® Solutions may be disposed of as an ordinary domestic waste rather than a hazardous waste. However, some state regulatory and local water board or sewer authorities may have certain restrictions on drain disposal of specific wastes from your facility.

Reorder No. 2266

CIDEX®

Activated Dialdehyde Solution (GLUTARALDEHYDE 2.4%)

INSTRUCTIONS FOR USE

A. INDICATIONS FOR USE 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. 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% glutaraldehyde. 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 procedure[1].

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 labelled 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**

BACTERIA		FUNGI	VIRUSES	
SPORES	VEGETATIVE ORGANISMS		NON-ENVELOPED	ENVELOPED
Bacillus subtilis Clostridium sporogenes	Staphylococcus aureus Salmonella choleraesuis Pseudomonas aeruginosa Mycobacterium tuberculosis	Trichophyton mentagrophytes	Poliovirus Type 1 Rhinovirus Type 14 Adenovirus Type 2 Vaccinia	Coronavirus Cytomegalovirus Influenza virus Type A [WS/33] 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 burrs. 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[5]
Brass[5]
Carbon Steel[6]
Stainless Steel[6]

PLASTICS
Polysulfone[1]
Teflon[1]
Polyethylene terephthalate (Polyester)[3]
Polymethylmethacrylate (Acrylic)[3]
Polystyrene[3]
Polyvinylchloride (PVC)[3]
Polycarbonate[4]
Acrylonitrile-butadiene-styrene (ABS)[6]
Nylon[6]
Polyethylene[6]
Polypropylene[6]

ELASTOMERS
Polychloroprene (Neoprene)[1]
Polyurethane[1]
Black natural rubber[6]
Red natural rubber[6]
Silicone rubber (Silastic)[6]

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 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 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. This product is not to be sold, distributed, or used for any other purpose.

CAUTION
Contains Glutaraldehyde
Harmful by inhalation and if swallowed.
Irritating to respiratory system and skin.
Risk of serious damage to eyes.
May cause sensitisation 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 Material Safety Data Sheet (MSDS) for the following.

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 sensitisation 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 reuse. 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, reusable medical devices **MUST BE THOROUGHLY CLEANED** 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) 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 Glutaraldehyde 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

CIDEX Solution is intended for use in the processing of critical and semi-critical medical devices that are to be used on humans.

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

Feces, mucous, 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 manufacturers labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

3) Usage

(a) Test the solution to ensure that the glutaraldehyde 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 submersed 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) Reuse CIDEX Solution in accordance with the conditions in section A2, 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 glutaraldehyde 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 to 9.2. 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 manufacturers' labeling for additional storage and/or handling instructions.

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.

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.

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

Glutaraldehyde 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 Wilkens, 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 your facility policy. Flush thoroughly with water.

Container Disposal
Do not reuse empty container. Rinse with water and dispose per your facility policy.

J) HOW SUPPLIED

Reorder No.	Description	Case Contains
2266	4.7L	4 x 4.7L containers/case
2920	CIDEX® Solution Test Strips	60 strips/container; 2 containers/case
2927	CIDEX® Solution Test Strips	15 strips/container; 2 containers/case

References supplied upon request

See section G2 Reference Information.

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.

Medos International Sàrl
Chemin-Blanc 38
CH-2400 Le Locle
Switzerland

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.

Made in U.K.

A. Intended Use

The CIDEX® Solution Test Strips are semi-quantitative chemical indicators for use in determining whether the concentration of glutaraldehyde, the active ingredient in CIDEX® Activated Dialdehyde Solution, is above or below the minimum effective concentration (MEC) established for CIDEX Activated Dialdehyde Solution.

CIDEX Solution Test Strips cannot be used to validate the sterilization or disinfection process.

B. Explanation of the Test

CIDEX Solution Test Strips are developed exclusively for monitoring the minimum effective concentration (MEC) of CIDEX Activated Dialdehyde Solution which has been activated for use. It is recommended that activated solution be tested daily before each usage with the test strips in order to guard against dilution, which may lower the glutaraldehyde level of the solution below its MEC.

CIDEX Solution Test Strips will NOT detect failure to activate the solution.

WARNING: Do not use CIDEX Activated Dialdehyde Solution beyond its maximum 14 day use life.

C. Chemical Principle of the Test Procedure

Glutaraldehyde reacts with sodium sulfite in the test strip to form a sulfite addition product and an equivalent amount of base (STEP 1). If sufficient glutaraldehyde is present, the â crease in pH causes a color change in the pH indicator (STEP 2).

STEP 1

$HCO(CH_2)_3CHO + 2Na_2SO_3 + H_2O \rightarrow$

Glutaraldehyde — Sodium sulfite — Water

$(CH_2)_3(CH(SO_3Na)OH)_2 + 2NaOH$

Sulfite addition product — Sodium hydroxide

STEP 2

NaOH + pH sensitive dye ➥ purple dye color

When the concentration of glutaraldehyde is sufficient, a color change from orange to purple occurs on the reagent pad at the end of the strips.

D. Reagents/Storage

The reagent pad at the end of the test strip is composed of paper impregnated with two reactive agents, sodium sulfite and pH-sensitive dye.
Store CIDEX Solution Test Strips in the original bottle with the cap tightly closed. Store at controlled room temperature, 15°-30°C (59°-86°F), and in a dry place.
The shelf life (expiration date) for the unopened CIDEX Solution Test Strips is stamped on the immediate container label. When opening the bottle for the first time, record the date opened in the space provided on the label.

PRECAUTIONS:

- **Do not use any remaining strips 90 days after opening the bottle. Do not leave the test strip bottle open for more than 30 minutes. Improper storage or use of test strips may result in false readings.**

LC-B2920-003 Rev. E
Cidex® Solution Test Strips IFU
Enlarged 125%
Size: 72 x 582mm
Colors: Black
Date: 5/21/04

- **To properly seal the test strip bottle, press down firmly with the palm of your hand on the lid. Please make sure that the bottle is closed completely.**
- **Do not refrigerate or freeze.**
- **Protect strips from exposure to light, heat, and moisture.**
- **Tightly re-cap test strip bottle after each use to minimize exposure to humidity.**

E. Specimen Collection and Preparation

CIDEX Solution Test Strips can be used to test activated solution directly in the tray, bucket or other container holding the solution. When this is not feasible, remove a sufficient volume of CIDEX Solution to fully submerge the CIDEX Test Strip indicating pad area, and place into a clean plastic container (polyethylene or polypropylene). Appropriate safety precautions should be taken according to label instructions and the Material Safety Data Sheet.

F. Directions for Use

1. Ensure that the CIDEX Activated Dialdehyde Solution has been activated according to its own Instructions for Use.
2. Always note the date the bottle was opened and the “do not use after” date in the space provided on the bottle.
3. Ensure that appropriate safety precautions are observed when testing CIDEX Activated Dialdehyde Solution, refer to product labeling and the Material Safety Data Sheet for CIDEX Activated Dialdehyde Solution.
4. Remove one Test Strip from the bottle and replace the bottle cap immediately.
5. Use a watch or timer to monitor the following steps.
6. Timing control is critical to accurate reading.
7. **Completely Submerge** indicating pad at the end of the test strip into the container of the activated solution being tested. Hold for **three seconds and remove.** Do not leave the strip in the test solution for longer than three seconds or “stir” the test strip in the solution. Incorrect dipping technique, such as swirling the test strip vigorously in the solution, will wash off the reagents in the test strip pad. This can cause a lack of purple color formation (FAIL) when testing a solution that will normally test as PASS.
8. **Remove** excess solution from the indicating pad by standing the strip upright on a paper towel. Do not shake the strip after removal. When removing excess solution, incorrect technique, such as violently shaking the test strip and/or blotting the test strip with the pad face down against a paper towel, can remove the reagents and solution. This can cause FAIL results for solutions that will normally test as PASS.
9. **Read** the results of the color reaction present on the indicating pad at **75 seconds after the test strip is removed from the solution.** If read in less than 75 seconds, the color change may be incomplete and may be interpreted incorrectly. If read past 75 seconds, color will gradually change to indicate “FAIL”.

   To indicate an effective concentration of the solution, the indicating pad will be completely purple. Any shade of purple is acceptable; the intensity will vary due to concentration variation. If **any orange** appears on the indicating pad apart from the top line, the solution is below the MEC and should be discarded. Refer to the color chart on the test strip bottle for interpretation of test results. Record the result of the test in a suitable log book.

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See Section I, Test Results Interpretation, for additional important information on the use of this product.

10. **Dispose** of the used Test Strip in a waste bin or per hospital policy.

G. Materials Required

The following materials are not provided with the CIDEX Solution Test Strips but will be needed for the test:

- watch or timer
- paper towel
- a clean polyethylene or polypropylene container will be required to hold the solution sample if the solution cannot be tested directly in the tray, bucket or container in which it is being held.

H. Quality Control Procedures

1. **Preparation of Control Solutions**
   To prepare positive and negative control solutions for testing, first verify that the labeled expiration date for the unactivated solution is appropriate. Activate the solution according to labeling instructions. This freshly activated, full strength solution may be used as a positive control. To prepare a negative control, dilute one part of full strength activated solution with one part of water. Label each control solution appropriately.
2. **Testing Procedure**
   Following the Directions for Use, submerge three test strips in each of the above freshly prepared solutions for three seconds each. Remove. The three strips dipped in the full strength positive control solution should exhibit a complete purple color on the indicating pad at 75 seconds. The three strips dipped in the diluted negative control should either remain completely orange or exhibit an incomplete color change to purple when read at 75 seconds. Refer to the color chart on the test strip bottle for interpretation of results.
3. **Testing Frequency**
   It is recommended that the testing of positive and negative controls be performed on each newly opened test strip bottle of CIDEX Solution Test Strips. After this initial testing, it is recommended that testing of freshly prepared positive and negative controls be performed on a regular basis as established by your own quality control procedures and program. This testing program will serve to minimize errors between different users, use of outdated materials or product that has been improperly stored or handled.
4. **Unsatisfactory QC Test Performance**
   If the results obtained from using the positive and negative controls indicate the test strip is not functioning properly, discard the remaining strips. **Do Not Use Strips.** For technical product information, contact Advanced Sterilization Products at 1-888-783-7723.

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I. Test Results Interpretation

Following the three second submersion in the activated solution being tested, remove excess solution from the pad by standing the strip upright on a paper towel. The CIDEX Solution Test Strip should then be compared to the color chart provided on the test strip bottle at 75 seconds. The entire indicating pad must be completely purple to pass the test indicating an effective concentration of the solution. If any orange appears on the indicating pad apart from the top line, this is a failure, verifying the solution is below MEC and should be discarded.

As the MEC of CIDEX Activated Dialdehyde Solution is approached during its use life, the test strip will give some PASSES and some FAILS. This is due to the safety margin provided by the test strip.

The solution must be discarded if the Test Strip indicates FAIL.

J. Limitations

Although CIDEX Solution Test Strips may give a color reaction with glutaraldehyde-based disinfectants from other manufacturers, their use is limited to the CIDEX Activated Dialdehyde Solution. Disinfectants from other manufacturers may claim different MECs which will lead to inaccurate test results using CIDEX Solution Test Strips.

CIDEX Solution Test Strips will not work with CIDEX® OPA Solution or CIDEXPLUS® Solution.

CIDEX Solution Test Strips will <u>not</u> detect failure to add the activator to the CIDEX Activated Dialdehyde Solution.

K. Performance Characteristics

The performance characteristics of CIDEX Solution Test Strips are based on testing the strips using samples of CIDEX Activated Dialdehyde Solution with known concentrations of glutaraldehyde at the MEC and above the MEC. The analytical method used to determine the glutaraldehyde concentrations in these samples is an analytical titration method[1]. The performance of CIDEX Solution Test Strips has been designed to indicate FAIL 100% of the time when the concentration of glutaraldehyde falls to 1.5%.

The accuracy and sensitivity limit of CIDEX Solution Test Strips is + 0.25%. Thus at concentrations of 0.25% above the MEC, the test strips will indicate FAIL about 25% of the time and PASS about 75% of the time. This provides the user with a high margin of safety.

L. Warnings & Precautions

1. Always follow the Instructions for Use.
2. THIS PRODUCT IS MOISTURE SENSITIVE AND WILL NOT PERFORM PROPERLY IF STORED INCORRECTLY. If the container is left open for more than 30 minutes, discard the Test Strips and use a fresh bottle of new Strips.

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3. Test Strips should not be returned to the bottle after being removed due to their moisture sensitivity - dispose of any unused Test Strips.
4. Keep out of reach of children.
5. Do not ingest the Strip and/or expose it to the eye.
6. Chemical indicators such as CIDEX Solution Test Strips cannot be relied upon as a means of validating the sterilization or disinfection process. Chemical indicators can only verify if the MEC is present.
7. Each Test Strip must be discarded after use and not reused.
8. Ensure that appropriate safety precautions are observed when testing CIDEX Activated Dialdehyde Solution, refer to product labeling and the Material Safety Data Sheet for CIDEX Activated Dialdehyde Solution.

M. Disposal

Dispose of used or expired Test Strips and their bottle in a waste bin or per hospital policy.

N. Bibliography

1. Advanced Sterilization Products
   Standard Test Method Number
   TP-25118-001 (available upon request).

O. How Supplied

PRODUCT CODES	DESCRIPTION	PACKAGE INFORMATION
2920	CIDEX® Solution Test Strips	60 Strips/Bottle 2 Bottles/Shipper
2927	CIDEX® Solution Test Strips	15 Strips/Bottle 2 Bottles/Shipper

Marketed By:

ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.
33 Technology Drive, Irvine CA 92618-9824

Made in UK
For technical information
call 1-888-783-7723.

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Cidex® Solution Test Strips

Composition: CIDEX® Solution Test Strips consist of sodium sulfite and dyes impregnated and dried on filter paper.

STORAGE

IMPORTANT: Keep cap tightly closed. Store bottle at controlled room temperature 15°-30°C (59°-86°F) and in a dry place. **CAUTION:** Do not use after 90 days of opening the bottle.

Marketed By:

ASP ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.

Made in U.K.
For technical information
call 1-888-783-7723

<Insert Date>

Important End-User Customer Notice of Product Obsolescence: CIDEXPLUS® 28 Day Solution

Dear Valued Customer,

In an effort to transition healthcare professionals to the latest ASP products in instrument reprocessing, ASP has made the decision to obsolete CIDEXPLUS® 28 Day Solution, a 3.4% Glutaraldehyde, in 2014. The majority of our customers already choose to use glutaraldehyde-free solutions and we want to support this shift. The ASP mission is to provide best-in-class infection prevention products and solutions for customers and their patients. By supporting our customers' choice to use glutaraldehyde-free solutions, we are doing just that!

Please notify all materials managers and department directors with the following information on part numbers being discontinued in 2014:

Part Number	Description
2683	CIDEXPLUS® 28 Day Solution: 1 Quart, 4/case
2785	CIDEXPLUS® 28 Day Solution: 1 Gallon, 4/case

Distributors will be able to purchase the above two products from ASP until the end of 2013. There may be limited supply available through your distributor in January 2014. Please check with your distributor to find out product availability.

ASP will continue to provide product support for CIDEXPLUS® 28 Day Solution until the remaining product inventory has been used or has expired. In addition, ASP will continue to sell test strips for use with CIDEXPLUS® 28 Day Solution, part number 2924.

Recommended Replacement Products: CIDEX® OPA Solution, Part Number 20390, is trusted by hospitals all the world over for providing cost-effective high-level disinfection for a wide range of endoscopes and other healthcare instruments. CIDEX® OPA Solution features include:

- Glutaraldehyde-free (0.55% *ortho*-phthalaldehyde) high-level disinfecting solution
- Rapid 5-minute soak time at 77 °F/25°C in an automated endoscope reprocessor
- Twelve minute soak time at 68 °F/20°C for manual reprocessing
- Shorter disinfection time than glutaraldehyde
- Low vapor pressure for minimal inhalation exposure risk

If you prefer to use glutaraldehyde, ASP will continue to offer CIDEX® Activated Dialdehyde Solution, Part Number 2266.

For more product information on CIDEX® Solutions, visit our website at www.aspjj.com/us/products/high-level or contact your local ASP representative.

We would like to thank you for your commitment to ASP and for your continued **trust** in the CIDEX® Solutions brand. If you have any questions, please contact 888-783-7723 or visit www.aspjj.com.

Sincerely,

Anthony Bishop

Vice President, Global Marketing

33 Technology Drive, Irvine, CA 92618. Tel: 949.581.5799. Fax: 949.581.5997

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