

CIDEX® OPA Solution, containing 0.55% *ortho*-phthalaldehyde, is a fast and effective way to high-level disinfect a wide range of endoscopes and other semi-critical devices. Follow these steps and refer to the specific CIDEX® OPA Solution label and package insert for complete instructions/information.

Please read and follow the Instructions for Use prior to using CIDEX® OPA Solution for important information, including contraindications, warnings and proper directions for use.

Contraindications

- 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.
- CIDEX® OPA Solution should not be utilized to process instrumentation for patients with known sensitivity to CIDEX® OPA Solution or any of its components.
- CIDEX® OPA Solution should not be used to sterilize heat-sensitive medical devices.

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

ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.
a Johnson & Johnson company

* When used or reused in a legally marketed automatic endoscope reprocessor that can be set to a minimum of 25°C.

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HOW TO USE CIDEX® OPA SOLUTION



1. Personal Protective Equipment

- Personal protective equipment must always be worn when handling contaminated instruments and equipment. Personal protective equipment includes gloves, eye protection and fluid-repellent gown.
- Contact with CIDEX® OPA Solution may discolor skin or stain clothing. If the solution contacts skin, wash with soap and water for a few minutes. The discoloration should disappear within 1 to 2 days. CIDEX® OPA Solution may also stain environmental surfaces such as countertops, walls and floors.
- Once you are wearing personal protective equipment, you are ready to begin the disinfection process.



5. Disinfect

- Immerse clean, dry instruments completely in the CIDEX® OPA Solution.
- Ensure all instruments are completely submersed in CIDEX® OPA Solution, and if applicable, fill all lumens.
- Cover the CIDEX® Solution Tray with a secure lid. Soak instruments for 12 minutes at 20°C to achieve high-level disinfection.
- Excessive soaking time is not recommended as it may result in residues that result in patient allergic reaction or tissue discoloration.
- Use CIDEX® OPA Solution in a well-ventilated area and in closed containers with tight-fitting lids. Failure to use CIDEX® OPA Solution without proper ventilation or engineering controls may result in an allergic reaction, urticaria (hives), or a rash. Use of CIDEX® OPA Solution without proper ventilation may also result in irritation to the respiratory tract and eyes, stinging sensation in the nose and throat or difficulty breathing.



2. Clean Instruments

- The first step in the high-level disinfection process is thorough cleaning. Contaminated instruments must be thoroughly cleaned prior to disinfection.
- 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® OPA Solution is compatible with enzymatic detergents (e.g., ENZOL® Enzymatic Detergent Solution) which are mild in pH, low foaming, and easily rinsed from instruments. Detergents that are either highly acidic or alkaline are not recommended as cleaning agents.
- Following cleaning, rinse instrument surfaces and lumens with large amounts of fresh water to remove residual detergent.
- Remove excess moisture from instruments prior to disinfection. This will help prevent excess water from diluting the CIDEX® OPA Solution below its Minimum Effective Concentration (MEC).
- Refer to instrument manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing.



6. Rinse Instruments

- Following disinfection, 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.

Failure to rinse devices per the Instructions for Use may result in patient side effects, including serious allergic reaction to residues or discoloration of tissues.



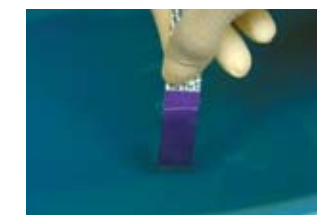
3. Using CIDEX® OPA Solution

- Before using the solution, be sure to read the directions for use on the bottle label and package insert. The shelf life of an unopened bottle of CIDEX® OPA Solution is two years. The solution requires NO activation.
- After opening the bottle, pour CIDEX® OPA Solution into a CIDEX® Sterilizing/Disinfecting Tray or appropriate container. If there is still solution remaining in the bottle, the bottle can be stored up to 75 days. The use of CIDEX® OPA Solution in an automatic endoscope reprocessor must be part of a validated reprocessing procedure. Note: CIDEX® OPA Solution can achieve high-level disinfection in five minutes at a minimum of 25°C in an automatic endoscope reprocessor.*
- It is important to record the date the solution was poured from the original container and the date its reuse life ends (not to exceed 14 days). Blank log book pages are available at www.asppj.com or through ASP Customer Support.



7. Dry

- Dry the instruments. Disinfected equipment should be used immediately or stored in a manner to minimize recontamination.
- See package insert for complete instructions/information on drying flexible endoscopes when using potable water for rinsing.
- Refer to the instrument manufacturer's labeling for additional storage and/or handling instructions.



4. Test

- Concentration of this product during its reuse life must be verified by the CIDEX® OPA Test Strip prior to each use to determine that the concentration of *ortho*-phthalaldehyde is above the MEC of 0.3%.
- It is recommended that CIDEX® OPA Solution be tested before each usage with CIDEX® OPA Test Strips to verify that the appropriate concentration of *ortho*-phthalaldehyde is present.
- CIDEX® OPA Solution must be discarded after 14 days even if CIDEX® OPA Test Strips indicate a concentration above the Minimum Effective Concentration (MEC).



8. Dispose

- CIDEX® OPA Solution can be discarded down hospital and office drains in accordance with local regulations.
- Glycine (free base) may be used as a neutralizer for CIDEX® OPA Solution prior to disposal, if required.