

STANDARD OPERATING PROCEDURE - 2017

CIDEX OPA SOLUTION USED FOR HIGH- LEVEL DISINFECTION

PURPOSE: To establish a standardized policy for the use of Cidex OPA for high-level disinfection of heat-sensitive items that cannot be sterilized any other means.

POLICY: Users of Cidex OPA for high-level disinfection will follow all of the manufacturer's instructions for use of the product.

RESPONSIBILITY: The Chief, Supply, Processing, and Distribution (SPD) is responsible for monitoring all disinfection functions of re-usable patient care items. Routine inspections of areas performing instrument processing will be conducted and processes validated.

BACKGROUND: The Food and Drug Administration (FDA) approved Cidex OPA for the high-level disinfection of non-critical and semi-critical items only. High-level disinfection is not approved for critical items. Classifications are defined by the Centers for Disease Control and Prevention (CDC) as follows:

Non-critical items – Medical devices or patient care equipment that does not ordinarily touch the patient or touches only intact skin.

Semi-critical items – Medical devices or patient care equipment that comes in contact with intact mucous membranes or non-intact skin, but does not normally penetrate body surfaces.

Critical items – Medical devices or instruments introduced directly into the blood stream or into other normally sterile areas of the body.

PROCEDURES:

1. Personnel performing instrument processing must be trained to perform this procedure. Appropriate personal protective equipment (PPE) must be worn when working with contaminated equipment and when using the disinfectant solution. The user must also be familiar with the safety precautions as noted on the Material Safety Data Sheet (MSDS) for this specific solution (refer to the MSDS book for information).
2. **Instruments to be disinfected must be properly cleaned and dried before soaking in the solution.**
3. Record the date within a designated logbook when the container is opened or the solution is poured into a soaking container (see attached sample log sheet). These dates must be visible and affixed to the containers. Note the expiration date assigned by the manufacturer. Once the container is opened, the unused solution in the bottle is good for up to 75 days. Solution used for soaking has an expiration date of no more than 14 days and must be discarded after that time.
4. Each and every day before using the disinfectant, use a test strip to check potency of the

solution. Note the expiration date on the bottle of test strips as imprinted by the manufacturer. Test strips are good for two years in an unopened bottle. Once opened, the date is recorded on the bottle; expiration occurs 90 days after that date. Test the solution as follows:

- A. “Dip the entire indicating pad at the end of the test strip into the container of the Cidex OPA Solution being tested for one second and remove. Do not leave the strip in the test solution for longer than one second or “stir” the test strip in the solution. Incorrect dipping technique, such as dipping much longer than the specified one second and/or swirling the test strip in the 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 PASS.
 - B. Remove excess solution from the indicating pad by standing the strip upright on a paper towel. Do not shake the strip after the 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, which can again cause FAIL results for solutions that will normally test as PASS.
 - C. Read the results of the color reaction present on the indicating pad 90 seconds after the test strip is removed from the solution. If read in **less** than 90 seconds, the color change may be incomplete and may be interpreted incorrectly. **Do not read** the pad **after** 2 minutes, as the color will gradually fade making interpretation difficult. Refer to the visual standard on the test strip bottle for interpretation of test results.”
 - D. Record PASS (+) or FAIL (-) results in the logbook.
5. For manual processing, an item must be immersed for at least 12 minutes at 68 degrees Fahrenheit (20 degrees Celsius) and then, it must be rinsed thoroughly. Three **separate** rinses in large volumes of sterile water (e.g. 2 gallons) must be completed. Discard the rinse water after each rinsing. Flush lumens with a minimum of 100 milliliters (ml) of sterile water.
6. For automatic endoscope reprocessors, immersion time is a minimum of 5 minutes at a minimum of 77 degrees Fahrenheit (25 degrees Celsius).
7. Refer to state and local regulations regarding disposal of disinfectant solution. In many areas, Cidex OPA must be neutralized before disposal. Twenty-five (25) grams of glycine are required per gallon of Cidex OPA to be neutralized. One hour of neutralization must take place before disposal in the sewer system.
8. Documentation of Cidex OPA testing and use will be maintained for purposes of tracking for 36 months.

Reference: Advanced Sterilization Products (ASP). (2003). Cidex OPA: Instructions for use.
Advanced Sterilization Products (ASP). (1999). Cidex OPA solution test strips:
Intended use.