



Ambulatory Clinic Policy and Procedure

Title:	High-Level Disinfection for Reusable Instruments	Policy Number:	7.15
		Version Number:	4
Regulation Reference:	Joint Commission 4.10	Effective Date:	12/2015
		Original Approval:	9/1999

POLICY STATEMENT:

It is the policy of the Texas Tech University Health Sciences Center (TTUHSC) Ambulatory Clinics to provide guidelines for staff using high-level disinfectants, to identify employee safety practices when working with high-level disinfectants and to assist staff to utilize high-level disinfectants in a safe and effective manner.

SCOPE:

This policy applies and will be distributed to all TTUHSC School of Medicine Clinics, also known as Texas Tech Physicians.

PROCEDURE:

Sterilization, by clinic autoclave, Central Sterile, or campus designated process, is required for all instruments or equipment that enter normally sterile tissues or through which blood flows, and /or if patients have a known or suspected infectious/contagious condition.

***NOTE: Contact with CIDEX OPA Solution may stain skin or clothing. If the solution contacts skin, wash with soap and water for a few minutes. The stain should disappear within 1-2 days. Solution may also stain environmental surfaces such as walls, floors and countertops.**

1. Sterilization Process:

<i>Nursing Actions:</i>	<i>Rationale:</i>
a. Test CIDEX OPA solution prior to each use with CIDEX OPA solution test strips. (See #2 below)	Verify that the Minimum Effective Concentration (MEC) of orthophthalaldehyde is present.
b. Don personal protective equipment: <ul style="list-style-type: none"> 1) Gloves-use double gloves or change single gloves frequently. 2) Eye Protection 3) Fluid-repellant gown 	PPE must always be worn when handling contaminated instruments and equipment or when working with chemicals. CIDEX OPA/ any gluteraldehyde solution should be used in a well ventilated area and in closed containers with tight fitting lids. Consult with Safety Services to conduct air quality and air flow testing in areas where gluteraldehyde is used.
c. Thoroughly clean all instruments as per manufacturer's recommendations.	The first step in the disinfection process is through cleaning with a protein-dissolving detergent. Instruments must be opened. Instruments with teeth may need brushing to remove tissue, built up or dried blood.

Nursing Actions:	Rationale:
d. Rinse instrument surfaces and lumens with large amounts of fresh water.	Residual detergent must be removed prior to disinfection.
e. Remove excess moisture from the instruments by drying gently with a lint free cloth.	This will reduce the dilution of CIDEX OPA solution by residual rinse water. Refer to the instrument manufacture's labeling for additional instructions on disassembling, cleaning and leak testing of particular instruments.
f. Read the directions for use on the bottle label and package insert, then pour CIDEX OPA solution into a CIDEX solution tray or appropriate container.	Anyone using any chemical should know about all warnings and precautions associated with the use of the product.
g. Solution left in the bottle may be stored for up to 75 days; provided that the 75 days does not extend past the expiration date on the container. The original container, once open, will have a label affixed to it noting the date it is opened.	Expired solutions may not be relied on to provide effective sterilization.
h. Record the date that the solution was poured from the original container, and the date that it can no longer be reused, not to exceed 14 days.	Record in a log book or on a label affixed to the container.
i. Immerse clean, dry instruments completely in the CIDEX OPA solution.	Ensure that all instruments are completely submerged, fill any lumens with solution and eliminate any air pockets.
j. Cover the CIDEX solution tray securely and soak instruments for 12 minutes at 20 degrees C (68F) or higher.	High-level disinfection is accomplished in 12 minutes. *Note: Critical medical devices intended for use in a sterile area of the body eg: Cataract Surgical Instruments are <u>not</u> to be sterilized using this method.
k. Following removal from CIDEX OPA rinse the device by immersing it in a large volume (eg. 2 gallons) of water. Repeat the rinse process at least twice, for a total of 3 rinses. Each rinse should be done using a fresh bottle of sterile or distilled water per manufacturer's recommendations . Flush all lumens with large volumes-not less that 100ml.	Each rinse should be a minimum of 1 minute in duration unless a longer time is specified by the device manufacturer.
l. Thoroughly dry the instruments.	See manufacturer's instructions for drying flexible endoscopes.
m. Disinfected instruments should be used immediately, or stored in a manner to minimize recontamination.	Refer to manufacturer's labeling for additional storage or handling instructions.
n. Discard CIDEX OPA solution after 14 days, even if the test strips indicate a concentration above the Maximum Effective Concentration (MEC) flush CIDEX container with a large amount of water. Flush drain with water.	CIDEX OPA solution may be discarded down hospital and office drains in accordance with local regulations.

2. Testing the CIDEX OPA Solution: See [7.15.A – CIDEX® OPA Test Strip Usage Instructions](#).

Nursing Actions:	Rationale:
<p>a. Don personal protective equipment:</p> <ol style="list-style-type: none"> 1) Gloves 2) Fluid-repellant gown 3) Face/Eye protection 	<p>PPE must always be worn when working with chemicals.</p>
<p>b. Check the date on the test strip bottle.</p>	<p>Test strips have a 2-year shelf life. Do not use outdated test strips. (Expiration date of the unopened bottle is stamped on the container label.)</p>
<p>c. Record the date that the bottle of CIDEX OPA Test Strips was opened on the container label. The bottle must always be kept tightly closed.</p>	<p>Do not use any remaining strips 90 days after opening the bottle or after the expiration date stamped on the bottle.</p>
<p>d. Prepare the control solutions to perform the Quality Control (QC) test:</p> <ol style="list-style-type: none"> 1) Verify the expiration date on the CIDEX OPA Solution. 2) Full strength CIDEX OPA Solution may be used as the positive control. 3) Dilute 1 part full strength CIDEX OPA Solution with 1 part water for the negative control. 4) Label each solution. 	<p>Positive and negative controls are required to verify the efficacy of the test strips.</p>
<p>e. Following the instructions for use, dip 3 test strips into each of the prepared solutions one at the time for 1 full second. Remove and stand upright on a paper towel.</p>	<p>Ensure that the strip is entirely submerged for 1 full second. Do not stir or shake in the solution.</p>
<p>f. Check for the following test results:</p> <ol style="list-style-type: none"> 1) Positive control solution strips should appear completely purple at 90 seconds. 2) Negative control solution strips should either remain blue or exhibit an incomplete change to purple when read at 90 seconds. 3) Refer to the color chart on the test strip bottle for interpretation of results. 	<p>Complete instructions are included with the test strips. Read these instructions carefully to assure understanding of the procedure.</p>
<p>g. If the results of the QC test indicate that the test strip is not functioning properly, discard the remaining strips.</p>	<p>Contact Advanced Sterilization Products (ASP) at 18887837723 for technical product information.</p>
<p>h. CIDEX OPA Solution will be tested prior to each use.</p>	<p>This ensures that the effective concentration of the disinfectant is present.</p>
<p>i. Discard CIDEX OPA Solution after 14 days, even if the test strips indicate a concentration above the Maximum Effective Concentration (MEC).</p>	<p>CIDEX OPA Solution may be discarded down hospital and office drains in accordance with local regulations.</p>

APPROVAL AUTHORITY:

This policy shall be recommended for approval by the Joint Ambulatory Policy Committee to the Council of Deans.

RESPONSIBILITY AND REVISIONS:

It is the responsibility of the Joint Ambulatory Policy Committee to review and initiate necessary revisions based on collaboration and input by and through Quality Improvement/Performance Improvement, Risk Management and the Office of Institutional Compliance.

RIGHT TO CHANGE POLICY:

TTUHSC reserves the right to interpret, change, modify, amend or rescind this policy in whole or in part at any time to reflect changes in policy and/or law.

CERTIFICATION:

This policy was approved by the Council of Deans on December 3, 2015.

ATTACHMENT:

[7.15.A – CIDEX® OPA Test Strip Usage Instructions](#)

*Note: Test strip instructions downloaded from [Advanced Sterilization Products](#).