THE UNIVERSITY OF TOLEDO MEDICAL CENTER
STERILE PROCESSING DEPARTMENT PROCEDURE

SUBJECT: **PROTOCOL FOR THE TESTING OF HIGH-LEVEL DISINFECTING SOLUTION, THE MANUAL DISINFECTION OF INSTRUMENTS, QUALITY ASSURANCE FOR TEST STRIPS AND ALL ASSOCIATED RECORDKEEPING**

PROCEDURE NO: SP7-4

PROCEDURE STATEMENT

Instrumentation that will come in contact with non-intact skin or mucous membranes may receive high level disinfection. Items used in sterile tissue must receive sterilization.

PURPOSE OF PROCEDURE

To guide the selection process for the sterilization/high level disinfection of surgical instrumentation.

PROCEDURE

FOR THE FOLLOWING PRODUCTS: CIDEX OPA, RESERT AND METRICIDE

Refer to IC Policy # 3364-109-EQP-302 & ANSI/AAMI ST58:2013

PERSONAL PROTECTIVE EQUIPMENT

A mask, face and eye protection and exam gloves should be worn while handling disinfecting solutions.

High-Level Disinfecting Solution

(Cidex-OPA, Metricide and Resert do not require activation.)

1: Open the solution bottle and enter the lot number and date bottle opened on the solution receptacle.
Enter the date opened on the bottle if you do not use the entire contents.

2: Pour desired amount of solution into the designated receptacle.

High-Level Disinfecting Solution Test Strips, Record and QA Procedure

1: Open the test strip bottle and enter the date that the test strip bottle was opened on the bottle.
The test strip bottle expires 90 days after opening.

On the HLD Chemical Test Strip record

1: Enter the test date.
2: Enter the expiration date that is printed on bottle.
3: Enter date bottle opened.
4: Enter date bottle expires. (90 days after opening)
5: Prepare a positive control by filling a small cup with newly prepared full strength solution.
6: Prepare negative control by filling a small cup with 1 part full strength solution and 1 part water.
7: Submerge 3 new test strips in the full strength solution and 3 strips in the half strength solution for 1 second.
8: The strips dipped in the full strength solution should exhibit a complete color change on the indicating pad at 90 seconds. Enter the results on the record.
9: The strips dipped in the half strength solutions should either remain unchanged or exhibit an incomplete color change at 90 seconds. Enter the results on the record.
Refer to the color chart on the bottle for interpretation results.
10: Testing is to occur on each newly opened test strip bottle, 14 days after the bottle has been opened and every 14 days up to 90 days or upon failure of the test strips.
11: If the QA test results are unsatisfactory, discard the test strips and obtain a new bottle.
12: Enter tester initials on the record.

Instrument High-Level Disinfection

1: Thoroughly clean Instrument surfaces and lumens in approved detergent or enzyme cleaner according to manufacturer's instructions. All bioburden must be removed from the instrument surface and lumens.
2: Thoroughly rinse instrument surface and lumens with fresh tap water.
3: Thoroughly dry instruments to be disinfected using a lint-free towel.
4: For Tee Probes, perform a leak test. If the leak test fails, document the failure along with action taken on the Device Procedure Log.
5: **MEC test MUST be performed for each HLD procedure.**

- Obtain an indicator strip and dip indicating pad in solution for 2 seconds, then remove. *(Do not dip pad for longer than 2 seconds or swirl strip in solution.)*
- Remove excess solution from the pad by standing strip upright on a paper towel. *(Do not shake strip after removal.)*
- Read the result of the color reaction after 90 seconds and discard the strip. *(Disregard the top 2mm of the strip as it may not show a complete color change.)*

An effective concentration will completely change the color of the pad. If the pad does not evenly turn color (apart from the 2mm at the top of the pad) the solution is below the MEC and must be discarded.

6: Immerse instruments in activated solution for prescribed time.
(45 minutes for Metricide, 12 minutes for Cidex OPA and 8 minutes for Resert.)
Lumened instruments should be flushed with the disinfecting solution using a sterile syringe prior to immersion.
7: Remove instrument promptly after process time is complete.
8: **Rinsing**

- For Cidex OPA, immerse device in copious amount of water (e.g. 2 gallons,) keeping device immersed for one minute, three times. Flush lumens with copious amount of water.
- For Metricide and Resert, thoroughly rinse the instruments and flush lumens in three separate copious volumes of water. Each rinse should be a minimum of 1 minute in duration. Use fresh portions of water for each rinse.

9: Thoroughly dry device with a clean towel.

Device Procedure log High-Level Disinfectant

All of the following information must be entered into the log sheet for each day's test.
1: Procedure date.
2: Patient Label (Patient name and 6 digit ID number.)
3: Physician or tech performing procedure.
4: Device and serial number (if applicable.)
6: Time instrument is placed in HLD solution along with operator's initials.
7: Time instrument is taken out of HLD solution along with operator's Initials.
8: MEC Test results (Pass/Fail.)
9: HLD Lot number and expiration date.
(14 days for Cidex OPA and Metricide, 21 Days for Resert.)
10: Test Strip Lot number and expiration date.
(90 days from bottle opening.)
11: Leak test results (Pass/Fail) *if applicable.*
12: Temperature of solution.
13: Document failure of MEC or leak test along with action taken.

Cidex OPA and Metricide Solution must be discarded 14 days after container is opened or if MEC test fails.
Resert solution must be discarded after 21 days after container is opened or if MEC test fails.

References: ANSI/AAMI ST58:2005/(R) 2010 IC Policy # 3364-109-EQP-302
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