TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER™
EL PASO

Ambulatory Clinic Policy and Procedure

Title: **CLEANING AND STERILIZATION OF REUSABLE INSTRUMENTS**	Policy Number: **EP 7.20**
Regulation Reference: Joint Commission	Effective Date: **05/2015**

Policy Statement:

It is the policy of the Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) 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 referencing (ANSI/AAMI ST7.9:2010 & A2:2011 & A3:2012).

Scope and Distribution:

This policy applies and is applicable to all TTUHSC El Paso Ambulatory Clinics and personnel conducting any cleaning, decontamination, disinfection, and sterilization. This policy will be distributed to all TTUHSC El Paso ambulatory clinics.

Procedure:

Sterilization by clinic autoclave or through campus designated processes is required for all instruments or equipment that enters or comes into contact with mucous membranes, normally sterile tissues or through which blood flows.

Definitions:

STERILIZATION describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods.

DISINFECTION describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects.

DECONTAMINATION removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.

CLEANING is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products.

CRITICAL DEVICES instruments or devices introduced directly into the human body or into contact with the bloodstream or normally sterile areas. **Sterilization is required**.

SEMI-CRITICAL instruments or devices that come into contact with intact skin or mucous membranes such as respiratory equipment, surgical mirrors, flexible endoscopes, etc. **High Level Disinfection is required**.

CLEANING & DECONTAMINATION	
Goal	Process
1. Don Personal Protective Equipment	All personnel conducting any type of cleaning, decontamination, or sterilization of items must wear the appropriate Personal Protective Equipment, which includes: Goggles or face shields, a non-porous apron, a mask, and heavy duty gloves.

2. Assess the device/instrument	• Place soiled device/instrument in tray for transport. • Spray 5-10 sprays of **(STERIS PRE-Klenz)** onto the device/instrument to prevent drying of any biological material. Make sure all items are opened and disassembled. • Determine if the device to be reprocessed is a **CRITICAL** or **SEMI-CRITICAL DEVICE/INSTRUMENT**. Assess for defects or conditions that may hinder the full sterilization process. Do not process if the device/instrument is defective. **(STERIS PRE-Klenz)** does not require prior to the cleaning/decontaminating process.
3. Clean and Decontaminate the device or instrument	Remove all visible soil, organic and inorganic material, body tissue, blood and body fluid from the surfaces of the device/instrument. Usually completed manually or mechanically using water, detergents or enzymatic products; usually 1/8-1/2 fl. oz. per gallon of the standardized product **(STERIS Prolystica 2x Concentrated Enzymatic Presoak And Cleaner)**. This STERIS product must be used as per manufacturer's instructions with special needs items being processed per their manufacturer's instructions. Make sure the device/Instrument is opened (hinges open) and lumens rinsed and checked for leaks. Refer to the manufacturer's guide for disassembly and cleaning. A sonic bath may be used with this product.
HIGH LEVEL DISINFECTION (for instruments that cannot be exposed to high heat)	
1. Rough Dry/Lumen prep for scopes	Rinse and rough dry surfaces before immersion into the sterilization solution **(STERIS Revital-Ox Resert High Level Disinfectant).** Fill lumens with the sterilization solution. This STERIS product must be used per manufacturer's instructions, undiluted.
2. Sterile Solution preparation	• Verify sterilization solution is within expiration date. • Document the date the original container was opened on the bottle and the log book. • The solution left in the opened contain may be stored up to 90 days from the date it was opened provided the 90 days does not extend past the expiration date. • Pour the desired amount into the second container (soak bucket, AER). Label with product name, date dispensed and expiration date of the solution on this container. This solution may be used up to 21 days, however best practice is to discard after use. • Pour 30 ml of solution into a small container. Confirm the hydrogen peroxide concentration is at the minimum recommended concentration (MRC) of 1.5% is present before each use with the **Revital-Ox Resert Solution Test Strip.** Verify expiration date of the test strip before use. Detailed use instructions in clinic. • Confirm the temperature of the sterile solution is 20 degrees Celsius/68 degrees Fahrenheit. • It is recommended to cover the secondary container to prevent contamination.

3. High Level Disinfection	• Place the pre-cleaned, rinsed and dried device/instrument in the undiluted sterile solution **(STERIS Revital-Ox Resert High Level Disinfectant).** • Immerse device/instrument ensuring all surfaces are in contact with the sterile solution, and lumens are filled with the sterile solution. • Soak the device/instrument for 8 minutes at 20 degrees Celsius/68 degrees Fahrenheit. Timed with a timer. • After the 8 minutes are completed remove the items and follow the manufacturer's instructions for draining the lumens.
4. Final Rinsing	• Thoroughly rinse the device/instrument by immersing completely in sterile water for a minimum of 1 minute, unless longer is specified in the manufacturer's instructions. • Manually flush all lumens with a large volume of sterile water, a (minimum of 100 ml) each, unless otherwise noted. • Maintain aseptic technique during this process.
5. Final Drying	• A final rinse using 70% Isopropyl Alcohol solution to purge each lumen is recommended. This aids in the drying process to decrease waterborne bacteria from colonizing. • Device/instrument must be used immediately or stored in a manner to minimize recontamination.
STEAM STERILIZATION	
1. AUTOCLAVE STERILIZATION	**FOLLOW INSTRUCTIONS 1-3 of Cleaning & Decontamination if sending device/instrument through the AUTOCLAVE process.**
2. LUBRICATION	• **After the Cleaning/Decontaminating** process, place device/instrument into the **STERIS Hinge Free (Milk Bath)** after mixing ONE part Hinge Free with SIX parts distilled or demineralized water for a period of 30-45 seconds. • Remove and allow draining. • Rinsing and drying is NOT necessary.
3. PACKAGING	• Place items in approved packages/wrappers along with appropriate Test Strip Indicators. Make sure all hinged devices/instruments are in the open position. • Log each item in the log book with load number, time, date, required temperature. • Load and operate the AUTOCLAVE per manufacturer's instructions. • After the cycle is complete, allow the appropriate amount of time for the items to dry/cool. Please refer to the manufacturer's instructions to prevent accidental burning. • Strict monitoring, maintenance and cleaning of AUTOCLAVES will be performed and documented per manufacturer's recommendations. • Biological testing will be performed and documented as per manufacturer's recommendations. • All personnel required to operate an AUTOCLAVE must receive proper training before use and training records maintained in the staff's file.

4. SPECIAL ITEMS	• Special Items such as a high designed sterilizer for a specific scope will be strictly managed, operated, and maintained per manufacturer's instructions. • If required, biological testing will be completed and documentation maintained per directions. • A procedure will be written out and displayed in the clinic of use and followed accordingly. • All personnel required to operate the high designed sterilizer must receive proper training before use and training records maintained in the staff's file.
5. Notes	• Do not use Revital-Ox Resert High Level Disinfectant solution as the **FINAL** treatment **PRIOR** to use, the items must be thoroughly rinsed. • Do not mix with other cleaning or disinfecting products together. • Store **(STERIS Revital-Ox Resert High Level Disinfectant)** in the original container at room temperature of 13-30 degrees Celsius/59-86 degrees Fahrenheit. • Devices/instruments must be used immediately or stored in a manner to minimize recontamination.

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Signatory approval on file by:	Michael J. Romano, M.D. Associate Dean of Clinical Affairs Clinic Operations Committee, Chair Texas Tech University Health Sciences Center El Paso		