TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER™
EL PASO

Ambulatory Clinic Policy and Procedure

Title: **DECONTAMINATION OF REUSABLE INSTRUMENTS**	Policy Number: **EP 7.20**
Regulation Reference: Joint Commission, CDC, ANSI/AAMI ST79:2010.	Effective Date: **01/2020**

Policy Statement:

It is the policy of the Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Ambulatory Clinics to provide guidelines for staff performing pre-cleaning, cleaning and decontamination of instruments and to identify employee safety practices.

Personnel/Training:

At TTUHSC El Paso, assigned clinic employees are responsible for cleaning, reprocessing, and preparing reusable devices for patient care. The process should be consistent throughout the campus. This includes standardized reprocessing steps for cleaning, decontamination, and/or sterilization. Written policy and procedure should be established and reviewed regularly.

Detailed step by step instructions for instrument reprocessing should be displayed/available in the processing area. These instructions and any revision to them should be approved by the Infection Control Nurse.

Assigned employees will be trained in these practices during orientation. Ongoing educational programs and annual competencies will be implemented to foster a safe environment for patients and healthcare employees.

Scope and Distribution:

This policy applies and will be distributed to all TTUHSC El Paso Ambulatory Clinics

Definitions:

SPAULDING CLASSIFICATION: The classification system divides medical devices into categories based on the risk of infection involved with their use. This classification system is widely accepted and is used by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), epidemiologists, microbiologists, and professional medical organizations to help determine the degree of disinfection or sterilization required for various medical devices. Three categories of medical devices and their associated level of disinfection are recognized. Critical, semi-critical and Non-critical.

CRITICAL: Instruments or devices introduced directly into the human body or into contact with the bloodstream or normally sterile areas. Such devices should be sterilized (e.g. surgical instruments, biopsy forceps).

SEMI-CRITICAL: Instruments or devices that come into contact with intact skin or mucous membranes and do not ordinarily penetrate sterile tissue. These devices should receive at least High-level disinfection, (e.g. respiratory equipment, surgical mirror, flexible endoscopes).

NON-CRITICAL: Instruments or devices that do not ordinarily touch the patient or touch only intact skin. These devices should be cleaned by disinfection. (E.g. bedrails, blood pressure cuffs).

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PRE-CLEANING: procedure done to remove and loosen debris before manual/automated cleaning is performed.

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.

DECONTAMINATION: Removes pathogenic microorganisms from objects so they are safe to handle (i.e., safe in the context of being reasonably free from a risk of disease transmission).

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

HIGH-LEVEL DISINFECTION (HLD): destruction of all vegetative microorganisms, mycobacterium, small or nonlipid viruses, medium or lipid viruses, fungal spores, and some bacterial spores. Most high-level disinfectants have the ability to sterilize given sufficient exposure time.

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. There are several types of sterilization processes available, including steam under pressure, ozone, ethylene oxide gas, hydrogen peroxide gas plasma (e.g. Sterrad).

The decision on the reprocessing method must be made in accordance with material compatibility, manufacturer's recommendations and national standard and guidelines. For thermostable equipment, sterilization should be preferred to disinfection.

Procedure:

1. Steps:

Step 1- Pre-Cleaning at bedside – **IMMEDIATELY AFTER USE**
• Standard universal precautions must be followed and appropriate Personal Protective Equipment (PPE) should be worn (e.g. gloves and eyewear).
• Make sure all items are opened or disassembled or untightened as allowed per manufacturer recommendations.
• Place soiled device/instrument in transport container, spray evenly with a product intended to loosen soil over device/instruments to prevent drying of secretions/other potential infectious material.
• Assess device for defects or conditions that may hinder the full sterilization process. ***Note:*** ***Do not process*** device/instrument if is defective. Contact manufacturer for specific instructions about decontamination and potential device repair (if applicable).
• Transport device in leak-proof, puncture resistance container with a tight-fitting lid from procedure room to dirty/decontamination room. Make sure container has a visible biohazard label/sticker to allow easy identification that the contents are contaminated and therefore hazardous.
Step 2- Manual Cleaning and decontamination, in dirty/decontamination room.
• Standard universal precautions should be followed at ALL times and appropriate PPE should be worn (e.g. goggles or face shields, long sleeved gown, surgical mask, heavy duty gloves etc.).

- Immerse instrument in prepared detergent solution.
- Enzymatic solution must be used as per manufacturer's instructions:
  -Dilute ⅛ to ½ fl. oz. of solution per gallon of warm water (1 to 4 ml per Litter of warm water).
  -**Clean device for a minimum of 1 minute to remove all visible material or fluids from the surface of the instrument using appropriate brush.**

- A sonic bath may be used with this product.

- Discard disposable brush immediately after use – **"For single use only".**
- Reusable brushes should undergo HLD or sterilization after each use.

- Used enzymatic detergent solution should be **discarded after each use.**

Step 3 - Rinsing

- Following the cleaning process, all Instruments should be thoroughly rinsed with tap water in a basin.

- Use distilled water in a second basin for the final rinse.
- **The rinsing water should be discarded at the end of each rinse**, as it will be contaminated with the cleaning solution.

Step 4 - Lubrication

- Immerse instrument in prepared instrument lubricant **(Milk Bath).** Mixed solution MUST be changed at least every 14 days.
- Hinge-Free solution must be used as per manufacturer's instructions:
  -Shake well before using.
  -Mix one part of Hinge-Free solution with six parts of distilled or demineralized water.
  -Immerse instruments in open position into the solution for 30 – 45 seconds.
  -Rinsing and wiping the instruments is NOT necessary.
  -Remove the instruments and allow them to drain.

Note: Hinge-Free used after every cleaning and before sterilization helps to extend the life or the surgical instrument.

Step 5- Packing

- Place items in approved packages/wraps along with appropriate test indicators/integrator (if applicable).

Step 6- Documentation

- Log device/instrument that will be transported to external Sterile Processing Department (SPD) for sterilization as appropriate.

Additional Notes

- Always follow manufacturer's instructions for all devices and/or solutions**.**
- Do not mix other cleaning or disinfecting products together.

2. Safety considerations
   - Only individuals properly trained in cleaning, decontamination, and handling of chemical solutions should process instruments. Work in a well-ventilated area to prevent formation of vapor. Users should refer to Safety Data Sheet (SDS) for first aid measures.

References:

1- Rutala WA, Weber DJ, and the Healthcare Infection Control Practices Advisory Committee. CDC guideline for disinfection and sterilization in healthcare facilities, 2008. Available at: https://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf (Accessed Nov/Dec 2016).

2- 2012 Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012.

3- Steris products Literature, Products Label and MSDS. Available at: https://www.steris.com/products/cleaners-and-disinfectants (Accessed Nov/Dec 2016).

4- FDA Web site:http://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofsingle-usedevices/ucm133514.htm (Accessed Dec 2016).

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