SECTION	Approval date:	
Infection Control	**Approved by:**	
POLICY AND PROCEDURE	**Effective date:**	
Instrument Sterilization	**Revision date:**	

POLICY:

This site will ensure that all reusable medical instruments are properly sterilized after each use.

PROCEDURE:

I. CLEANING PRIOR TO STERILIZATION

Prior to undergoing the sterilization process, soiled instruments/equipment are thoroughly cleaned, rinsed, dried, and inspected for the presence of dried blood or other debris. Trained personnel will be able to demonstrate or verbally explain procedure(s) used for cleaning prior to sterilization, according to site-specific policy and/or manufacturer/product label directions.

II. COLD CHEMICAL STERILIZATION

The use of liquid cold chemical sterilants shall be restricted to reprocessing devices that are heat-sensitive and incompatible with other sterilization methods. All other items should be heat sterilized (using an autoclave) or disposable. Product manufacturer's directions are strictly followed for instrument pre-soaking treatment, solution preparation, solution exposure procedures, safety precautions (e.g., room temperature, area ventilation), and post-sterilization processes. Sterilization exposure times and solution expiration date/time is communicated to staff. Written site-specific policy/procedures or Manufacturer's Instructions for cold sterilization are available on site for staff reference.

The OSHA Hazard Communication Standard requires manufacturers and importers of hazardous chemicals to develop Material Safety Data Sheets (MSDS) for each chemical or mixture of chemicals. MSDS for cold chemical sterilants shall be readily available on site to staff who work with the products to which they could be exposed. Staff shall attend training classes in safety awareness about the use and exposure to cold chemical sterilants used on site. Personnel are familiar with and is able to recognize signs and symptoms of exposure to cold chemical sterilants used on site. Staff shall be aware of the procedures and are able to perform the appropriate clean up in the event of spillage. The appropriate PPE for cold chemical sterilant clean-up shall be readily available.

III. AUTOCLAVE/STEAM STERILIZATION

The autoclave manufacturer's directions are strictly followed for instrument pre-cleaning, machine loading, operation safety precautions, minimum time-temperature criteria, and post sterilization processes. Written operating procedures for autoclave are available on site to staff. If instruments/equipment are transported off-site for sterilization, equipment-handling and transport procedures are available on site to staff.

IV. AUTOCLAVE MAINTENANCE

A. The autoclave is maintained and serviced according to manufacturer's guidelines. The autoclave is serviced annually by a qualified technician, if the manufacturer's guidelines are not available. A dated sticker indicating the maintenance date will be placed on the autoclave or a service receipt will be kept on file to indicate documentation of mechanical problems, result/outcome of routine servicing, calibration, and repairs.

B. An autoclave instrument sterilization log shall be kept on file and shall include the following:
   - Date
   - Time
   - Duration of run cycle
   - Temperature
   - Steam pressure
   - Load identification information
   - Operator of each run

V. SPORE TESTING

A. Autoclave spore testing is performed *at least monthly*, unless otherwise stated in the manufacturer's guidelines. Spore testing reports shall be maintained on file and shall include the following:
   - Date
   - Results
   - Types of spore test used
   - Person performing/documentation test results

B. For positive spore tests, the autoclave is removed from service immediately until inspection is completed and a negative retest occurs. The following procedures shall be followed with a positive spore test:
   1. **Report** problem to Office Manager or Doctor
   2. **Repair** autoclave
   3. **Retrieve** all instruments sterilized since last negative spore test
   4. **Re-test** autoclave
   5. **Re-sterilize** retrieved instruments

VI. STERILE PACKAGES

A. Storage areas for sterilized packages are maintained clean, dry, and separated from non-sterile items by a functional barrier (e.g., shelf, cabinet door, and drawer).

B. Sterilized package labels include:
   - Date of sterilization
   - Load run identification information
   - General contents (e.g., suture set) – each item in a sterile package need not be listed on the label if a master list of package contents is available elsewhere on site
   - Identity (initials or signature) of staff member who sterilized the instruments

C. Maintenance of sterility is event related, not time related. Sterilized items are considered sterile until use, unless an even causes contamination. Sterilized items are not considered sterile if package is opened, wet/moist, discolored, or damaged. Compromised packages shall be removed from sterile package storage area and immediately, repackaged, relabled and resterilized.

D. This site's process for routine evaluation of the integrity and condition of sterilized packages is as follows:

   ☐ Monthly inspection of sterile packages by assigned personnel

   ☐ Other: _____