PCP:	Page 1 of 3
SECTION: Infection Control	
POLICY AND PROCEDURE: Instrument Sterilization	Approved date: _____ Approved by: _____ Effective date: _____ Revised date: _____ Revised date: _____

POLICY:

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

PROCEDURE:

I. CLEANING PRIOR TO STERILIZATION

A. 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

A. 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. (See FDA Cleared Sterilants and High Level Disinfectant list attached.)

III. AUTOCLAVE/STEAM STERILIZATION

A. 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, results/outcome of routine servicing, calibration, and repairs.

B. An autoclave log will be kept on file and will 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 will be maintained on file and will include the following:
- date
- results
- types of spore test used
- person performing/documenting 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 will be followed with a positive spore test:

VI. (REPORT/REPAIR/RETRIEVE/RETEST/RE-STERILIZE)
- ***report*** problem to Office Manager or Doctor
- ***repair*** autoclave
- ***retrieve*** all instruments sterilized since last negative spore test
- ***re-test*** autoclave
- ***re-sterilize*** retrieved instruments

VII. 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, drawer).

B. Sterilized package labels include:
   - date of sterilization
   - load run identification information
   - general contents (e.g. suture set)

C. Each item in a sterile package will not be listed on the label if a master list of package contents is available elsewhere on site. It is understood that maintenance of sterility is event related, not time related. Sterilized items are considered sterile until use, unless an event causes contamination. Sterilized items are not considered sterile if package is opened, wet/moist, discolored or damaged, and should be kept removed from sterile package storage area. This site has a process for routine evaluation of sterilized packages.