SAN FRANCISCO HEALTH PLAN
Here for you

Policy and Procedure

Policy Name:	Sterility of Equipment		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	California Department of Health Care Services under Title 22, California Code of Regulations, Section 53230. (Requires the review and certification of Primary Care Practitioner (PCP) sites.) Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review		

Policy:

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

Definitions:

- Cold/Chemical Sterilization/High Level disinfection: 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 procedures for cold sterilization and /or high level disinfection are available on site to staff. Centers for Disease Control and Prevention (CDC), the use of liquid chemical germicides to sterilize instruments ("cold sterilization") are limited. Sterility is not verified or assured with cold chemical sterilization and/or high level disinfection. The first choice is always heat sterilization. The CDC refers to heat sterilization as "the method of choice when sterilizing instruments and devices. If an item is heat sensitive, it is preferable to use a heat-stable alternative or disposable item." The use of liquid chemical sterilants should be restricted to reprocessing devices that are heat-sensitive and incompatible with other sterilization methods. All other items should be heat sterilized or disposable.
- Control Methods and Work Practices to prevent or reduce exposure to the cold chemical sterilants. Cold chemical sterilants have toxic properties and are hazardous. Cold chemical sterilants must be used strictly in accordance with the manufacturer's directions. Always consult the manufacturer for safety precautions and MSDS information. The appropriate PPE must be use to avoid inhalation or skin contact exposure to during the cold chemical sterilization/high level disinfection process.
- Control Methods and Work Practices to prevent or reduce exposure to the cold chemical sterilants. Cold chemical sterilants have toxic properties and are hazardous. Cold chemical sterilants must be used strictly in accordance with the manufacturer's

directions. Always consult the manufacturer for safety precautions and MSDS information. The appropriate PPE must be use to avoid inhalation or skin contact exposure to during the cold chemical sterilization/high level disinfection process.
Examples of chemicals include glutaraldehydes (Cidex), peracetic acid and hydrogen peroxide-based solutions. Glutaraldehyde is a common cold chemical sterilant. Exposure to glutaraldehyde can cause the following health effects: throat and lung irritation, breathing difficulty, nose irritation, nosebleed, burning eyes and conjunctivitis, rash, hives, headaches, and nausea. Exposure to glutaraldehyde may be prevented or reduced by using the following control methods and work practices: use local exhaust ventilation, keep glutaraldehyde baths under a fume hood where possible, avoid skin contact (use appropriate PPE-gloves and aprons made of nitrile or butyl rubber, wear goggles and face shields), use only enough sterilants to perform the required sterilization procedure, seal or cover all containers holding the sterilants, and attending training classes.

- Cold Chemical Sterilants Spillage: .Staff should attend training classes in safety awareness about the use and exposure to cold chemical sterilants used on site. Staff is familiar with and is able to recognize signs and symptoms of exposure to cold chemical sterilants used on site. Staff should be aware of procedures for clean up in the event of cold chemical sterilants spills. The appropriate PPE for cold chemical sterilants clean up should be readily available.
- Autoclave/Steam Sterilization: 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. Documentation of sterilization loads includes: date, time and duration of run cycle, temperature, steam pressure, and operator of each run. If instruments/equipment are transported off-site for sterilization, equipment-handling and transport procedures are available on site to staff. Documentation of instruments and personnel transporting must be maintained.
- Autoclave Maintenance: Autoclave is maintained and serviced according to manufacturer's guidelines. Documentation of maintenance should include: mechanical problems, inspection dates, results/outcome of routine servicing, calibration, repairs, etc. Note: If the manufacturer's guidelines are not present on site, then the autoclave is serviced annually by a qualified technician. A dated sticker on the autoclave or a service receipt is acceptable documentation of appropriate maintenance.
- Spore Testing: Autoclave spore testing is performed at least monthly, unless otherwise stated in manufacturer's guidelines. Documentation of biological spore testing includes: date, results, types of spore test used, person performing/documenting test results. Written procedures for performing routine spore testing and for handling positive spore test results are available on site to staff. For positive spore tests, the autoclave is removed from service immediately until inspection is completed and a negative retest occurs. Procedures include: report problem, repair autoclave, retrieve all instruments sterilized since last negative spore test, re-test autoclave and re-sterilize retrieved instruments (Report/Repair/Retrieve/Retest/Re-sterilize). Biologic spore test products vary, and are designed for use based on specific autoclave type. Biologic control testing challenges the autoclave sterilization cycle with live, highly resistant, nonpathogenic spores. If spores are killed during processing, it is assumed that all other microorganisms are also killed and that the autoclave load is sterile.
  Note: Documentation of monthly spore testing must be maintained onsite for sterilization performed offsite.
- Positive Mechanical, Chemical, and/or Biological Indicators: Sterilization failure can occur for reasons such as slight variation in the resistance of the spores, improper use of the sterilizer, and laboratory contamination during the culture. Sterility is not verified or assured with cold chemical sterilization. Autoclave/steam sterilization offers three methods of monitoring the

sterilization process: mechanical (time, temperature, pressure in the sterilizer), chemical (internal and external indicator on the package which suggest that the sterilizer was functioning properly), and biological (spore test of device). Staff should adhere to site-specific protocol and/or manufacturer/product label for management of positive indicator (s).

- Package and Storage of sterilized items: Following the sterilization process, medical and surgical devices must be handled using aseptic technique in order to prevent contamination. Storage areas for sterilized packages are clean, dry and separated from non-sterile items by a functional barrier (e.g., shelf, cabinet door, and drawer). Sterilized package labels include date of sterilization, load run identification information, and 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.
- Storage of sterilized packages: Storage areas for sterilized packages are clean, dry and separated from non-sterile items by a functional barrier (e.g., shelf, cabinet door, and drawer). 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. Site has a process for routine evaluation of sterilized packages.

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.

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 is 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

Monthly cleaning per manufactures recommendations. This includes the recommended cleaning solutions for the Autoclave

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, and 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

First Name Last Name – Title	Date
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