SAN FRANCISCO HEALTH PLAN
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Policy and Procedure

Policy Name:	Cold Chemical Sterilization		
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 or any superseding APL 29 CFR 1910.1200, 1915.99, 1917.28, 1918.90, 1926.59, and 1928.21. 29 CFR 1910.1030(d)(3)(i), 29 CFR 1910.1030(d)(3)(ii), 29 CFR 1910.1030(d)(4)(ii)(A), 29 CFR 1910.1030(d)(4)(iii)(B), 29 CFR 1910.132, 29 CFR 1910.134		

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 used 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.
- 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.

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.COLD/CHEMICAL STERILIZATION PROCESS

A. Ensure the date the chemical sterilant was opened is included in the product container

B. Use _____(name of cold chemical sterilant/s)

C. Clean, rinse and dry reusable instruments to remove any dried blood or other debris using insert products

D. Pour cold chemical sterilant into a container large enough to accommodate instruments, wear _____ (list PPE per product instructions)

E. Completely submerge instruments in container. (Scissors should be opened to ensure cleaning between blades).

F. Close the container lid and label the container.

G. Document the following on the cold chemical sterilization log: solution name, date and time, and staff initial

H. Leave items soaking for _____ following the recommended processing time according to product guidelines.

I. Remove items from the container using sterile gloved hands or sterile transfer forceps.

J. Pour sterile water over and through the items until they are completely rinsed of the chemical solution.

K. Place the sterile items on a sterile towel and dry them with another sterile towel.

L. Package the items in sterile wraps.

M. Document date of sterilization and content on sterilized package

N. Change the chemical sterilant from the cold chemical cleaning container every _____.

References:

- 29 CFR 1910.1200, 1915.99, 1917.28, 1918.90, 1926.59, and 1928.21.
- 29 CFR 1910.1030(d)(3)(i), 29 CFR 1910.1030(d)(3)(ii), 29 CFR 1910.1030(d)(4)(ii)(A), 29 CFR 1910.1030(d)(4)(iii)(B), 29 CFR 1910.132, 29 CFR 1910.134
- CDC's Guidelines on other sterilization methods, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/other-methods.html
- CDC guidelines on sterilizing heat sensitive dental instruments, available at: https://oshareview.com/2013/10/cdc-guidelines-sterilizing-heat-sensitive-dental-instruments-dental-infection-control/
- CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.html
- Glutaraldehyde exposure and safety tips, refer to the CDC guidance, available at: https://www.cdc.gov/niosh/docs/2001-115/default.html
- CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf
- CDC Summary of Recommendations regarding Disinfection and Sterilization, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html

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Appendix - Copy of MSDS sheets for all cold chemicals used