UCSF Health
UCSF MEDICAL CENTER

Processing and Storage of Reusable Patient Care Devices

POLICY 4.11
Patient Care
Processing and storage of reusable patient care devices
Issued: 12/2024
Last Approval: 12/24

Office of Origin: Hospital Epidemiology and Infection Prevention

I. PURPOSE

A. To ensure that reusable patient care devices are processed and stored in a manner that prevents contamination, protects patient and staff safety, and maintains device functionality.

II. REFERENCES

A. Centers for Disease Control and Prevention. Guideline for disinfection and sterilization in healthcare facilities, 2008. U.S. Department of Health and Human Services. https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/?CDC_AAref_Val=https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

B. American National Standards Institute, & Association for the Advancement of Medical Instrumentation (2017). Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

C. Healthcare Infection Control Practices Advisory Committee. Core infection prevention and control practices for safe healthcare delivery in all settings. November 2022. https://www.cdc.gov/infectioncontrol/guidelines/core-practices/index.html

D. UCSF Medical Center Hospital Epidemiology and Infection Prevention Policy 1.1 Standard Precautions and Transmission-Based Isolation

E. Hospital Epidemiology and Infection Prevention Agents Policy 5.5 Available for Disinfection and Antisepsis

F. UCSF Medical Center Administrative Policy 1.05.01 Soiled Instrument Handling (Outside of Operative Areas

G. UCSF Medical Center Endoscopy Department Policy 01.10.20 Endoscopy: Cleaning and Decontamination

H. UCSF Medical Center Endoscopy Department Policy 02.10.20 Automated Endoscope Reprocessing (AFR)

I. UCSF Medical Center Endoscopy Department Policy 02.10.20 Manual High-Level Disinfection

J. UCSF Medical Center Administrative Policy 6.03.21 Reprocessing of Single-Use Disposable Medical Devices

K. UCSF Medical Center Nursing Procedure Trophon 2 Disinfection Ultrasound Probes

L. UCSF Medical Center Sterile Processing Department Policy 04.10.20 Transportation and Storage of Sterile, Processed, or Contaminated Items

M. UCSF Medical Center Sterile Process Department Policy 03.04.20 Sterilization Process Failure

N. UCSF Medical Center Hospital Epidemiology and Infection Prevention Policy 7.4 Patient (and/or visitor) exposure to blood or body fluids

III. DEFINITIONS

A. **Cleaning**: The removal of visible dirt, soil, and any other material. Thorough cleaning is needed for effective disinfection, high-level disinfection, or sterilization.

B. **Disinfection**: A process that kills or inactivates all microorganisms except for some spore forms.

1. **High-Level Disinfection (HLD):** Kills vegetative bacteria, mycobacterial species, fungi, lipid and non-lipid enveloped viruses, but does not reliably destroy prions or large quantities of bacterial spores.

2. **Low-Level Disinfection:** Kills most vegetative bacteria, fungi, and lipid enveloped viruses. Will not reliably kill spores or nonlipid viruses and is sometimes less active against some Gram-negative bacteria (e.g., Pseudomonas) and mycobacterial species.

C. **Manufacturer's Instructions for Use (MIFUs):** In compliance with the FDA's labeling requirements, manufacturers of medical devices provide specific instructions for cleaning and disinfection or sterilization. MIFUs include the steps required for cleaning, disinfection (including the level of disinfection) or sterilization, frequency of processing, the products that are compatible for use the device/instrument, and other device or instrument management requirements. Requirements may include updated practice recommendations issued through manufacturers' communications.

D. **Point-of-use (POU) cleaning**: Cleaning of items that is performed at the location where the items were used (e.g., cleaning surgical instruments in the surgical suite after they are used in a procedure and before they are transported for reprocessing) to remove excessive gross soiling in order to prevent hardening of debris or the development of biofilm.

H. **Single-use device**: A device labeled by the manufacturer as being for only a single use.

E. **Spaulding classification/categories of patient care items:** According to the Spaulding classification, the level of processing required is based on the nature of the item requiring processing and the manner in which it is to be used:

1. **Critical:** Enters sterile tissue. These items should be sterile and when reused must undergo sterilization.

2. **Semi-critical:** Encounters mucous membranes or non-intact skin. These items when reused must undergo high-level disinfection at minimum or sterilization.

3. **Non-critical:** Encounters intact skin. These items should be low-level disinfected.

F. **SPD**: Sterile Processing Department

G. **Sterilization**: A process that kills all microorganisms (bacteria, viruses, spores and fungi).

1. Required for critical devices (e.g., instruments that enter the vascular system or contact normally sterile tissue).

IV. POLICY

A. Reusable patient care devices must be processed and stored in accordance with evidence-based guidelines and MIFU to ensure safe patient care and to minimize the risk of healthcare-associated infections resulting from device contamination.

1. Applies to all UCSF Medical Center staff and learners who handle reusable patient care devices that require cleaning, high-level disinfection, or sterilization.

V. PROCEDURES

A. Clean and sterile devices must always remain separated from soiled/contaminated devices.

B. Only devices that are FDA-labeled as reusable are reprocessed at UCSF Health

1. See Policy 6.03.21 Reprocessing of "single-use" disposable medical devices for details.

C. Adhere to all MIFUs.

1. Services/clinical areas purchasing devices are responsible for reviewing and ensuring adherence to all MIFU.

a. Prior to purchasing devices or accessories, the purchasing service/clinical area should ensure that the equipment, materials, physical space, resources, and expertise needed to meet the MIFU are available.

b. If there is lack of clarity or ambiguity in the MIFU, services/clinical areas must ensure that these are resolved through the UCSF Health Product Supply, Equipment Oversight and Procurement review process prior to purchasing.

D. Point-of-use (POU) cleaning and transport

1. Reusable devices and instruments should be opened and disassembled (e.g., open all hinged instruments) and sprayed/moistened at the POU with a hospital-approved pretreatment foam/gel or by immersion in an enzymatic solution immediately after use with the goal of keeping instruments from drying until transport to SPD.

2. POU cleaning of channeled endoscopes should include flushing of channels with sterile water or an enzymatic solution.

3. Adhere to the UCSF Medical Center Administrative Policy 1.05.01 Handling of soiled instruments (outside of perioperative areas) policy.

4. Adhere to the surgical Instrument Care and Handling Procedure for handling of soiled surgical instruments.

E. Low-level disinfection

1. Reusable non-critical medical devices (e.g., glucometers, oximeter probes) must be cleaned and disinfected according to MIFU which may include cleaning after each use or when visibly soiled.

2. Use a hospital-approved disinfectant that is consistent with the device's MIFU. See the UCSF Medical Center HEIP Policy 5.5 Agents available for disinfection and antisepsis for approved disinfectants.

a. If a hospital-approved disinfectant consistent with MIFU is not available, consultation with Hospital Epidemiology and Infection Prevention (HEIP) is required.

3. All staff using hospital-approved disinfectants are responsible for adhering to directions for use on the product labeling, including contact time.

F. High-level disinfection (HLD)

1. Devices must be cleaned according to MIFU and visually inspected for residual soil prior to HLD.
2. Endocavitary ultrasound probes
    a. For endocavitary ultrasound probes undergoing HLD using Trophon devices, follow UCSF policies and protocols outlined in the Nursing Procedure Trophon 2 Disinfection of Ultrasound Probes
3. All semi-critical devices must at minimum undergo HLD. See below for situations where sterilization is strongly recommended or required.
    a. Flexible endoscopes, especially lumened endoscopes (e.g., duodenoscopes, bronchoscopes), that are MIFU-approved for sterilization using methods available through UCSF SPD should ideally undergo sterilization.
    b. Flexible endoscopes used as critical devices (i.e., entering sterile body cavities, tissues, or vascular spaces) should undergo sterilization using MIFU-approved methods. If sterilization is not an option, these devices must at minimum undergo HLD.
    c. Sterilization is required for all endoscope accessories that penetrate mucosa (e.g., biopsy forceps, sphincterotomes).
    d. See additional UCSF Endoscopy policies and procedures for details.

G. Sterilization

1. All instrument sterilization must be performed by the UCSF SPD.
2. Devices must be cleaned according to MIFU and visually inspected for residual soil prior to sterilization.
3. The sterilization process is monitored using a combination of mechanical, chemical, and biological indicators to ensure the effectiveness of the sterilization process in accordance with the sterilizer or sterilizer accessory MIFU. See SPD policies for specific sterilization processes for details.
4. If immediate-use steam sterilization is required, adhere to the Expedited Sterilization/Immediate Use Steam Sterilization policy.

H. Storage of devices and equipment following HLD or sterilization

1. Follow MIFU and UCSF policies and protocols for storage of devices and equipment following HLD or sterilization.
    a. Devices must be thoroughly dried prior to storage or reuse in accordance with MIFU.
2. All devices must be stored in a manner that protects them from damage or contamination.

I. Response to reprocessing errors or failures

1. SPD staff will follow the Sterilization Process Failure policy in the event of a reprocessing error or failure.
2. If there is concern for possible patient or healthcare worker exposure, refer to Policy 7.4 Patient (and/or visitor) Exposure to Blood or Body Fluids.

J. Training

1. Each clinical unit/area is responsible ensuring that staff are trained to adhere to the components of this policy that are relevant to their job activities.

VI. RESPONSIBILITY

Questions about the implementation of this policy should be directed to UCSF Hospital Epidemiology and Infection Prevention (HEIP) and/or SPD.

VII. HISTORY OF POLICY

Approved: xx/xxxx