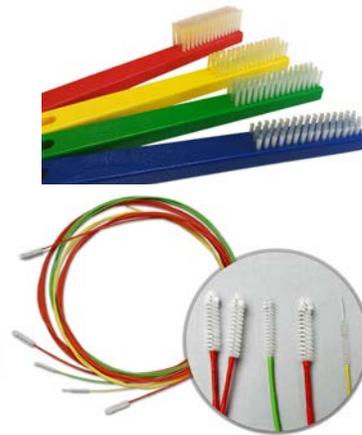


Effective Cleaning of Medical Devices



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Decontamination
and Reprocessing
of Medical Devices
for Health-care
Facilities



Decontamination and Reprocessing of Medical Devices for Health-care Facilities

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One can clean without sterilizing,
but one cannot sterilize without cleaning.

Why should all medical devices be thoroughly cleaned before processing?

- Devices and instruments used with patients or for operations are covered with blood, body fluids and tissue.
- Devices touch with chemicals and fluids, dirt and dust, especially hinged instruments and hollow tubes.
- Before decontamination, used devices are prepared at point of use to ensure their safe transport and a minimal risk to CSSD staff.

Point-of-Use Preparation

- Objectives: To prolong the life of medical devices and surgical instruments
- Dried blood and saline can cause the decomposition of stainless steel and make instruments more difficult to clean.

Guidelines for Point-of-Use Preparation

- Wear personal protective equipment (PPE)
- Remove any linen and disposable items and dispose appropriately
 - Sharps (blades, needles) should be correctly discarded
 - Segregate sharps that can cause injury
- Remove gross soil from instruments by wiping with a damp clean cloth
- Pre-cleaning (e.g. soak or spray) prevents soil from drying on devices and easier to clean

Guidelines for Point-of-Use Preparation

- Cleaning products should be appropriate for medical devices and approved by the device manufacturer.
- If detergent-based products are used, ensure that they are mixed to the **correct in-use dilution**.
- Avoid prolonged soaking of devices.

Guidelines for Point-of-Use Preparation

- Do **not use saline** to soak devices as it can damage devices.
- Contaminated items should be contained in dedicated, fully enclosed, leak- and puncture-proof containers prior to transport
 - Soiled instruments should be opened and kept moist
 - Spray with a specific **enzymatic spray** or **cover with a moist towel with water or foam, spray, or gel.**
 - Do not transport used devices in containers with water as water is a splash hazard.

Guidelines for Point-of-Use Preparation

- Do not soak used instruments in disinfectant before cleaning.
 - May **damage/corrode** the instruments.
 - Disinfectant may be **inactivated** and become a source of microbial contamination and formation of biofilm.
 - May pose a **risk to personnel** and result in inappropriate handling and accidental damage.
 - May contribute to the development of **resistance** to disinfectants.

Prepared tray with surgical instruments ready for transportation to CSSD



Cleaning

- Cleaning: Removal of visible soil, organic and inorganic material from devices and surfaces.
- Cleaning is essential before disinfection and sterilization.
- Inorganic and organic materials on instruments interfere with the effectiveness of disinfection and sterilization processes.
- Deposits of dust, soil and microbial residue on equipment can contribute to hospital-associated infections.

Fundamental Roles of Cleaning

- Cleaning is **the first step in reprocessing** devices after use.
- Failure to properly clean may allow foreign material located outside and inside of the device to hinder disinfection and/or sterilization processes.
- Cleaning is accomplished by **manual** cleaning with detergent and water, brushing or flushing, or by using **ultrasonic and/or washer disinfectors**.

Effects of Not Properly Clean Devices

- Risk of **blood-borne virus transmission** (HIV, HBV, HCV, Ebola)
- Sputum and mucous residue (TB and other pathogens)
- **Biofilm formation** in the lumens, thread of screws and difficult to reach areas.
- Biofilm protects bacteria by covering them with an impenetrable layer of mucous and deposits (e.g. *Pseudomonas aeruginosa*).
- **Hard water**, mineral and calcium deposits, devices lose efficiency and function.

Effects of Not Properly Clean Devices

- Not removing detergent and chemical build-up lead to the destruction of integrity of the device or its coating.
- Devices cannot be disinfected or sterilized in the presence of dirt and organic matter as poor penetration of chemicals occurs.
- Inactivation of some disinfectants by organic matter
- Allergic reactions in patients
- Endotoxin and pyrogen release

Factors that Affect Efficacy of Cleaning

- Amount and type of soil present. Detergents can become diluted or ineffective in the presence of soil.
- **Water quality and temperature:**
 - Some cleaning chemicals are used at specific temperatures
 - Poor water quality might deposit toxins on medical devices
 - Water hardness (excess dissolved minerals) can alter the effectiveness of detergents and can cause spotting and leave deposits on medical devices.

Staff Training

- Personnel who perform cleaning should be trained in the use of all equipment, chemicals and tools.
- **Personnel must**
 - Be familiar with medical devices
 - Know which cleaning method is appropriate
 - Know how to adequately clean each specific device (e.g. lumens, disassembly and re-assembly of items)

Cleaning Chemicals (Detergents)

- Follow the manufacturer's recommendation for
 - Type of soil which the detergent is effective
 - Compatibility with the device to be cleaned
- Select appropriate detergents for an ultrasonic cleaner



Cleaning Chemicals (Detergents)

- A mild alkaline detergent is preferred for manual cleaning, ultrasonic cleaning, or washers.
- Mild alkaline detergents (pH range, 8.0 - 10.8) are more efficient cleaning agents for surgical instruments than neutral pH detergents or surfactant-based detergents.
- Only use appropriate detergents for instrument cleaning.
- Detergents used for home cleaning or laundry use are not suitable for the cleaning medical devices.

Using Enzymatic Detergents

- Gross soil should be removed by rinsing with detergent and water.
- If blood or exudates have dried or hardened, soak in a warm enzymatic solution.
- Enzymatic detergents break down protein matter, may be used for sensitive equipment as manufacturer's IFU.
- Enzymatic detergents are not disinfectants.
- Rubber or nitrile gloves are recommended when handling enzymatic solutions - enzymatic detergents will degrade latex gloves.



Preparation of Detergents

- Detergents, function best at their optimal dilution.
- Making a stronger solution does not necessarily mean it will be more effective.
- For effective cleaning, it is essential that the detergents are prepared at the concentration recommended by manufacturer.
- To achieve the correct concentration, the correct volume of concentrated detergent has to be added to the correct volume of water at the correct temperature.

Cleaning Methods

- Manual cleaning
- Mechanical cleaning
 - Ultrasonic cleaners
 - Automated washers or Washer- disinfectors



Manual Cleaning

Indications for manual cleaning

- Medical devices that cannot be immersed (i.e. electrical or battery-powered devices)
- Devices that require special cleaning (i.e. narrow bore lumen or delicate devices)
- Pre-cleaning prior to mechanical cleaning in ultrasonic and/or washer-disinfector

Manual Cleaning

- Devices should be **disassembled** so that all surfaces can be cleaned.
- Ensure that the **detergents** used is **compatible** with the devices.
- **Submerge devices** during cleaning to minimize aerosolization.

Manual Cleaning

- Remove gross soil using tools (brushes and single-use cloths)
- Clean lumen devices with an appropriate brush, flush with a detergent solution and rinse with potable water.
- Check devices with lumens for obstructions and leakage.



Immersion Method



- Add appropriate quantity of detergent following IFU.
- Clean devices under water surface
- Use **soft (nylon) bristle brushes** so that the surface of the instrument is not damaged
- Brushes used to clean lumens must be the **same diameter** as the instrument to ensure that all internal surfaces can be reached.
- Brushes must also be **long enough** to exit the distal end of the instrument.



Immersion Method

- Brushes should be thermally disinfected and dried at the end of the day.
- If this is not possible, brushes should be cleaned and left dry.
- Brushes must be replaced when damaged.
- In another sink/basin, immerse the device in clean purified water and rinse the device thoroughly.
- Mechanically dry; if this not available, air-dry or hand-dry using a disposable clean, non-lint cloth.



Non-Immersion Method

- Clean the device by wiping surfaces thoroughly with a disposable, clean, non-lint cloth and detergent
- Ensure that moisture does not enter critical areas of the device (e.g. power connections) until all visible soil is removed.
- Rinse the device by wiping surfaces thoroughly with a damp, disposable, clean, non-lint cloth until all detergent residue is removed

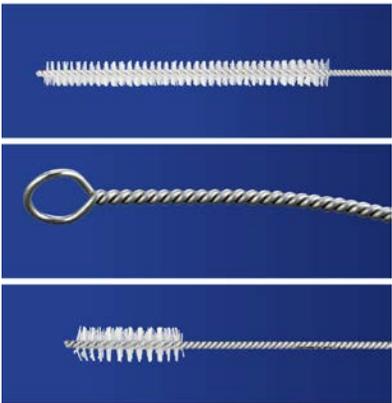
Non-Immersion Method

- Mechanically dry; if this is not available or not recommended by the manufacturer, air-dry or hand-dry using a disposable clean, non-lint cloth.
- Disposable cloths should be discarded after each use.
- Detergent solution and water should be changed at each cleaning session and when visibly soiled.
- Chemical disinfection prior to cleaning is unnecessary, ineffective and of little value in the presence of organic matter.

Rinsing

- Rinsing after cleaning is necessary to remove soil and residual detergent.
- Perform the final rinse of lumens of intravascular/ intrathecal devices with commercially-prepared, sterile, pyrogen-free water or reverse osmosis processed water.
- Distilled water is not necessarily sterile or pyrogen-free.

Care of Cleaning Tools



- Cleaning tools need to be cleaned, disinfected and dried after every shift.
- Inspect brushes and other cleaning equipment for damage after each use and discard if necessary.
- The use of single-use cleaning tools is recommended.
- If reusable tools are used, they should be disinfected at least daily.

Mechanical Cleaning

Advantages of using automated process include:

- ❖ Faster throughput of devices
- ❖ Greater consistency of results
- ❖ Higher standards for cleaning that can be validated
- ❖ Less risk to personnel

Mechanical Cleaning

Important considerations when using mechanical cleaning equipment include:

- Staff training
- Water quality
- Cleaning chemicals' dilution
- Equipment is in proper working condition

Washer disinfectors and ultrasonic cleaners are only effective when they are operated, loaded and serviced in compliance with the manufacturer's IFU.

Mechanical Cleaning

- Whenever possible, clean devices by mechanical means.
- Use washers in accordance with the manufacturer's IFU.
- Manually clean heavily soiled devices before mechanical cleaning, if necessary.
- Ensure that the device to be cleaned is compatible with the mechanical cleaning equipment, cycle parameters and cleaning chemicals that are being used.

Mechanical Cleaning

- **Ultrasonic washers** are strongly recommended for any **semi-critical or critical medical device** that has joints, crevices, lumens or other areas that are difficult to clean.
- **Washer-disinfectors** are strongly recommended for medical devices that **can withstand mechanical cleaning** to achieve the required exposure for cleaning and to reduce potential risks to personnel.

Ultrasonic Cleaners

- Ultrasonic cleaners are effective for hard-to-reach parts of surgical instruments (e.g. box locks, serrations, hinges and lumens).
- Ultrasonic vibrations pass through the cleaning solution and create bubbles. As the bubbles become larger, they become unstable and implode, a process called *cavitation*.
- This creates a vacuum in the solution that draws the debris from the instruments into the surrounding fluid.





Ultrasonic Cleaners

Requirements

- Instruments must be **pre-cleaned** of gross soil prior to using the ultrasonic cleaner
- **Water temperature** should be between 27° C and 43° C and never above 60° C because proteins coagulate above that temperature
- The manufacturer's recommendations for the **concentration and temperature of detergents** should be followed.
- **Water should be changed daily** and each time it is visibly soiled.

Ultrasonic Cleaners

- The ultrasonic unit should be **degassed each time it is filled** to remove excess bubbles.
- Degas is done by filling the unit, closing the lid and running a cycle for 5-10 minutes.
- Instruments should be **opened and completely submerged and lumens completely filled**.
- **Lid must be closed** prior to running to prevent aerosol production.

Ultrasonic Cleaners

- Use **specific detergent** as recommended by manufacturer.
- After cleaning with an ultrasonic machine, instruments need to be rinsed and dried.
- Ultrasonic cleaner needs to be **cleaned at the end of each day.**

Ultrasonic Cleaners

- Ultrasonic process needs to be **validated daily** and the results documented to ensure that devices are safe to use:
 - Visual inspection of all devices removed
 - Foil test
 - Commercial tests at least once a year

Automated Washers



- Washer-disinfectors work on the use of **pressurized water** to physically remove bioburden.
- Automated washers are a very **effective method** for cleaning and disinfecting instruments because of the detergents and thermal action used.
- **Multiple steps are included** in the cycle including pre-rinse, enzymatic wash, detergent wash, and lubrication.
- A final rinse at a temperature that thermally disinfects using de-ionized water will help to prevent mineral deposits and spotting and improve drying.

Automated Washers

Recommendations

- Washer racks should **never be overloaded** and instruments should be in an open position and contained within the basket.
- **Multi-level trays** should be placed separately on the washer rack and all lids removed.
- **Spray arms** should be inspected daily to ensure that they are in good condition.
- Not necessary to pre-clean instruments prior to placing in an automated washer, which saves time and is safer for personnel.



It is strongly recommended that

catheters, tubing, and medical devices with small lumens that are very difficult to clean be designated as **single-use medical devices** and not be reprocessed and reused.

Do's and Don't of Cleaning

Do's of cleaning

- Ensure detergent is prepared at correct concentration and temperature and used for recommended contact time.
- Keep instruments moist and clean as soon as possible after the procedure.
- Disassemble instruments prior to cleaning.
- Open hinged/jointed instruments to ensure access to all surfaces.

Do's of cleaning

- Use appropriate sized brushes to clean lumen items.
- Use soft bristle brushes to clean serrations and box locks.
- Inspect instruments after cleaning.
- Clean instruments under the surface of the water to reduce risk of aerosol production.
- Follow manufacturer's instructions for the cleaning of all medical devices.

Don't of Cleaning

- **Don't** use metal brushes or any abrasive item when cleaning instruments
- **Don't** clean instruments under running water
- **Don't** overload trays in a washer-disinfector
- **Don't** obstruct spray arms in a washer-disinfector
- **Don't** submerge power equipment or electrical items (unless they have a waterproof cap)
- **Don't** use a detergent that is not intended for medical devices

Thank You