15. Reprocessing of Medical Equipment: Cleaning, Disinfecting and Sterilizing

Routine Practices in reprocessing areas include:

- No eating/drinking, storage of food, smoking, application of cosmetics and handling contact lenses
- No storage of personal effects, including food and drink
- Hand hygiene facilities located at entrances of the reprocessing areas
- Hand hygiene training of staff
- No hand and arm jewelry or nail enhancements are to be worn
- Personal protective equipment to be available and education provided about selection and use of this equipment.

Hand hygiene to be done:

- Before beginning a task
- Before breaks
- Upon completion of work
- After going to the toilet, blowing nose and other personal body functions
- After removing gloves
- Whenever hands are contaminated with body fluids.

or

Soiling of the hands = Use soap and water

No visible soiling of hands = soap and water or alcohol hand sanitizing

The Safe and Healthy Worker in Reprocessing Area

All staff working in reprocessing should be immune to Hepatitis B.

Personal protective equipment should be worn during cleaning and reprocessing of medical equipment due to the risk of blood and body fluid exposure. If a worker experiences an exposure, that is, a break in her skin or a splash to her face while reprocessing medical equipment, report immediately and be assessed by a clinician.

For Your Safety:

- Know manufacturer's recommendations for cleaning of equipment
- Know the manufacturer's recommendations for storage, dilution, use and disposal of the products
- Only use disinfectants with a DIN (Drug Identification Number) which indicates approval for use in Canada
- Have the Material Safety Data Sheets (MSDS) available for the products used and know where the information is on these sheets
- Use the recommended personal protective equipment

Basic Principles

Procedures for cleaning medical equipment shall be based on the manufacturer's instructions and must include the principles of Infection Prevention and Control, Occupational Health and Safety, Biomedical Engineering and Environmental Services.

Cleaning is always essential prior to disinfection or sterilization. An item that is not clean cannot be disinfected or sterilized.

Gross soil (e.g. feces, sputum, blood) must be removed immediately at point-of-use, before transport to reprocessing area. Once the medical equipment has been received in the reprocessing area, it must be sorted and soaked.

A dedicated area for reprocessing is necessary. The layout of this area should facilitate the flow of clean to sterile without risk of recontamination of equipment. This one way workflow ensures that the work flows in "clean" direction. Each level of reprocessing (including cleaning, disinfection and sterilization) reduces the microbial load on the medical equipment being reprocessing.

Single use equipment is not designed for cleaning and reprocessing. It is designed for one use only and then disposal.

Factors Affecting the Reprocessing Procedure

Many factors affect reprocessing, especially when chemical reprocessing is used.

These factors include:

• Cleanliness of the surface of the equipment:

- the greater the bio-burden, the more difficult it is to disinfect or sterilize the equipment

• Characteristics of equipment/device:

- long, narrow lumens and channels are difficult to clean

- rough or porous surfaces may trap microorganisms

• Type and concentration of the product:

- products used for disinfection must be mixed according to the manufacturer's recommendations.

- dry the equipment after cleaning, before immersing in disinfectant, to prevent dilution of the disinfectant solution.

- check the expiry date before use and discard the solutions on or before expiry date; diluted products are unstable once mixed.

- follow the manufacturer's directions for duration of use.

- use chemical test strips for all high-level liquid disinfectants to assess their strength. During reuse the concentration of active ingredients may decrease as dilution of the product occurs and organic material accumulates.

- use the appropriate disinfectant for the task. Some microorganisms are more resistant to disinfection than others, this must be taken into consideration when choosing the product and the process.

- if the concentration of the disinfectant is too low, it will not achieve the level of disinfection required.

• Duration and temperature of exposure to the product:

- use manufacturer's recommendations for temperature and exposure time that is required to achieve the desired level of disinfection/sterilization.

• Physical and chemical properties of the reprocessing environment:

- water hardness can affect some disinfectants, use distilled water.

If the concentration is too high, it increases the risk of damage to the equipment and toxic effects on the technician.

Disinfection of Reusable Medical Equipment (see Appendix C)

Disinfection is the inactivation of disease-producing microorganisms. Disinfection does not destroy bacterial spores (e.g. C. difficile).

Disinfection of medical equipment falls into two major categories :

- Low-level disinfection
- High-level disinfection

The level depends on the purpose and use of the equipment.

See Spaulding Classification Appendix B for further details on categories.

Low-Level Disinfection (LLD)

Low-level disinfection eliminates bacteria, some fungi and enveloped viruses. LLD is used for non-critical medical equipment and some environmental surfaces.

The Non-Critical category of equipment includes equipment that touches only intact skin and not mucous membranes or does not directly touch the patient. Examples include commodes, blood pressure cuffs, exam tables and counters.

LLD is performed after the equipment is thoroughly cleaned, rinsed and is dry. Some cleaning products used in health facilities combine cleaning and disinfecting in one solution and thus reduces this to a one-step cleaning/ disinfecting method. Virex 256 is one of these cleaner/disinfectant solutions.

The container used for disinfection must be washed, rinsed and dried when the solution is changed.

Non-critical medical equipment requires decontamination using a low-level disinfectant.

High-Level Disinfection (HLD)

High-level disinfection eliminates bacteria, enveloped and non-enveloped viruses, fungi, and mycobacteria (e.g. tuberculosis).

HLD is used for semi-critical medical equipment. This includes equipment that come in contact with non-intact skin or mucous membranes but do not penetrate them. Semi-critical medical equipment require decontamination using, at a minimum, high-level disinfection.

High level disinfectants use products that include one of these following:

- 2% glutaraldehyde,
- 6% hydrogen peroxide
- 0.2% peracetic acid
- 7% accelerated hydrogen peroxide
- 0.55% ortho-phthalaldehyde (OPA).

HLD is performed after the equipment is thoroughly cleaned, rinsed and dried.

Sterilization is the preferred method of equipment decontamination. Some equipment (i.e. scopes) cannot be autoclaved so need high level disinfection.

Liquid Chemical High Level Disinfection

When selecting a disinfectant for reprocessing medical equipment in the health care setting consider the following:

- Has a Drug Identification Number (DIN) from Health Canada
- Achieves the desired purpose
- Compatible with the equipment and surfaces to be disinfected
- Compatible with detergents, cleaning agents and disinfection and/or sterilization processes
- Intended use of the equipment after disinfection (see Spaulding Criteria Appendix B)
- Monitoring method of the product concentration/dilution
- Rinsing recommendations for rinsing (e.g. water quality, volume, time)
- Correct use of PPE
- Disposal, environmental safety and biodegradability.

The manufacturer's recommendations for chemical disinfectants must be followed.

Products must have a stated:

- Contact time
- Shelf life
- Storage instruction
- Appropriate dilution
- Required PPE

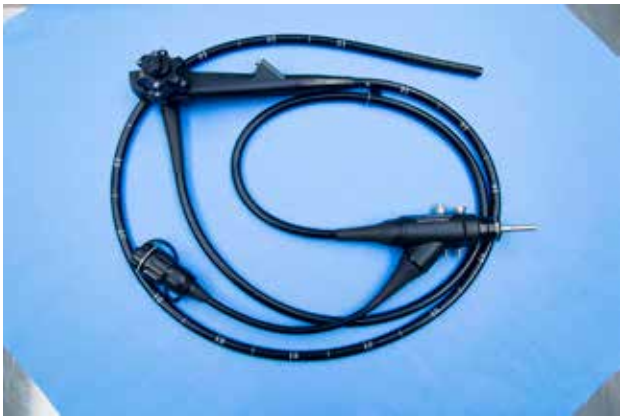
The process of high-level disinfection requires:

• Chemical test strips be used to determine whether an effective concentration of active ingredients is present, especially after repeated use

• Prepared solutions not be topped up with fresh solution

• For manual disinfection the container used for disinfection must be kept covered during use and washed, rinsed and dried when the solution is changed

• Rinsing of medical equipment following chemical disinfection needs three separate rinses of sterile water. The rinse solutions must be changed after each process.



Scopes are critical medical equipment. They require high level disinfection. This is done using specialized equipment and procedures.

Sterilization

Sterilization is the destruction of all disease-producing microorganisms including bacteria, viruses, spores and fungi (e.g. Clostridium and Bacillus species) and prions. Sterilization is used on critical medical equipment and, where possible, semi-critical medical equipment.

For equipment that cannot withstand heat sterilization chemical sterilants can be used. However to achieve chemical sterilization, the concentrations of chemical and time of exposure must meet standards.

Steam Sterilization (Autoclaving) is the preferred method of decontamination for semi-critical medical equipment.

STOP! clean your hands

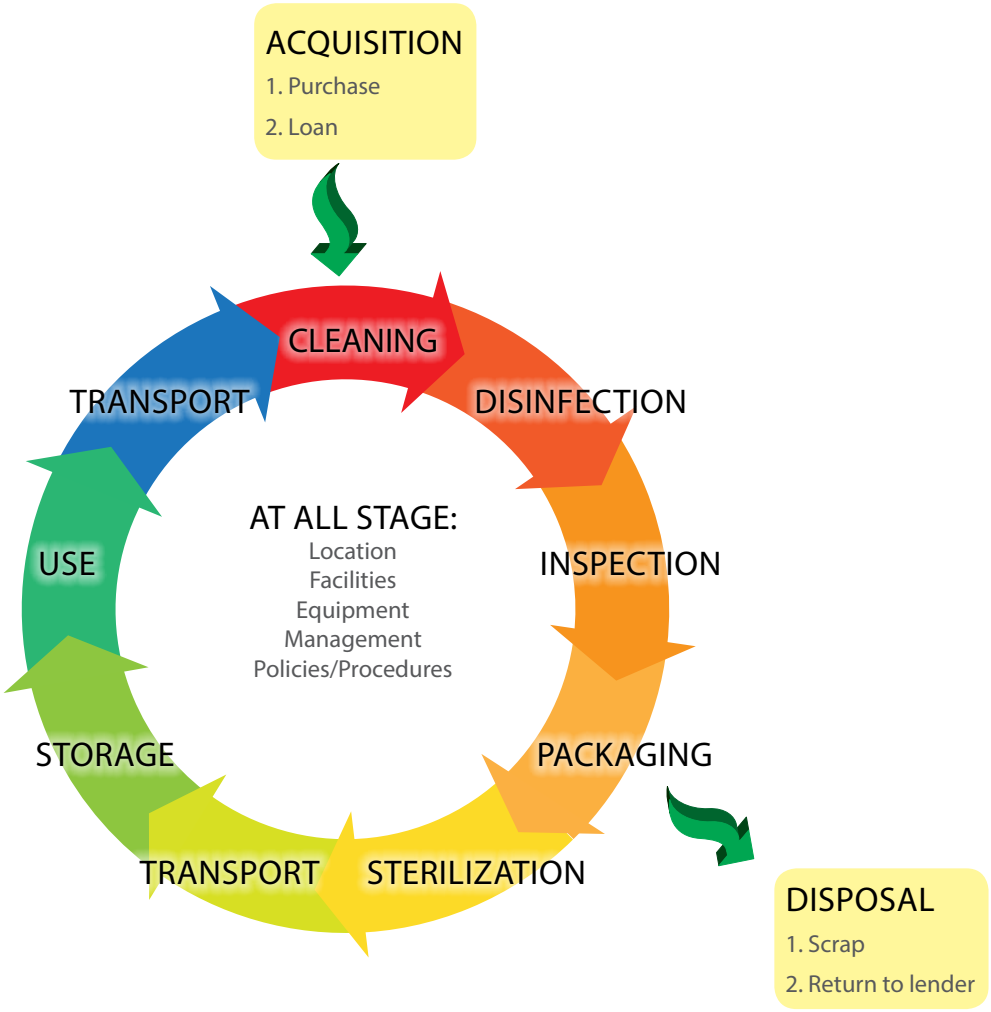
The Sterilization Cycle for Medical Equipment: (See Appendix D)

Medical equipment that has contact with sterile body tissues or fluids are considered critical items. All critical medical equipment must be sterilized.

Microbial contamination on critical equipment could result in transmission of severe disease.

Critical items include suture instruments, foot care equipment, biopsy forceps, ophthalmology equipment and dental equipment.

Steps in reprocessing critical medical equipment:



Steps to Sterilization:

1. Pre-Cleaning

Gross soil (e.g. feces, sputum, and blood) must be removed immediately at point-of-use. If cleaning cannot be done immediately, the medical equipment must be submerged in tepid water and detergent or enzymatic cleaner (e.g. Empower) to prevent any organic matter from drying. Soaking in bleach solution may damage the finish on the equipment.

Consider factors that affect the ability to clean medical equipment prior to cleaning.

a) Disassembly - if the instruments have parts, disassembly allows for the cleaning agent, disinfectant and/or sterilant to come in contact with all surfaces of the device.

b) Sorting – segregation of sharps and delicate equipment prevents injury to personnel and damage to the equipment.

c) Soaking – prevents soil from drying on equipment and makes it easier to clean. (Empower is in stock in warehouse, see stores list Appendix E).

2. Cleaning



Scrub with solution **with** stiff bristle brush → then wipe dry

The following procedures are included in the cleaning process:

a) Physical Removal of Organic Materials

- Completely submerge items that will tolerate fluids during the cleaning process to minimize aerosolization of microorganisms and assist in cleaning

- Remove gross soil using tools such as a wire bristle brushes and lint-free cloths

b) Manual Cleaning

- Clean equipment that have lumens with a brush, according to the manufacturer's instructions, then flush with a detergent solution (Empower) and rinse with water

- Use wire bristle brush to manually clean surfaces, hinges and tight spots

c) Care of Cleaning Tools

- Inspect brushes and other cleaning equipment for damage after each use

- Clean, disinfect, dry and store tools used to assist in cleaning (e.g. brushes, cloths)

d) Rinsing

- Rinse all equipment thoroughly after cleaning with water to remove residues

- Perform the final rinse for equipment containing lumens with commercially prepared sterile water

Rinsing following cleaning is necessary, as residual detergent may neutralize the disinfectant.

e) Drying

- Equipment may be air dried or dried by hand with a clean, lint-free towel

- Dry stainless steel equipment immediately after rinsing to prevent spotting

Drying is an important step that prevents dilution of chemical disinfectants.

3. Post Cleaning

Equipment which receives high-level disinfection should also be labeled, tagged or colour-coded to indicate that it has been reprocessed. Steam sterilized items may be identified using chemical indicators (CIs), such as autoclave tape, which changes colour during sterilization.

Keep cleaned equipment separate from dirty equipment to avoid recontamination and mixing up of instruments.

Wrapping/Packaging

Equipment that is to be sterilized requires wrapping prior to sterilization.

- Materials used for wrapping must be prepared in a manner that will allow adequate air removal, steam penetration and evacuation to all surfaces. Wrapping material must be the steri-peel pouch or blue wrap.

- Each package to be steam sterilized should include an indicator strip inside the pack and closed with autoclave tape (if blue wrapped) and heat sealed (if in a pouch).

Note the colour change with the indicator after autoclaving in the picture below.

or

+

Before

After

See CSA Z314.3-09, 'Effective Sterilization in Health Care Facilities by the Steam Process' for information on packaging materials, containers and methods.

4. Sterilization

Autoclaving time and settings must be based on specifications for the autoclave that is being used. This time and temperature must be achieved to properly sterilize the equipment.

Steam sterilization must be done with distilled water. This controls mineral build up in the autoclave which will affect the function and reduce the lifespan of the machine.

Correct Preparation + Correct Time + Correct Temperature

= Effective Sterilization

5. Post steam sterilization and storage

Handling of the packages after sterilization include:

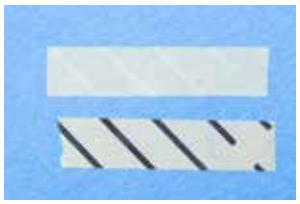
- Allow packages to dry so no moisture is visible on the outside, before removing from the autoclave and storing

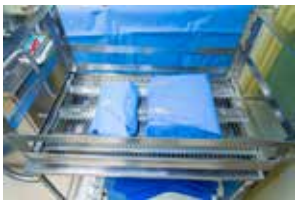
- Check to make sure that the colour changes have occurred on the interior indicator strip and the indicator on the outside of the package

Sterilized packages must be transported in a way to prevent contamination i.e.: dry, clean and with no break in the wrapping.

Before

After





6. Maintaining Sterility

Maintaining the sterility of medical equipment until point of use is the purpose of the sterile process. This includes:

- Medical equipment purchased as sterile must be used before the expiration date

- Sterile packages that lose their integrity must be re-sterilized prior to use (i.e. soiled, wrapping broken, or seal broken)

Storage Areas

The area for storage of sterile equipment should be located adjacent to the sterilization processing area, preferably in a separate, enclosed, and with limited access area.

Requirements for this area include:

- Containers used for storage of equipment should be moisture-resistant and cleanable (i.e. cardboard boxes must not be used)

- Equipment is stored in a clean, dry, and dust-free area--not at floor level, and at least one meter away from debris, drains, and moisture to prevent contamination

- Equipment is stored in an area where they are not subject to tampering by either humans or vermin

- Equipment is handled and transported in a manner that avoids contamination or damage to the equipment

- Supplies and materials not used for reprocessing must not be stored in sterile processing areas.

Unacceptable Methods of Disinfection/Sterilization

The following methods of disinfection/sterilization are not recommended:

- Boiling
- Ultraviolet light
- Glass bead sterilization
- Microwave ovens
- Chemiclave

7. Using Sterilized Equipment

At point-of-use, upon opening the packaging and the equipment, must be checked for:

- Absence of change in colour of tape on outside of package and absence of change in colour on the internal indicator strip

- Discolouration or soiling on equipment that would indicate inadequate cleaning before sterilization

- Defective equipment

- Moisture on packaging or equipment.

If any of the above points, the equipment needs to be removed from service and reprocessed or replaced.

Quality Assurance

Reprocessing practice audits should be done to assure sterilization:

- Cleaning processes must be audited on a regular basis

- A quality improvement process must be in place to deal with any irregularities and concerns resulting from the audit.

References:

• Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings, Provincial infectious Diseases Advisory Committee (PIDAC), Ministry of Health and Long Term Care, Ontario May 2013

Community Health Nursing Standards, Policies and Guidelines 2011 10-008

Applicable Canadian Standards Association :

CSA Z314.3-09 Effective Sterilization in Health Care Facilities by the Steam Process

CSA Z314.8-08 Decontamination of Reusable Medical Devices

Scope cleaning Section : To be added at a later date

Appendix A:

Microbes in Order of Increasing Resistance to Disinfection and Sterilization

Bacterial spores (e.g., Clostridium difficile, Bacillus anthracis)

Mycobacteria (e.g. TB)

Harder to Kill

Non-lipid or small viruses (e.g. polio virus, coxsackie)

Fungi (e.g. candida, aspergillus)

Lipid or medium sized virus (e.g. herpes, HIV, hepatitis B/C)

Easier to Kill

Vegetative bacteria (e.g. staphylococcus, pseudomonas)

Appendix B:

Spaulding's Classification for Medical Equipment and Required Level of Processing/Reprocessing

The classification system developed by Spaulding divides medical equipment into three categories, based on the potential risk of infection involved in its use:

Classification	Definition	Level of Processing	Examples
Critical equipment	• Equipment that enters sterile tissues, including the vascular system	Cleaning followed by sterilization	Suture & surgical instruments Biopsy instruments Foot care equipment
Semi critical equipment	• Equipment that comes in contract with non-intact skin or mucous membranes but does not penetrate them	Cleaning followed by high level disinfection (as a minimum) Sterilization preferred	Respiratory therapy equipment Anesthesia equipment
Non-critical equipment	•Equipment that touches only intact skin and not mucous membranes • Equipment that does not directly touch the patient	Cleaning followed by low level disinfection In some cases, cleaning alone is acceptable	ECG machine Blood pressure cuffs Oximeter Bedpans, urinals, commodes

Appendix C

High Level Disinfection of Medical Equipment

PURPOSE:

To provide safe equipment for re-use through disinfection

MATERIALS:

- Disposable gloves
- Enzymatic detergent (Empower)
- Disinfectant solution (Metricide 28)
- Lint-free towels
- Basins for soaking

If needed:
- Face shield
- Gown

CLEANING STEPS

1

Do a Risk Assessment

- Determine risk of exposure to germs and the Personal Protective Equipment (PPE) required for the task
- Wear the correct PPE to safely do the job

2

Soak immediately after use:

- Immerse immediately in soapy water or enzymatic detergent (Empower)

3

Clean

- Scrub all surfaces with steel bristle brush
- Use enzymatic detergent
- Check all sides for blood

4

Rinse with tap water

5

Drip dry

6

Immerse in high level disinfectant solution
(Metricide for 20 minutes)

7

Dry with lint-free cloth

8

Label as disinfected and ready to use

9

Storage

- Keep dry, dust free and prevent contamination

If possible high level disinfection is done by steam sterilization.

STOP! clean your hands

Appendx D

Procedure for Sterilization

PURPOSE:

To provide safe equipment for re-use through sterilization

MATERIALS:

- Disposable gloves
- Enzymatic detergent (Empower)
- Lint-free towels
- Basins for soaking

If needed:
- Face shield
- Gown

CLEANING STEPS

1 

Do a Risk Assessment

- Determine risk of exposure to germs and the Personal Protective Equipment (PPE) required for the task
- Wear the correct PPE to safely do the job

2 

Soak

- Immerse in soapy water or enzymatic detergent (Empower)

3 

Clean

- Scrub all surfaces with steel bristle brush
- Use enzymatic detergent

4 

Rinse with tap water

5 

Dry with lint-free cloth or gauze

6

or

Package

- Use surgical wrap with sterile indicator strips inside
- Close with autoclave tape

Package

- Put in peel pouch with sterile indicator
- Heat seal or peel'n' stick closure

7

Ready to autoclave

8

Insert package into autoclave for sterilization

9

- Autoclave: Set to manufacturer's settings
- Dry in the autoclave before removal

10

OK, when strip changes colour

11

Transport

• Assure packing is not contaminated

12

Storage

• Store in clean location.

• Keep dry and dust-free to prevent contamination

Appendix E:

Supplies for Reprocessing of Medical Equipment

Meditech number	Product Name	Uses	Comments
001450	Metricide 28	Chemical solution for high level disinfection	4 litre jug
003261	Metricide 28 test strips	For testing Metricide solution	
000606	Autoclave tape	To close blue wrap, stripes change colour when autoclave reaches temperature and time	
000595	Sterile indicator strips	To put in package, changes colour when the inside of the pack reaches temperature and time	
001423	Empower	Enzymatic detergent for soaking instruments before cleaning	
001459	Nitrile gloves (small)		
001460	Nitrile gloves (medium)		
001461	Nitrile gloves (large)		
000495	Omni wrap 24x24	For wrapping packages for steam sterilizing	
000494	Omni wrap 30x30	For wrapping packages for steam sterilizing	
000496	Omni wrap 45x45	For wrapping packages for steam sterilizing	
000633	Wrap dual peel tubing 3"x 100'	Clear plastic tubes for steam sterilizing	To be heat sealed
000632	Wrap dual peel tubing 4" x 100'	Clear plastic tubes for steam sterilizing	To be heat sealed
000631	Wrap dual peel tubing 6" x 100'	Clear plastic tubes for steam sterilizing	To be heat sealed
002168	Tote wipes	Disposable lint-free wipes	For drying and instruments
009712	Wire bristle brush	Removal of material from instruments	

Appendix F:
Cleaning Instructions for Home Oxygen Equipment

Concentrator:	Wipe the outside of the cabinet once per week with a damp cloth. Unplug the unit prior to wiping.
Filter:	Replace the filter in the unit every 4 months and between clients.
Nasal Cannula:	Wipe the cannula tips every day with a soapy cloth and rinse. Replace every month or more often if cracked, broken or discoloured.
Oxygen Tubing:	Wipe the outside of the tubing with a damp cloth every week. Do not soak the long tubing in water, as it is very difficult to get all the water out. Replace every 4 months.
Humidifier Bottle:	Use only when the physician's order is greater than 4 liters/minute. Throw the water out when the water level reaches the refill line on the outside of the bottle. Wash the bottle once every week following the cleaning steps in the Oxygen Masks section. Replace the bottle every month.
Oxygen Masks:	Wash once a week in warm soapy water following these cleaning steps: 1. Take apart the mask or bottle as much as possible. 2. Soak all parts in warm soapy water. 3. Rinse thoroughly in running water. 4. Soak in a 1-part white vinegar to 3-parts water solution for 20 minutes, rinse thoroughly and let air dry. Store in a plastic bag when not in use. Always keep a spare replacement on hand. Replace the oxygen mask every month or more often if cracked, broken or discoloured.

March, 2014