Infection Prevention and Control for Health Care Offices/Clinics

Prince Edward Island
CANADA

Health and Wellness

Medical Instruments

General Principles

Medical instruments are important tools of the profession. All equipment should be in good working order with preventative maintenance as required. Whether a product is reusable or designated as single-use has important infection control implications. Reusable items must be cleaned and disinfected or sterilized after use, according to manufacturer's instructions.

Single-Use Medical Devices

Many items used in the health care industry are designated by the manufacturer to be single-use only, e.g., syringes, plastic vaginal specula, mouthpieces for pulmonary function testing. Items labeled "for single-use only" should not be reused.

Cleaning, Disinfection and Sterilization of Medical Instruments

Medical instruments must be cleaned, and then either disinfected or sterilized after each use. The cleaning step is actually the most important, as residual organic debris will compromise the disinfection and sterilization process. In addition to generic guidelines for reprocessed medical equipment, the manufacturer's guidelines for specific instruments should also be consulted and followed.

A classification system was developed to categorize medical instruments according to whether they contact sterile tissue, mucous membranes or intact skin. They are classified into one of three categories according to Spaulding: "critical", "semi-critical" or "non-critical". This classification determines their reprocessing requirements.

SPAULDING'S CLASSIFICATION OF MEDICAL INSTRUMENTS (modified)		
CLASS	USE	REPROCESSING (minimum requirement)
Critical	Enters sterile body site or vascular system.	Cleaning followed by sterilization.
Semi-Critical	Comes in contact with intact mucous membranes or non-intact skin.	Cleaning followed by high-level disinfection.*
Non-Critical	Comes in contact with intact skin.	Cleaning followed by low or intermediate-level disinfection.
*For some semi-critical instruments (e.g., thermometers, ear syringe nozzle), intermediate-level disinfection can be used.		

i) Cleaning of Instruments

- Staff must be protected when performing these activities. Personal protective equipment such as face protection, gloves and gowns are recommended.
- Instruments should be cleaned as soon as possible after use so that organic material will not dry. Organic material must be removed before disinfection or sterilization procedures are initiated as it interferes with these processes.
- Placing the instrument in a pre-soak of water or a solution of instrument detergent/enzymatic will help prevent drying of secretions and help facilitate the cleaning process.
- Instruments should be cleaned with an instrument detergent/enzymatic diluted in water according to the manufacturer's directions or alternatively, by ultrasonic machines also using instrument detergents.
- Careful attention must be paid to delicate or lumened instruments. Appropriate cleaning tools must be employed and care used to clean every surface. The cleaning tools must also be appropriately cleaned and disinfected.
- If possible, one designated staff person should be assigned the responsibility for cleaning and disinfection of equipment. Appropriate education or continuing education is strongly recommended for this person with regard to all equipment and when new equipment is purchased.
- The manufacturer's instructions should be followed and documented for each instrument reprocessed. This will provide references for orientation and training of staff, ensure consistency in reprocessing, and can be used to develop quality improvement activities. Written procedures should be kept near the reprocessing area. Procedures should be reviewed and revised regularly (see sample template format for procedure in Appendices 7 and 8).

Thorough cleaning of instruments to mechanically remove all organic material is of the utmost importance prior to either sterilization or disinfection. Organic matter, if present, will inactivate or interfere with the sterilization or disinfection process.

Do not use hand soap to clean instruments as emollients in soap could remain on the surface of the instrument and interfere with the disinfection or sterilization process.

ii) Sterilization and Disinfection: General

Instruments that are considered to be critical items require sterilization.

Factors which interfere with sterilization and disinfection include:

- organic material, such as mucous, blood, pus, feces, saliva, etc.;
- nature of the microbial contamination and the number of organisms present;
- incorrect dilution (improper mixing) of the disinfectant;
- inadequate exposure (contact) time between instruments and sterilant/ disinfectant;
- dilution of the sterilant/disinfectant, e.g., addition of wet instruments;
- loss of strength due to expired date;
- inadequate penetration of the sterilant/disinfectant into the instrument, e.g., channeled scopes;
- incorrect pH or temperature of the disinfectant;
- water hardness;
- incompatible detergents;
- presence of materials such as rubber and plastic.

iii) Sterilization

Sterilization completely kills all forms of microbial life including the most resistant forms, e.g., bacterial spores.

1. Steam Sterilization

Steam sterilization is the most practical and economical method for sterilizing medical instruments. Small tabletop steam sterilizers that are carefully maintained can be used for many years and are highly recommended for clinic and office settings.

GUIDELINES FOR STERILIZATION WITH STEAM AUTOCLAVES

Unwrapped instruments Non-porous, no lumen	3 minutes exposure	132-135°C
Small wrapped packs	30 minutes	121-132°C

Small autoclaves, similar in size to microwave ovens, are ideal for office use. Distilled water is recommended as the water source to prevent scale deposits on the instruments. It should be noted that microwave ovens are NOT appropriate for sterilization.

Unwrapped instruments should be used immediately so as not to contaminate the item; otherwise instruments should be wrapped (see Packaging on page 34).

The table below outlines suggested decontamination procedures for selected office instruments. The availability and utilization of institutional central sterilization departments by some physicians may influence the choice of reprocessing for some critical and semi-critical items. **Remember all items must be cleaned prior to disinfection or sterilization.**

Table 2 - Suggested decontamination procedures for selected office instruments

Instrument or item	Category	Requirements	Suggested Procedures
Acupuncture needle	C	ST	Sterilize or disposables preferred.
Alligator forceps	SC	HLD	High-level disinfectant or sterilize.*
Anal/nasal speculum	SC	HLD	High-level disinfectant or sterilize.*
Baby scales and/or work surfaces	NC	ILD/LLD	Wipe down with a low-level disinfectant (not phenolic when children exposed).
Biopsy forceps/pinches	C	ST	Sterilize or disposables preferred.
Blood pressure cuff, reflex hammers	NC	ILD/LLD	Wipe down with a low-level disinfectant (not phenolic when children exposed).
Colposcopy equipment	C	ST	Sterilize.
Cryosurgery tips	SC	HLD	Immerse the tip according to manufacturer's instructions.
Ear cleaning equipment, ear curettes, otoscope tips	SC	HLD/ILD	Sterilize or boil 20 minutes or immerse in household bleach 1:100 (if plastic), or alcohol (70-90% ethyl) for 20 minutes. Clean the otoscope handle regularly. Disposable tips preferred.
Electrocautery tip for use on skin needle electrode (for elec-trodessication)	C	ST	Sterilize.
Endocervical curvettes	C	ST	Sterilize.
Fish hook cutters	C	ST	Sterilize.
Flexible fiberoptic endoscopes** (i.e., gastrointestinal, broncho-scopic, nasal)	SC	HLD	Clean all surfaces and channels carefully and immerse in HLD as recommended by manufacturer. Rinse well with water (preferably sterile), then 70% alcohol and hang to dry.
Flexible fiberoptic endoscope accessories (i.e., brushes, biopsy forceps)	C	ST	Sterilize.
Foot care instruments	C	ST	Sterilize.
Glucometers	NC	LLD	Establish routine cleaning procedure, and follow manufacturer's instructions for safe use.
Kimura spatula	C	ST	Sterilize or disposable spatula preferred.

Continued...

*For semi-critical items, high-level disinfection is the minimum standard for reprocessing. If sterilization is more accessible, it is preferred.

**Flexible fiberoptic endoscopes are particularly difficult to reprocess, given their lumens and delicate connections. Written policies for cleaning and disinfection should be available, and dedicated staff trained for these tasks. Refer to published guidelines for further information.

LEGEND:

C=Critical **SC=Semi-Critical** **NC=Non-Critical** **ST=Sterilization**

LLD=Low-Level Disinfection **ILD=Intermediate-Level Disinfection** **HLD=High-Level Disinfection**

Table 2 continued - Suggested decontamination procedures for selected office instruments			
Instrument or item	**Category**	**Requirements**	**Suggested Procedures**
Laryngoscope blades	SC	HLD	Also assure laryngoscope handle is thoroughly washed after each use.
Laryngeal mirror	SC	HLD	Sterilize or high-level disinfectant.*
Neurologic test pin	C	ST	Sterilize or disposables preferred.
Peak Flow Meters	SC	HLD	Use disposable mouthpiece and disposable filters. Clean whole instrument in hot water and mild detergent/disinfectant, immerse in 1:50 dilution household bleach for 20 minutes. Rinse in tap water.
Pessary and diaphragm fitting ring	C	ST	Sterilize.
Respiratory therapy equipment (mouthpieces, nasal prongs, etc.)	SC	HLD	Disposables preferred.
Rigid metal sigmoidoscope, proctoscope, nasal endoscope, laryngoscope and laryngoscope blades	SC	HLD	Clean all surfaces and channels carefully, and sterilize or high-level disinfectant.
Scalpels	C	ST	Disposables preferred.
Stethoscope, bandage scissors	NC	ILD/LLD	Wipe with alcohol frequently (stethoscope: diaphragm and bell), ideally after each use.
Stitch cutter	C	ST	Sterilize or disposables preferred.
Surgical instruments	C	ST	Sterilize.
Suture removal equipment	C	ST	Sterilize or disposables preferred.
Tonometer, contact lenses	SC	HLD	Immerse in 1:50 dilution household bleach (1,000 ppm free chlorine) or 3% hydrogen peroxide for 10 minutes. Rinse in water and dry well.
Thermometer (glass)	SC	ILD	Immerse in 70-90% ethyl alcohol for 20 minutes or disposables, sheaths, or electronic thermometers preferred.
Ultrasound probes (skin contact)	NC	LLD	After each use, wipe gel off and clean thoroughly with LLD.
Ultrasound probes (mucous membrane contact, vaginal probes)	SC	HLD	After each use, wipe with detergent disinfectant, and then high-level disinfectant. Always use a probe cover.
Vaginal speculum (metal)	SC	HLD	High-level disinfectant or sterilize.* Disposable specula available.
Vaginal tenaculum	C	ST	Sterilize.

*For semi-critical items, high-level disinfection is the minimum standard for reprocessing. If sterilization is more accessible, it is preferred.

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2. Dry Heat Sterilization (hot air ovens)

Dry heat should be used only for the materials that cannot be sterilized by steam. The principle advantage of dry heat sterilization is its penetrating power. The disadvantages are that heating is slow, and long exposure times and high temperatures are required, which could damage materials.

Time-temperature relationships for sterilization with hot air are:

170°C (340°F)……..60 minutes

160°C (320°F)……120 minutes

150°C (300°F)……150 minutes

140°C (285°F)……180 minutes

These temperatures relate to the time of exposure after the attainment of the specific temperature. The time does not include the heating lag.

Monitoring the Sterilization Process

It is imperative that the sterilization process be monitored to ensure the integrity of the process.

A logbook should be kept for each load.

Manual indicators on the machines, such as time, temperature and pressure gauges, must be monitored and recorded.

- Temperatures must reach a specific level and be maintained for specific periods to kill microorganisms. The greater the temperature, the less time required.
- Pressure is necessary to create the steam. Manufacturers set the pressure gauge.
- Steam must be saturated for effective sterilization. For tabletop autoclaves, water must be manually added.

Chemical indicators, such as tape that changes colour, are useful for distinguishing between processed and unprocessed items. Chemical indicators do not, however, imply that sterilization has taken place. Tapes are usually placed on wrapped products.

Biological indicators (BI) must be used regularly (see sidebar) to ensure that sterilization has occurred. All biological indicators must be used according to the manufacturer's instructions and records should be kept of these results. If biological testing indicates that sterilization has not been achieved, sterility of the instruments cannot be assured. It is very important that a process be in place in the event of a failure. If this occurs it is important to have a record describing the cause of the failure, corrective action and any recall of items.

How often should you use biological indicators? Although some guidelines say a minimum of weekly, the Canadian Standards Association (CSA) recommends daily biological indicator (BI) testing. The frequency of use of the sterilizer might be considered when deciding the frequency of testing.

What to do if the failure is a positive BI:

- Repeat the test. If practical, do not release any items that were processed since the last negative test. If this repeat test is negative, and there is not an indication of a system malfunction – continue as normal.
- If the repeat BI is positive again, review all items that were processed since the last negative test. Review the process to ensure this is not a false positive.

Check with your sterilizer manufacturer to determine which biological indicator is appropriate for the specific sterilizer.

Complete a report that includes time, date, load description, results of mechanical and chemical monitoring, contact the manufacturer, and after repair and maintenance, rechallenge the autoclave with the BI. Resterilize the recalled items once the results of the BI are negative.

- Have a procedure for patient notification if instrument(s) were used on patient(s).
- Have a back up procedure to ensure your equipment will be sterilized as required, e.g., set of disposable devices, arrangement with a colleague to use their autoclave.

References:

1. Effective Sterilization in Health Care Facilities by the Steam Process, Z314.3-01. CSA International.
2. Handbook on Infection Control in Office-Based Health Care and Allied Services, April 2004, CSA PLUS 1112, Canadian Standards Association. Available on-line at: http://www.cssinfo.com/info/csa.html.

Preventative Maintenance

Regular preventative maintenance and cleaning is required to assure the effectiveness of the machine. Records should be kept of any preventative maintenance and repairs performed. Use the instruction manual or contact the manufacturer. Assure distilled water is filled to the correct level and drained according to manufacturer's recommendations. Check the gasket for defects and deterioration. Assure proper placement of packs, and do not overload the chamber.

Packaging and Storage of Instruments

There are many types of packaging materials available, each with advantages and disadvantages. The following criteria must be kept in mind.
The packaging material:

- must allow the sterilant to enter the pack;
- must maintain the sterility of the contents and be impervious to the environment; and
- should minimize the contamination risk when the package is opened.

Do not soak any sterile instruments in solutions before use. Keep all devices in sterile packs until use.

The most useful wrapping materials in the physician's office are plastic/peel pouches. They are easy to use, often with features such as self-sealing closures and chemical indicator strips, and come in a variety of sizes that can accept single or small groups of instruments. Be sure to mark the date the product was sterilized on the product wrapping.

Storing Instruments after Sterilization

Inventory control and rotation should be used to avoid long storage.

It is critical that steam-sterilized packs be subject to a drying cycle prior to handling for storage. Wrapped packs should be carefully stored in clean, dry, dust-free areas (closed shelves), not at floor level, and should be away from debris, drains, moisture and vermin to prevent contamination and maintain sterility until the time of use. All stored equipment and instruments should be left undisturbed as much as possible since handling may draw contaminants in through a bellows effect.

Check the following to determine if the integrity of the package has been compromised:

- Is the seal still intact?
- Is the package free from tears, dust, soil and dampness?
- Have the chemical indicators on the pack changed to the appropriate colour?

Shelf Life of Sterile Items

For items reprocessed in the office, if the integrity of the package has been maintained, the item remains sterile. A plastic dust jacket may greatly extend the shelf life of the package and should be used on muslin or crepe wrapped packs. If a sterile tray/package has been purchased and has an expiry date/label, follow manufacturer's guidelines and discard when outdated.

Time does not contaminate - events do.

References:

1. Handbook on Infection Control in Office-Based Health Care and Allied Services, April 2004, CSA PLUS 1112, Canadian Standards Association. Available on-line at: http://www.cssinfo.com/info/csa.html.

2. Freidman C, Peterson K. Infection Control in Ambulatory Care, 2004, An Official APIC publication.

3. Effective Sterilization in Health Care Facilities by the Steam Process, Z314.3-01. CSA International.

iv) Disinfection

Disinfection is a relative term. Disinfection is a process that kills or destroys nearly all disease-producing microorganisms. Disinfectants are used on inanimate objects. There are three levels of disinfection depending on the resistance of the organism to inactivation.

The following list ranks the spectrum of microbial life in terms of resistance to destruction by heat or chemicals:

Microbes in Order of Increasing Resistance to Destruction

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

⇧

Mycobacteria (e.g., TB)

⇧

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)

⇧

Vegetative bacteria (e.g., *staphylococcus*, pseudomonas)

Note: Prions, the cause of Creutzfeldt-Jakob disease (CJD) and variant CJD, are more resistant to sterilization than spores.