

Foot Care Devices

Note: Terms are defined in the **Definitions** section.

If you have any questions or comments contact IPC at jpcsurvstdadmin@ahs.ca.

Best practice recommendations

Objectives

This infection prevention and control (IPC) best practice recommendation (BPR) for **foot care devices** (FCD) was developed to:

- minimize the risk of exposure or injury, and to prevent transmission of micro-organisms to **clients** and personnel
- describe best practice for:
 - single-use FCD
 - client-owned FCD often used for routine clipping and filing
 - multi-client **reusable FCD** often used for routine, difficult (such as on deformed feet or nails), or invasive foot care (such as paring corns and callouses)
 - **reprocessing** multi-client reusable FCD

Applicability

This recommendation applies to all Alberta Health Services (AHS) staff, medical staff, volunteers, students and other persons acting on behalf of AHS.

IPC principles

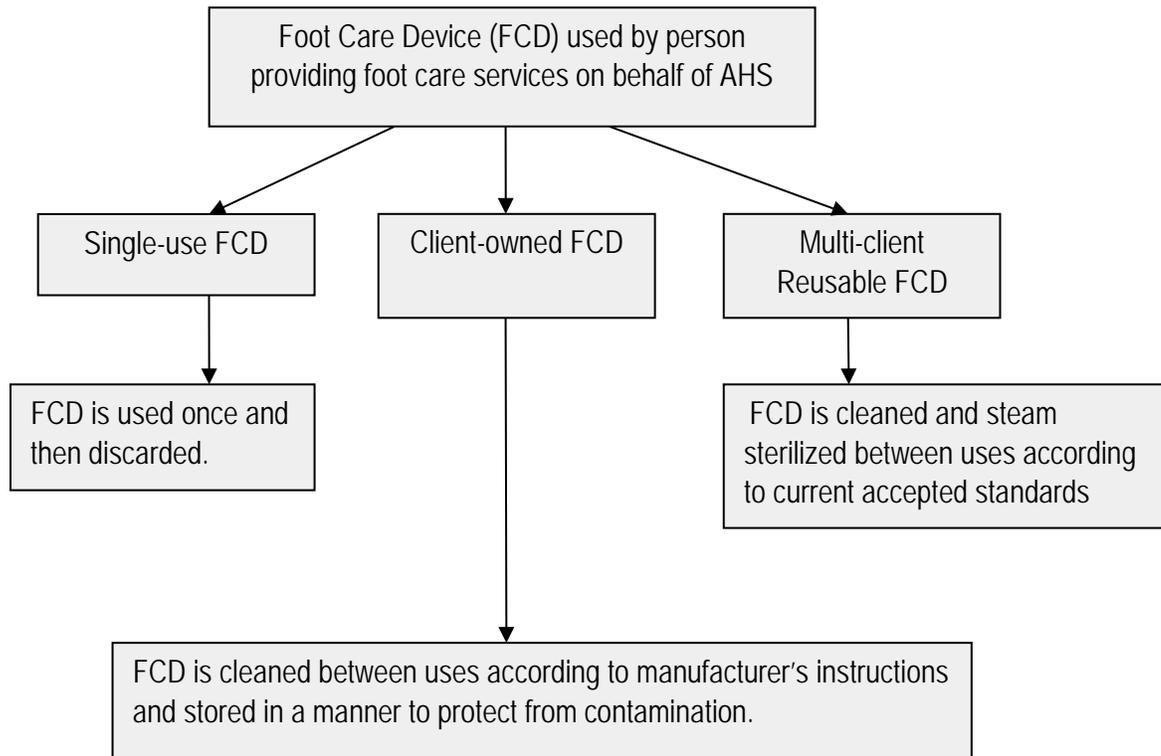
Routine practices are a standard of care used for all clients at all times to reduce the risk of infection transmission. More information visit [AHS Routine Practices](#).

Foot care devices (FCD)

All devices used for foot care, including devices used for electronic nail filing, must be intended by the **manufacturer** for use on human beings (see **Medical Device** definition page 9).

Management of Single-use, Client-owned and Multi-client Reusable FCD (see Figure 1 below).

Figure 1: Management of Single-use, Client-owned and Multi-client Reusable FCD



Single-use FCD is used once and then discarded.

- FCD must be treated as single-use when:
 - it is labelled as a single-use medical device by the manufacturer;
 - the labelling is unclear as to whether or not it is a single-use medical device; or
 - there are no manufacturer's reprocessing instructions for it.

Client-owned FCD

- A client's own dedicated FCD must:
 - never be used for another individual.
 - be cleaned, at a minimum, between uses according to **manufacturer's instructions**.
 - be inspected regularly and replaced if damaged, corroded or becomes no longer functional.

Multi-client reusable FCD

- Multi-client reusable FCD must be cleaned and steam sterilized according to the manufacturer's instructions prior to reuse on another client. Sterility must be maintained until use on the next client.
- Foot care providers (staff or contracted providers) must have the right number of sterile FCDs to provide foot care for every client.
- Multi-client reusable FCD should be reprocessed in a **centralized medical device reprocessing area** (see Centralized Medical Device Reprocessing Area definition page 8).
- Reprocessing of multi-client reusable FCDs must meet Alberta Health IPC Standards. Providers unable to meet Alberta Health Standards may choose to reprocess multi-client reusable FCD through a designated medical device reprocessing area or use single-use FCD available in kits and discard after use.
- Foot care providers who clean and sterilize multi-client reusable FCD must be aware of, and follow, relevant Alberta Health Standards, AHS policies and guidelines and Canadian Standards Association (CSA) Standards (see References page 10).

Key requirements for reprocessing multi-client reusable FCD

Foot care providers responsible for reprocessing of FCD must be educated and competent in reprocessing practices and follow infection prevention and control principles for handling and transport, **cleaning**, packaging, **sterilization**, quality monitoring, and cool down and storage.

- A designated reprocessing area is:
 - dedicated to reprocessing;
 - set up with a clear one-way workflow, where reprocessing moves in one direction from the dirtiest task to the cleanest task in order to prevent cross-contamination (see Appendix A:Suggested Reprocessing Area Design and Layout);⁹
 - cleaned regularly; and
 - kept free of excess and unrelated devices and supplies.²
- Foot care providers must use personal protective equipment (PPE) appropriate for the task e.g., chemical and puncture resistant gloves, eye protection, procedure mask, protective gown when reprocessing devices.

Reprocessing requirements

1. Handling and transport

- Remove visible soil from FCD at the point-of-care before transport to the reprocessing area. Gross (visible) debris should be removed with cloth or gauze moistened with water or detergent.
- FCD, if not cleaned immediately, must be kept moist by using a wet towel moistened with water, a holding solution or foam, or a spray or gel product specifically intended for this use (not saline). Follow manufacturer's instructions.

- Transport contaminated FCD in a labelled, closed, and leak proof container.
- Procedures should be in place to:
 - identify contaminated FCD which have not undergone reprocessing and
 - differentiate multi-client FCD, to be reprocessed, from similar looking single-use FCD, to be discarded.

2. Cleaning

- Follow the manufacturer's instructions for the FCD including specifications for detergent type, water temperature and cleaning methods.
- Whether or not FCD appear soiled; clean FCD before sterilization. The cleaning step is essential before sterilization. The cleaning process includes disassembly (if required), sorting and soaking, physical removal of soil, rinsing, drying, physical inspection, corrosion reduction/lubrication (if required) and packaging.
- Clean, package and sterilize all hinged FCD in the open position.
- Follow manufacturer's instructions if disassembly is required for sterilization.
- Follow manufacturer's instructions for detergents and/or enzymatic cleaning agents (household products are not suitable). Use recommended dilutions and soak times and change the solution according to the manufacturer's instructions.
- Perform manual cleaning below the surface of the water to minimize splashing and generation of aerosols.
- After cleaning, rinse items thoroughly to remove residue, by submerging the items in water, not by holding them under running water.
- Inspect to ensure the FCD are clean and in good working condition.
- Dry using a clean, lint-free, soft absorbent towel. Use of paper towel or air drying is not acceptable.
- Discard disposable cleaning accessories (e.g., brushes and sponges).
- Clean and sterilize reusable cleaning accessories between uses and store in a clean, dry location.

Ultrasonic cleaners

- Follow the manufacturer's instructions for installation, maintenance, loading and use including:
 - removing visible soil from FCD prior to placement in the ultrasonic cleaner.
 - changing the cleaning solution when visibly soiled and at least daily.

- always keeping the lid of the ultrasonic closed when the cycle is on.
- following the ultrasonic cycle, rinse FCD to ensure removal of debris.
- testing the ultrasonic cleaner weekly using a foil test (or method recommended by the manufacturer) and document the results including the name of the responsible person.

3. Packaging

- Use tip-protectors, validated for sterilization, to protect sharp tips and prevent perforation of peel-pouches.
- Wrap FCD in approved packaging material prior to steam sterilization.
- Individual self-sealing peel-pouches are recommended for individual devices or small sets.
- Seal peel-pouches according to manufacturer's instructions.
- Do not overfill peel-pouches. Devices must not place stress on the seams of the peel pouch.
- Each package to be sterilized must have an external process **chemical indicator** (CI) and an internal CI.
- If using non-woven wrap, apply wrap according to established CSA standards (See Appendix B "AHS IPC MDR Audit Wrapping Techniques").
- Label each package with contents, date, load number, sterilizer used (if more than one) and responsible person.
- Label peel pouches on the plastic side and wrapped packages on the autoclave tape using a soft-tipped approved marker or label applicator validated for use in steam sterilization.
- Keep a log of each load, devices within the load, and person responsible for releasing the load.

4. Sterilization

- Follow manufacturer's instructions for installation, loading, operation, routine and preventative maintenance and quality assurance monitoring of sterilization equipment.
- Load the sterilizer so that steam is able to circulate freely around each package and enter and exit from each package. Packages should never contact the inside walls of the sterilizer chamber.
- Load peel-pouches on edge (paper to plastic). If peel-pouches must lie flat, consult the manufacturer's instructions to determine if the package should be placed paper-side up or plastic-side up.
- Do not stack packages.
- Use steam sterilization for FCD that are compatible with heat and moisture.

- Use a sterilizer suitable for sterilizing FCD [e.g., validated for packaged devices and hollow devices (if any are used)]; which can be monitored; that produces dry packages at the end of the cycle; and can accommodate required turn-around time. Check with sterilizer manufacturer's written claims. (See Appendix C: Alberta Health Services Criteria to Consider if Purchasing a Sterilizer)

5. Quality monitoring

- There are three types of indicators to monitor sterility: physical or mechanical, chemical and biological.
- Results of monitoring must be documented and recorded. (See Appendix D: Best Practice Recommendations for Foot Care Devices Sample Sterilization Log Sheet.)
- If any of these indicators fail, devices should not be used.

Physical or mechanical indicators

- Monitor and document the physical parameters of each sterilization cycle (time, temperature and pressure).
- The sterilizer should be equipped with an electronic data log or paper printout documenting the physical parameter of each sterilization cycle.
- In the absence of a printout or data logging system, observe the gauges on the outside of the sterilizer to ensure that the correct sterilization time, temperature and pressure have been achieved.
- Document the results including the person responsible for releasing the load.

Chemical indicators

- Chemical indicators measure predetermined values such as time, temperature, or steam quality.
- Monitor and document results of external chemical indicators (CIs) before releasing devices for use. Look for a color change in the external chemical indicator.
- Perform a **Bowie-Dick** air removal test each day a pre-vacuum (dynamic air removal sterilizer) is used and document the result.

Biological indicators

- Monitor the sterilization cycle with a **biological indicator** (BI) each day the sterilizer is used.
 - **Note:** BIs are contained in a BI challenge test pack. A BI test pack can be commercially prepared or can be constructed in-house by placing a BI inside a pack that is the most difficult to sterilize among those most frequently processed. Place the BI test pack in the area of the sterilizer considered least favourable to sterilization. The “cold-point” in table-top sterilizers varies with sterilizer design but is normally

located in an area near the drain. Run the BI in a cycle with normally fully loaded chamber (check your sterilizer's user manual for details).

- Maintain a log of BI results.
- Follow a written recall procedure in the event of a failed biological indicator (See Appendix E: CPSA Recall Procedure for Positive Biological Indicator).

6. Cool down

- Sterile packages shall not be touched or otherwise handled until the load is cooled to room temperature.
- Ensure packages are dry following sterilization. Inadequate drying or dampness compromises package sterility because the seal, the integrity, or the barrier protection ability of the package is compromised.
- Packages or peel pouches that are wet or have internal condensate after cool down are contaminated and must be reprocessed.

7. Storage

- Maintain sterility of FCD until point-of-use.
- Sterility of packages or peel pouches is event related.
- Stock rotation (first in and first out) must be in place as an element of inventory management.
- Ensure sterile devices are stored in a manner to protect devices from contamination and preserve package integrity. Damaged, torn, wet or dropped packages are considered contaminated. Reprocess FCD if the package integrity is compromised.
- Store sterile, packaged FCD in a clean area protected from excess humidity, temperature extremes, contamination, vermin, or excessive handling and crushing.
- Do not store sterile packages beneath the sink or in the soiled holding or cleaning areas.
- At the point of use, upon opening the packaged FCD, inspect the packaging for integrity, and review the results of the internal and external CI.
- Clean and disinfect contaminated transport containers before using the container to transport clean or sterile medical devices.

Definitions

Bowie-Dick Test means an indicator used to determine whether a dynamic air removal type (pre-vacuum) sterilizer has properly evacuated the air from the load. The air removal or Bowie-Dick test is not a test for sterilization.

Biological Indicator means a test system containing viable micro-organisms providing a defined resistance to a specified sterilization process.

Centralized Medical Device Reprocessing Area means an area within a healthcare setting for cleaning, disinfection or sterilization of medical devices. In community settings and offices, the area can be any segregated area where reprocessing of devices takes place away from clients and clean areas.

Chemical Indicator means a test system that reveals change in one or more pre-defined process variables based on a chemical or physical change resulting from exposure to a process.

Cleaning means the removal of contamination from an item to the extent necessary for its further reprocessing and its subsequent use.

Client means any person receiving healthcare within any healthcare setting. For readability this BPG uses the term “client” to represent client/patient/resident.

Critical means the device presents a high risk of infection if the device is contaminated with any micro-organisms including bacterial spores, because of their potential to cut skin and enter sterile tissues. For the purpose of this document FCD, with the exception of client-owned FCD, are considered critical medical devices.

Event-related sterility means that if items have undergone proper sterile processing (i.e., they have been correctly decontaminated, wrapped, sterilized, stored and handled), sterility can be maintained almost indefinitely, unless the integrity of the package is compromised.

Foot care means healthcare services performed on a client’s feet, which may include clipping, cutting, filing of nails and callous removal.

Foot care device (FCD) means device used to perform care on client’s feet including, but not limited to, nail nippers, files, rasps, scalpel handles and nail probes.

Manufacturer means a person who sells a medical device under their own name, or under a trade mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Manufacturer’s Instructions means the validated, written directions provided by the manufacturer or

distributor of a medical device or product that contain the necessary information for the safe and effective use of the medical device or product.

Medical device means any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for a human being for any of the following purposes:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury or handicap;
- Investigation, replacement or modification of the anatomy or of a physiologic process; or
- Control of conception;

and that does not achieve its principal intended action (Intended Purpose) in or on the human body by pharmacological, immunological, or metabolic means, but that can be assisted in its function by such means.

Non-critical means a medical device that touches only intact skin (but not mucous membranes) or does not directly touch the client. For the purpose of this document client-owned FCD are classified as non-critical.

Reprocessing means the steps performed to prepare a used medical device for reuse.

Reusable FCD means a FCD intended by the manufacturer for multiple uses.

Single-use FCD means a critical or semi-critical medical device designated by the manufacturer for single-use only and may be indicated by, but not limited to, the following terms used for labelling by the manufacturer:

- Disposable;
- Consumable;
- Not for re-use or do not re-use;
- Discard after single-use;
- Do not use twice;
- Or a symbol such as: 

Sterilization/Sterilize/Sterilized means the validated process used to render a product free from viable organisms.

Related documents

ALBERTA HEALTH SERVICES ROUTINE PRACTICES [HTTP://WWW.ALBERTAHEALTHSERVICES.CA/IPC/HI-IPC-ROUTINE-PRACTICES-INFO.PDF](http://www.albertahealthservices.ca/IPC/hi-ipc-routine-practices-info.pdf)

ALBERTA HEALTH SERVICES HAND HYGIENE POLICY

[HTTPS://EXTRANET.AHSNET.CA/TEAMS/POLICYDOCUMENTS/1/CLP-HAND-HYGIENE-PS-02-POLICY.PDF](https://extranet.ahsnet.ca/teams/policydocuments/1/clp-hand-hygiene-ps-02-policy.pdf)

ALBERTA HEALTH SERVICES SINGLE-USE MEDICAL DEVICES POLICY

<https://extranet.ahsnet.ca/teams/policydocuments/1/clp-single-use-medical-devices-ps-07-policy.pdf>

References

1. ALBERTA HEALTH. 2019. REUSABLE & SINGLE-USE MEDICAL DEVICES STANDARDS : STANDARDS FOR THE REPROCESSING OF REUSABLE MEDICAL DEVICES AND FOR THE USE OF SINGLE-USE MEDICAL DEVICES IN ALL HEALTH CARE FACILITIES AND SETTINGS. Retrieved from <https://open.alberta.ca/publications/9781460145470>
2. CANADIAN STANDARDS ASSOCIATION. 2018. Z314-18. CANADIAN MEDICAL DEVICE REPROCESSING.
3. ALBERTA HEALTH SERVICES SINGLE-USE MEDICAL DEVICES POLICY. 2016. <https://extranet.ahsnet.ca/teams/policydocuments/1/clp-single-use-medical-devices-ps-07-policy.pdf>
4. PROVINCIAL INFECTION CONTROL NETWORK OF BRITISH COLUMBIA. (PICNET) 2016. REPROCESSING OF EQUIPMENT AND INSTRUMENTS USED IN THE PROVISION OF HEALTHCARE. RETRIEVED FROM <https://www.picnet.ca/wp-content/uploads/picnet-discussion-paper-foot-care-equipment-reprocessing-2016.pdf>

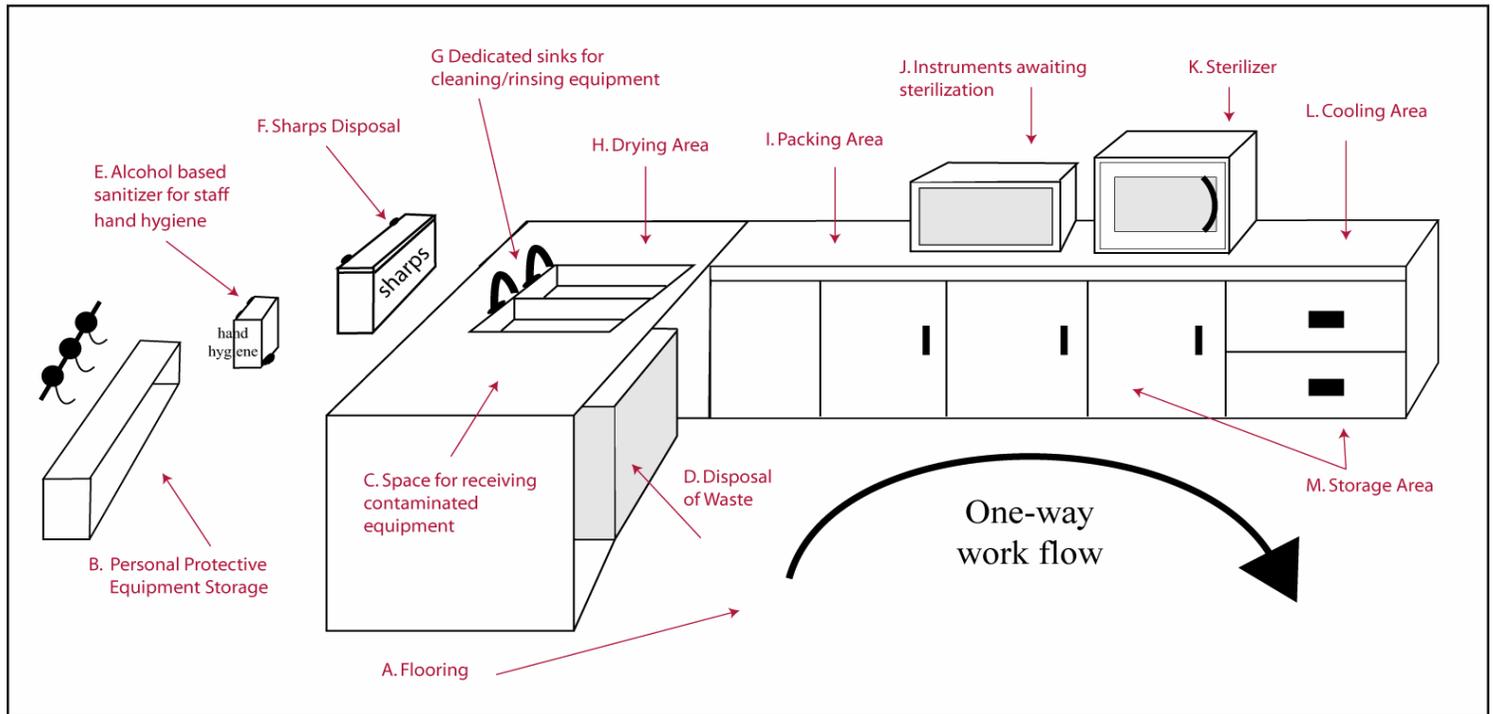
This document was developed by the Infection Prevention and Control (IPC) Committee for Best Practice Recommendations for Foot Care Devices with representation from AHS Environmental Public Health Services, AHS IPC from each zone including community, continuing care, rural, urban, and acute care sectors, as well as IPC representation from the Health Protection Branch of Alberta Health, Covenant Health; and the Good Samaritan Society. AHS experts from the medical device reprocessing area and workplace health and safety also reviewed and provided feedback on the draft BPG for FCD.

In addition, this draft was reviewed by external stakeholder groups. Respondents included: Alberta Health, Health Protection, and Health Benefits and Compliance Branches; First Nations and Inuit Health Branch; Capital Care; and Health Professional Regulatory Bodies including the College and Association of Registered Nurses of Alberta (CARNA), College of Licensed Practical Nurses of Alberta (CLPNA), College of Physicians and Surgeons of Alberta (CPSA), and the College of Podiatric Physicians of Alberta (CPPA).

- Appendix A: Suggested Reprocessing Area Design and Layout
- Appendix B: Alberta Health Services IPC MDR Audit Wrapping Techniques
- Appendix C: Checklist for Table-top Steam Sterilizers
- Appendix D: Sample Sterilization Log Sheet
- Appendix E: CPSA Recall Procedure for Positive Biological Indicator

Appendix A: Suggested Reprocessing Area Design and Layout

Suggested Reprocessing Area Design & Layout



Copied with permission from the College of Physicians and Surgeons of Alberta IPAC Physician Toolkit, Suggested Reprocessing Area Design and Layout, page 27. [http://cpsa.ca/wp-content/uploads/2015/04/IPAC Reprocessing A Physician Toolkit.pdf?pdf=Reprocessing-Toolkit](http://cpsa.ca/wp-content/uploads/2015/04/IPAC%20Reprocessing%20A%20Physician%20Toolkit.pdf?pdf=Reprocessing-Toolkit)

A. Flooring – Is easy to clean, and is not slippery when wet.
B. Personal Protective Equipment Storage - A dedicated space for storage of personal protective equipment.
C. Space for receiving contaminated equipment
D. Disposal of Waste - Bins must be available for disposal of waste.
E. Alcohol Dispenser – An alcohol dispenser for hand hygiene.
F. Sharps Disposal - A secure biohazard sharps disposable container is required.
G. Dedicated sinks for cleaning/rinsing equipment – In the absence of two sinks dedicated for equipment cleaning and rinsing, a basin for rinsing equipment post decontamination is an acceptable alternative.

H. Drying Area – An area for drying equipment post rinsing.

I. Packing Area - A clean separate area for packing equipment for sterilization.

J. Instruments awaiting sterilization - A labeled container for instruments awaiting sterilization is recommended.

K. Sterilizer - It is important that a daily sterilizer log book be kept by each autoclave in use.

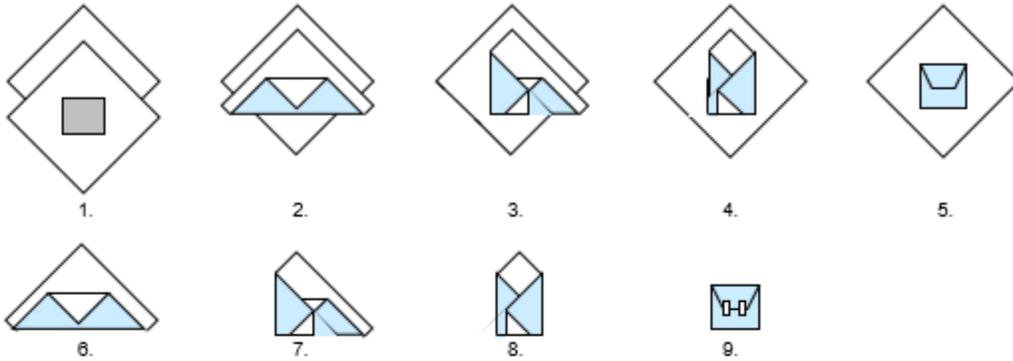
L. Cooling Area - A clean area for allowing sterilized packs to cool before storage.

M. Storage Area - There needs to be adequate storage areas for cleaned, packaged and sterilized instruments.

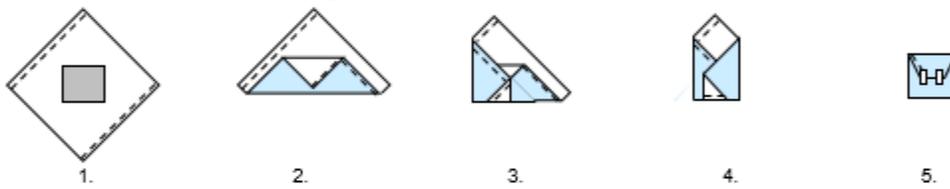
Appendix B: Alberta Health Services IPC MDR Audit Wrapping Techniques

Note: Underside of wrapping is shaded.

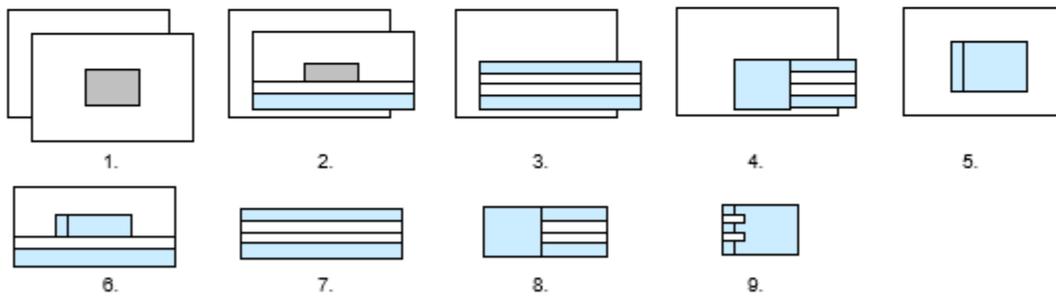
Sequential Double-Wrapping – Envelope Fold



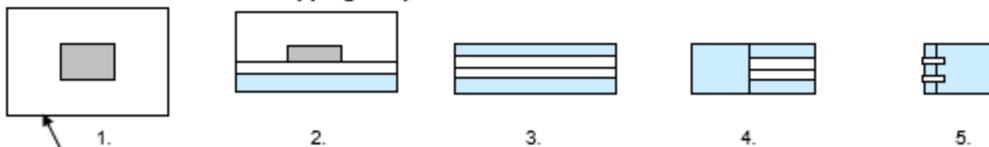
Simultaneous Double-Wrapping – Envelope Fold



Sequential Double-Wrapping – Square Fold



Simultaneous Double-Wrapping – Square Fold



Two single-layer wrappers or one bonded double-layer wrapper.

Appendix C: Checklist for Table-top Steam Sterilizers

All sterilization processes should follow the manufacturer's instructions for installation, operation, preventative maintenance and quality assurance of the equipment. Sterilizers also should be subjected to rigorous testing and monitoring on installation and following disruptions to their normal activity. Sterilizer records should include results of time, temperature and pressure to ensure that effective sterilization has been achieved. In order to meet these requirements, table-top sterilizers should meet the following criteria:

Criteria Met?		Criteria	Comments
Yes	No		
<u>If considering purchasing a sterilizer</u>			
		1. Is it possible to send reusable medical devices requiring sterilization to Central Service/Sterile Processing Department?	
<u>Sterilizer:</u>			
		2. The sterilizer has a printer/data logger to document a permanent record of time/temperature/pressure, sterilizer identification, date, time and load or cycle number.	
		3. The sterilizer uses a dynamic air removal cycle, this may be stated as a 'steam flush pressure pulse' or a 'pre-vacuum' system. Note: this method of air removal is important if reprocessing complex instrumentation, lumened or wrapped items.	
		4. The sterilizer has a Health Canada medical device license.	License number:
<u>The sterilizer manufacturer supplies the following information in writing:</u>			
		5. Statement of sterilizer's ability to sterilize the proposed medical devices (e.g., lumened instruments, power tools, wrapped sets of instruments). Summary of documentation is supplied to support validation claim.	
		6. Any unique requirements for installation and maintenance of the sterilizer. These may include operational constraints specific to altitude (e.g. Calgary is at approximately 3500 feet elevation; Ft. McMurray is at approximately 1213 feet elevation) and water supply (e.g., reservoir, potable, treated water).	
		7. Recommended sterility assurance monitoring: <ol style="list-style-type: none"> a. Appropriate biological and chemical monitors. b. Appropriate Class II (Bowie-Dick) chemical indicator for pre-vacuum sterilizers. 	
		8. Recommended maintenance procedures and schedules and qualifications of technical support providers.	

Appendix E: CPSA Recall Procedure for Positive Biological Indicator

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