

Reprocessing of Critical Foot Care Devices

Background

Foot care devices have been associated with healthcare associated infections and outbreaks.¹⁻⁶ The goal of this document is to provide infection prevention and control (IPAC) recommendations for the management of critical foot care equipment and/or devices. This will include cleaning, disinfection, sterilization, transportation, and storage.

Position Statement

Clients expect and require safe care regardless of where the procedure is performed. Therefore, each client interaction requires a sterile set of foot care equipment/devices.

1. Reusable foot care equipment/devices are considered critical devices.⁷⁻¹³
2. All healthcare providers:
 - Shall have sufficient numbers of foot care equipment/devices/kits to ensure sterile equipment, either single use or properly reprocessed, for each individual client treatment.
 - Are responsible to ensure that the client is not placed at risk of infection when reusing any foot care equipment/devices during the provision of care.
3. Reprocessing of reusable foot care equipment/devices shall meet manufacturers' instructions for use (MIFU), current national guidelines such as Canadian Standards Association (CSA), the Public Health Agency of Canada (PHAC/Health Canada), and provincial standards.^{9,13}
 - Reusable equipment/devices are sold with manufacturer instructions for use (MIFUs), including for proper cleaning and sterilization, and shall not be purchased, used, or reprocessed without these. Determine reprocessing methods in advance of purchase. Single-use medical equipment/devices do not have such instructions and shall not be reprocessed^{7, 8, 13, 16}
 - Critical medical equipment/devices shall be sterile for use and MIFUs for parameters for sterilization shall be followed.
 - If the process used for reprocessing cannot meet the current standards, single use disposable items shall be used and discarded after use.
 - Nail clippers should be deemed single use if no MIFUs are available or if the MIFUs do not meet recognized standards.
4. Medical equipment/devices used to provide foot care should be used according to the MIFU (i.e., for the intended purpose and following instructions for use, as per the manufacturer) and designed

for use on humans, specifically feet (e.g., rotary sanding device and accessories). Medical equipment/devices that are designated as class II or higher require a medical device licence. Health Canada's Medical Devices Active Licence Listing (MDALL) / Medical Devices Establishment Licence Listing (MDEL) are resources to verify if the equipment or establishment is approved in Canada.

5. Options to achieve a *sterile set of foot care equipment/devices for each client interaction* include:

Option 1: Use single-use sterile disposable equipment/devices and discard appropriately after use.^{10, 11}

Option 2: Multi-client reusable foot care equipment/devices reprocessed using the contracted services of a centralized Medical Device Reprocessing Department (MDRD). The contracted MDRD meets the CSA standards and has qualified technicians to perform the reprocessing (cleaning and steam sterilization).¹⁰

- This equipment requires thorough decontamination (cleaning and disinfection), packaging, and steam sterilization between each client use, and shall follow of CSA standards for storage of sterile supplies to ensure they maintain sterility.
- Best practices for transportation and storage of soiled and reprocessed equipment/devices shall be incorporated and meet current CSA standards.
- There shall be a robust process for recall of reprocessed equipment/devices in the event of reprocessing failure. Load records, proper labelling, and chemical and biological indicators are required.

Option 3: The healthcare provider chooses to reprocess reusable equipment/devices themselves, with the following considerations incorporated into practice:

- Purchase current pertinent CSA standards documents^{13, 15} for reprocessing practices and purchasing, and follow these along with provincial reprocessing guidelines.
- Healthcare provider shall have written procedures based on current standards.^{13, 15}
- Education: "Personnel involved in all medical device reprocessing functions shall be prepared for the tasks that they are required to perform through formal education and training . . ." ¹³ including at minimum:
 - Following national and provincial guidelines.^{9,13}
 - Education and competency related to all equipment/devices used in the process; maintenance, quality testing, monitoring of the sterilization process; packaging, storage and transportation of reprocessed equipment/devices including chemicals; and sterilization equipment.
 - Training to a level required for the volume and complexity of the equipment.^{7,8}
- Reprocess equipment following the MIFUs for the device and the sterilizer.
- Ensure the MIFUs for each piece of equipment meet recognized accepted standards for reprocessing.
- Steam sterilization is required for foot care instruments and the sterilizer requires a printout or electronic record for each cycle.¹³
- Follow quality assurance recommendations, including monitoring and documentation of mechanical, chemical, and biological indicators.¹⁵

- There shall be a robust process for recall of reprocessed equipment/devices in the event of reprocessing failure, including labelling of all packages with the sterilization date, load, sterilizer number, name of the medical device, and initials of the person packaging the device.
- Best practices for transportation and storage of soiled and reprocessed equipment/devices shall be incorporated. If using event-related sterility, a quality system is required with policies and procedures for the storage process.
- Incorporate a preventative maintenance schedule according to equipment MIFUs, including maintenance procedures, cleaning frequency of autoclave and reprocessing area, and annual autoclave calibration by a certified technician.
- There shall be a procedure outlining actions to be taken if parameters of cleaning and sterilization are not met, including documentation of steps taken to remediate.
- The foot care provider shall follow Occupational Health & Safety guidelines (e.g., Routine Practices and Additional Precautions, appropriate personal protective equipment, safe sharps management, hand hygiene, and the procedure for staff exposures that occur during reprocessing).⁷

Note: The use of liquid chemicals for sterilization of instruments is not recommended for critical equipment/devices that are used for sterile procedures due to the limitations in maintaining sterility to point of use.⁽¹⁴⁾ “Devices cannot be wrapped or adequately contained during processing in a liquid chemical sterilant to maintain sterility following processing and during storage.”¹⁶

Unacceptable methods of sterilization include Immediate-Use Steam Sterilization (IUSS) formerly referred to as Flash sterilization, glass bead sterilizer, microwave oven, boiling, Chemiclave, steam sterilizers without printouts or electronic recording, dry heat (in this setting) and ultraviolet irradiation⁸

Stakeholders

Healthcare providers performing foot care in any health care setting, which includes, but is not limited to care provided in private homes, clinics, and healthcare settings. (See healthcare setting definition.)

Glossary

Class II equipment/devices: All invasive devices that penetrate the body through a body orifice or that come into contact with the surface of the eye are classified as Class II. See Classification Rules for Medical Devices: <https://health-products.canada.ca/mdall-limh/index-eng.jsp> .

Client: includes patient, client, resident

Critical Medical Equipment/Devices: Medical equipment/devices that enter sterile tissues, including the vascular system (e.g., biopsy forceps, foot care equipment, dental hand pieces, etc.). Critical medical equipment/devices present a high risk of infection if the equipment/device is contaminated with any microorganism, including bacterial spores. Reprocessing critical equipment/devices involves meticulous cleaning followed by sterilization.⁸

Foot care: Routine care includes a clinical assessment of the feet, education for the client, and care that only involves the epidermal layer of the skin or nails. Routine care may include the filing of corns or calluses, the filing or trimming of nails, and skin care. Invasive foot care includes contact with non-intact skin and surgical interventions with entry into or contact with the epidermal, dermal, deep fascial, and osseous structures. Foot care is performed by healthcare providers (e.g., chiropodists, podiatrists, nurses, advanced independent practice nurses) within their defined scope of practice.

Healthcare provider: Any healthcare professional delivering foot care service to a client as well as those performing reprocessing duties.

Healthcare setting: Any location where healthcare is provided, including home healthcare, offices of other health professionals, outpatient clinics, emergency care, hospitals, complex continuing care, rehabilitation hospitals, long-term care homes, mental health facilities, , community health centres and clinics, physician offices, dental offices, independent health facilities, out-of-hospital premises, and public health clinics.

Manufacturer’s instructions for use (MIFU): The written instructions for use provided by the manufacturer or distributor of a product that contain the necessary information for the safe and effective use of the product. ¹³The manufacturers validated instructions for use must be followed to ensure proper and safe use of a product regardless of other guidelines.

Medical Devices Licenses:

Medical Devices Active Licence Listing (MDALL): Reference tool for licensed medical devices in Canada by Health Canada, accessible at <https://health-products.canada.ca/mdall-limh/index-eng.jsp>

Medical devices establishment licence listing (MDEL): List of holders of an active medical devices licence by Health Canada, available at <https://health-products.canada.ca/mdel-leim/index-eng.jsp>

Single-use/Disposable: A term given to medical equipment/devices designated by the manufacturer for single-use only. Single-use equipment/devices must not be reprocessed.

Sterilization: The level of reprocessing required when processing critical medical equipment/devices. Sterilization results in the destruction of all forms of microbial life¹³ including bacteria, viruses, spores, and fungi. Equipment/devices must be cleaned thoroughly before effective sterilization can take place.

As per the Canadian Standard Association (CSA):

“SHALL” is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard;

“SHOULD” is used to express a recommendation or that which is advised but not required; and

“MAY” is used to express an option or that which is permissible within the limits of the standard, an advisory or optional statement.

Participants in Development of Position Statement

This position statement was developed by Reprocessing Interest Group

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Appendix: Foot Care Equipment

In the delivery of foot-care services, equipment often intentionally or unintentionally comes into contact with blood, body fluids, or non-intact skin, requiring sterilization. Therefore **it is imperative to manage all equipment as if it has been contaminated. Soil is not always readily visible. Infection prevention and control best practices indicate there should be one reprocessing system for all equipment from any client.**

Reprocessing of reusable foot care equipment/devices must meet MIFUs, and the current national guidelines such as Canadian Standards Association (CSA), the Public Health Agency of Canada (PHAC/Health Canada) as well as provincial standards. ^{9,13}

Adapted from Spaulding's Classification

Class	Use	Minimum Level of Reprocessing	Examples
Critical	Equipment/devices that enter sterile body site (e.g., below the epidermis), including the vascular system	Thorough cleaning followed by sterilization	<ul style="list-style-type: none"> • Scalpel handle • Scissors • Callus parer • Halstead mosquito forceps • Probe • Nail splitter • Curette • Nail Elevator • Debris evacuator • Double ended Blacks file • Barrel nail nipper • Diamond Deb File • Single ended Black file • Stainless steel foot paddle handle <p><i>These are examples and not an inclusive list for foot care</i></p>

Single-Use Equipment/Devices (These examples are not an inclusive list):

- Scalpel blades
- Callus Parer blade
- Foot paddle sanding pad

- Monofilament
- Nail Clipper - unless the MIFU state otherwise
- Toe Nail Nipper - unless the MIFU states otherwise
- Ingrown nail nipper – unless the MIFU states otherwise
- Nail files/emery board/orange stick

Management of Burrs

- Burr/disk on rotary sanding tools - Rotary Sanding Tools: Equipment/devices used to provide foot care, must be approved for medical use and designed for use on the humans, specifically, feet (e.g., rotary sanding device and accessories). If used, it should be purchased from an authorized medical manufacturer. The burr (unless stated otherwise by manufacturer)/disk must be considered to be a single use device and cannot be reprocessed.
- Reprocessing of burrs deemed reusable by the manufacturer may be reprocessed following the MIFUs, and the MIFUs must meet current national guidelines such as Canadian Standards Association (CSA), the Public Health Agency of Canada (PHAC/Health Canada) as well as provincial standards.^{9,13}