FOOT CARE INSTRUMENTS STERILIZATION STANDARDS

Pre-amble

It is critical that the podiatric surgeons of British Columbia attain a high standard of medical instrument reprocessing in their practice of podiatric medicine, one that ensures each instrument used on patient care meets the necessary standard.

This document sets out the minimum requirements of the College of Podiatric surgeons of British Columbia.

General Requirements

The instruments used by Podiatric Surgeons for foot care are considered “Critical” and therefore require sterilization after each patient use.

The goal of sterilization is to minimize the risk of exposure or injury and to prevent the transmission of micro-organisms. It is required and assumed that each person performing the cleaning and sterilization processes be properly trained and practice the principles of Routine Practices and Transmission Based Precautions at all times.

There must be a designated registrant at every podiatric practice facility, who is responsible to the College to ensure that relevant training protocols and practices are in place in the facility, and that the same are utilized and adequately monitored to ensure their efficacy.

Preparation and Cleaning of Reusable Podiatric Instruments

Pre-cleaning at point of use:

Pre-cleaning (e.g., soak or spray) prevents soil from drying on devices and it makes them easier to clean:

1) Segregate devices that incorporate any sharp components to prevent injury to personnel.
2) Cleaning products used should be appropriate for medical devices and approved by the device manufacturer.
3) If detergent based products are used, ensure that they are mixed to the correct in-use dilution.

4) Avoid prolonged soaking of devices.
5) Do not use saline as a soaking solution as it damages some medical devices. Likewise it is not advised to use liquid chemical sterilants or high-level sterilants as a soaking solution due to increased difficulty in cleaning and their general toxicity.

Handling and Transportation of contaminated instruments

Soiled instruments are to be handled in a manner that reduces the risk of exposure and/or injury to personnel and clients, or contamination of environmental surfaces.

1) Contaminated devices shall be transported to a designated decontamination area as soon as possible after use.
2) Contaminated devices shall be transported in a manner that will prevent the spill of liquids.
3) All carts and containers containing contaminated devices shall be identified as such.
4) Sterile and soiled devices shall not be transported together due to the risk of cross-contamination.
5) Devices should be kept moist in a transport container by adding a product specifically intended for this use.
6) The containers should be decontaminated after each use.

Preparation for Cleaning

Once medical devices have been received in the reprocessing area, they should be

1) Disassembled which facilitates access of the cleaning agent, disinfectant and/or sterilant to the device surfaces
2) Sorted
3) Pre-treated if needed (e.g., soak or spray)

Cleaning

Cleaning entails the removal of debris and can be done manually or using mechanical cleaning machines (e.g., washer-disinfector, ultrasonic washer) after gross soil has been removed. This step is essential as any remaining organic debris will compromise the sterilization process of the instruments.

The ultrasonic solution shall be changed at least daily or more frequently if it becomes visibly soiled or if the manufacturer's instructions specify more frequent changes.

After cleaning, the instruments should be rinsed with water to remove any residual detergent and visually inspected.

Devices should be dried prior to sterilization.

Instrument Preparation and Packaging

Clean instruments should be inspected, assembled, and packaged for sterilization. Hinged instruments should be processed open and unlocked.

Sterilization of Reusable Podiatric Medical Instruments

Steam (Autoclave)

Steam under pressure is the preferred method of sterilization. It is recommended that the manufacturers' instructions for installation, operation and ongoing maintenance be followed.

Immediate Use Steam (Flash)

Instruments that are processed without packaging and should be used immediately after processing. Storage is unacceptable. Devices used in this manner should be traced to the patient in case of an adverse event

Low- Temperature

This should be used only for instruments that are heat and moisture sensitive. The specific instructions and guidelines provided by the manufacturer should be followed.

All sterilization equipment must be approved by Health Canada.

Monitoring of the Autoclave Efficacy

This is to verify that sterilization has occurred. All three monitors must be used as prescribed below;

1) Physical monitors – this monitors the physical conditions in the chamber such as temperature, time, and pressure. This should be recorded for each cycle. If no automated report is available, then a log book must be maintained and readily available for inspection.

2) Biologic Indicators – this verifies the lethality of the sterilization process. The biological indicator (BI) should be used in accordance with the manufacturers' instructions. This is to be performed weekly and recorded.

3) Chemical Indicators – this will indicate that the package has been processed through a sterilization cycle. This DOES NOT indicate that the instrument is sterile and therefore does not replace the need for use of the BI. Used at each cycle.

Recording Keeping

A log book must be maintained that records:

1) Change of water dates
2) Cleaning and servicing dates
3) Results of spore tests.

Failed BI Tests

In the event of a failed BI test (failed spore test) then the device shall

1) Be removed from service
2) Repeat the BI test
3) If repeat BI indicates sterility has been obtained, then it may be returned to service
4) If the repeat BI test fails, than the sterilizer must be removed from service until it can be inspected, repaired, and successfully re-challenged in three consecutive empty chamber cycles.

Storage of Sterilized Instruments

Instruments should be stored in an enclosed space and where they will not become wet or contaminated.

This document borrowed many of the principles put forth by the "Best Practices Guidelines for Cleaning, Disinfection, and Sterilization of Critical and Semi-Critical Devices in BC Health Authorities, Dec. 2011.