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POSITION STATEMENT

Reprocessing Toenail Burrs and Rotary Sanding Devices in the Podiatric Community-based Clinical Office

Details

Department/program: Physician Practice Enhancement Program

Date: February 16, 2022

Purpose

Position statements from the College provide background information and express or clarify the College's intent on a particular matter. They are intended as guidance for stakeholders in areas where events are evolving or changing rapidly, the implementation of processes and procedures may be premature, or it is timely to communicate the College's broad intent before or as policies and procedures are developed.

This document addresses best practices around the reprocessing of toenail burrs and rotary sanding devices used specifically on toenails and skin conditions in podiatric community-based clinical offices. This position statement does not address the reprocessing of burrs used in podiatric surgical procedures (i.e. bone).

Background

Toenail burrs and rotary sanding devices have been used in podiatry for toenail care and skin conditions (i.e. calluses) for decades. There are a variety of toenail burrs and rotary sanding devices available for purchase by health-care practitioners and the general public. Sometimes the distinction between a toenail burr or rotary sanding device intended for industrial use versus medical use is not obvious to the user. To complicate the matter, supply vendors may sell burrs and rotary sanding devices intended for industrial use (milling, woodwork) as well as burrs and rotary sanding devices intended for medical use (podiatric, dental).

Medical grade burrs and rotary sanding devices are considered Class I medical devices per Health Canada. A device that is considered medical grade also implies that the manufacturer has provided specific instructions on how to clean and disinfect or sterilize the device.

Industrial devices have not been validated for use on humans. They have not undergone the validation process that medical grade devices undergo by the manufacturer, which includes instruction for the user on how to safely clean and disinfect/sterilize the device. Any cleaning or reprocessing steps taken by the health-care practitioner on a non-medical grade device are unvalidated (untested). This means that the materials were not specifically selected to tolerate cleaning and disinfection/sterilization between uses as is required of a medical grade device. Therefore, performing any cleaning and/or disinfection/sterilizations steps on these non-medical grade devices may contribute to the breakdown of the device and put the patient and the user at risk.

There are guidelines and position statements published by both provincial and national interest groups such as Infection Prevention and Control (IPAC) Canada and the Provincial Infection Control Network of British Columbia (PICNet) that include the agreement that all reusable foot care devices must be considered reusable critical devices based on Spaulding's classification. This classification is used to determine how a device will be reprocessed, according to the perceived level of risk. A reusable critical device must be sterilized when used between patients due to the intentional or unintentional contact with blood, body fluids, or non-intact skin. These position statements also state that all foot care devices such as burrs and rotary handpieces must be medical grade (designed for use on humans).

Position

Based a comprehensive review that included national and provincial standards and guidelines on foot care devices, as well as manufacturer's instructions for use, the College's directions on the use of toenail burrs and rotary sanding devices in community-based clinical offices are the following:

Toenail burrs

- The College will only accept the use of medical grade toenail burrs.
    - Medical grade implies that they are intended to be used on humans and that they have been approved by Health Canada or the United States Food and Drug Administration (FDA) for sale. **Note:** They may have been manufactured elsewhere but must be Health Canada or FDA approved for sale.
- Non-medical grade toenail burrs must be discontinued from use.
- Single use disposable toenail burrs are preferred, however reusable medical grade toenail burrs are acceptable, provided they have been validated to be reprocessed by steam sterilization (according to the manufacturer's instructions for use (MIFU)).
- Reusable toenail burrs must be cleaned, dried, packaged for steam sterilization, steam sterilized and stored appropriately between each use on patients.
- Using a steam sterilizer to reprocess reusable medical grade burrs must include all required best practice parameters and quality assurance testing (such as biological indicator tests, internal/external chemical indicator tests, etc.).
- All sterilized reusable medical grade toenail burrs should remain in packaging until point of use.

- The MIFU must be followed for all aspects (cleaning, packaging, steam sterilization) of the reprocessing of reusable medical grade burrs (e.g. requirement to use an ultrasonic washer for the cleaning step).
- If no MIFU is available for a reusable medical toenail burr, then the burr must be considered single use disposable and discarded after use.

Rotary sanding devices

- The College will only accept the use of medical grade rotary sanding devices.
    - Medical grade implies that they are intended to be used on humans, and that the manufacturer of the device provides instructions for use that describe how to clean and disinfect it between uses on patients.
    - If no MIFUs are provided for post-procedure cleaning and disinfection, the rotary sanding device must be discontinued from use.
- Non-medical grade (intended for commercial use, woodwork) rotary sanding devices must be discontinued from use.

Note: Health Canada has determined that rotary sanding devices meet the requirements for a class II medical device. At this time it appears that no current manufacturer for this device has completed the Health Canada approval process. The College's direction is that even without the current Health Canada medical device approval, the rotary sanding device must clearly be intended for human use and also have validated manufacturer's instructions for use that describe how to clean and disinfect it.

Suction system for toenail dust abatement (system) during procedure

- Medical grade rotary sanding devices must include a closed suction system (medical grade attachment with either a vacuum or water system) to abate toenail dust during procedure. During the procedure, toenail dust is generated and aerosolized in the room. Without the appropriate closed suction system this dust poses a health risk to the operator and the patient.

References

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Contact

For further information, please contact the Physician Office Medical Device Reprocessing Program (POMDRA).