



CLEANING AND STERILIZING REUSABLE MEDICAL DEVICES

ISSUE

Proper cleaning and sterilization of reusable devices in Canadian healthcare facilities is critical in preventing patient exposure to infectious agents. Communication and implementation of the manufacturers' validated processes should be optimized with a view to developing best practise solutions that ensure patient safety.

MEDEC'S POSITION

- Manufacturers must provide clear and accurate instructions that explain proper reprocessing procedures for the device and any relevant standards that may be applicable.
- Healthcare facilities that reprocess reusable medical devices should ensure those devices are re-processed according to the manufacturers recommended procedures.
- Healthcare facilities that reprocess reusable medical devices should implement reprocessing protocols that ensure personnel are trained and knowledgeable on all relevant procedures recommended by the various manufacturers of the reusable devices.
- Healthcare facilities should validate their ability to meet manufacturer specific cleaning and sterilization parameters.
- A standard sterilization parameter for all reusable devices is neither practical nor sustainable.



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BACKGROUND OVERVIEW

Proper cleaning and sterilization of reusable medical devices are critical in preventing patients from exposure to potential infectious agents. Throughout 2003/2004, there were several instances of breaches of reprocessing in Canadian healthcare facilities that may have exposed patients to infectious agents. Several thousand patients were recalled and in a few cases, serious infection occurred subsequent to procedures involving inadequately reprocessed devices. Several class action lawsuits have also been launched.

Cleaning and sterilization of reusable devices is a shared responsibility between manufacturers and healthcare facilities. Manufacturers must provide instructions for reprocessing. Hospitals should ensure adequate training for reprocessing staff and the development and implementation of a reprocessing protocol.

Recently, some healthcare facilities have begun requesting that reusable devices conform to a single standard reprocessing protocol that specifies a single sterilization parameter for all reusable devices. This request may in some cases be specified as a condition of purchase to

the supplier. A standard sterilization parameter for all reusable devices is neither practical nor sustainable.

Sterilization and cleaning of reusable devices are determined by several variables including device type and design, material characterization and device maintenance. Reusable devices are designed for specific uses and thus vary widely. Material, volume, surface texture and features, all create a need for different cleaning and sterilization procedures. Manufacturers provide specific instructions for cleaning and sterilizing devices based on the particular properties and features of the device.

A single reprocessing protocol does not work for all types of devices. It is also unreasonable to expect industry to design or validate its products to fit one particular reprocessing protocol given the wide variances in types of devices and manufacturers. Hospitals should therefore ensure they have adequate resources and training for reprocessing staff to cover the various reprocessing protocols that exist for different types of devices.



A STANDARD STERILIZATION PARAMETER FOR ALL REUSABLE DEVICES IS NEITHER PRACTICAL NOR SUSTAINABLE.

CONCLUSION

Patient safety is a priority for MEDEC members, therefore it is critical for healthcare facilities that reprocess reusable devices to follow manufacturers' recommended instructions for use on the proper cleaning and sterilization of reusable devices. It is important that healthcare facilities recognize the variation among devices, and that a "one process fits all" approach will not work and may in fact place patients at increased risk. All devices should be sterilized according to manufacturers' specifications for the safest possible outcomes.

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