ciphi ontario Fact Sheet
Leading, Promoting and Advocating for Environmental Public Health Professionals in Ontario

Sterilization Equipment & Process

Critical instruments/equipment are those that penetrate the skin or mucous membranes, enter normally sterile tissue and/or have direct contact with the bloodstream. Sterilization is the method of reprocessing recommended for all critical items. Sterilization kills or permanently inactivates all forms of microbial life on an object, including bacteria, viruses, spores and fungi. Examples of critical equipment/devices that require sterilization include tattoo and piercing needles, body-piercing jewellery for new piercings, tissue separators, dermal punch or biopsy tools and items implanted under the skin during body modification procedures.

Infection Risks

There is a risk of infection transmission when critical instruments/equipment become contaminated with microorganisms and when these are not appropriately cleaned and sterilized after use on a client and before use on a subsequent client. Critical instruments and equipment are therefore expected to be sterile for each use. Critical items may be purchased pre-sterilized or may be reprocessed (cleaned and sterilized) on-site using an approved sterilizer.

Additional Considerations

Items purchased sterile:

- For instruments/equipment/devices purchased as pre-packaged, sterile, operators are to obtain documentation from the manufacturer that indicates the equipment/devices are sterile, and that specifies the method of sterilization used.
- If pre-packaged sterile items are labelled with an expiry date, items are not to be used beyond the date of expiry. If sterile items do not have a specified expiry date, these may be used as long as packaging integrity is maintained.

Sterilization equipment:

- Sterilizers and ultrasonic cleaners are to meet Health Canada and CSA Group standards.
- Sterilizers are to include a drying cycle for all sterilization cycles for wrapped or packaged equipment/devices.
- Dynamic air removal (e.g., pre-vacuum) steam sterilizers are preferred.
- All sterilizers and ultrasonic cleaners are to be operated and maintained according to the MIFU.
- Ultrasonic cleaners are to be provided with a lid, cleaned, disinfected and refilled with clean solution daily, and tested weekly (at a minimum) for efficacy.
- Documentation of preventative maintenance or repairs done on or to a sterilizer is to be maintained.
- All new steam sterilizers are to be equipped with either a printout or a digital display that provides details of all three mechanical parameters reached during each cycle.

- Sterilizer qualification tests are to be run when installing new sterilizers, after relocating sterilizers, after major repairs or after mechanical malfunctions, power outages or other emergency scenarios. The sterilizer is not to be used until results of three consecutive spore tests are all negative.
- When a sterilization failure has occurred, the equipment/devices in that load is not to be used. The equipment/devices are to be cleaned, repackaged, and re-sterilized.
- When a sterilization failure has occurred, the operator is to use an alternate method of sterilization or an alternate procedure that prevents disease transmission.
- If equipment/devices from a failed load have been used, operators are to conduct appropriate notification and investigate the cause of the sterilization failure.
- A written backup plan is to be prepared and reviewed annually in the event of sterilizer malfunctions.

Sterilization process:

- Prior to cleaning, equipment and instruments that consist of multiple components are to be disassembled according to the manufacturer's instructions for use (MIFU).
- Reusable equipment/devices are to be thoroughly cleaned prior to sterilization in order to ensure the sterilization process is effective. Ultrasonic cleaners are to be used for critical equipment instruments that have lumens, crevices or other areas that are difficult to clean.
- All items are to be cleaned, dried and packaged prior to sterilization, with instruments placed in packages in the open and unlocked position. Only packages intended for use with steam sterilizers are to be used.
- All items are to be sterilized according to the parameters in the MIFU.
- Operators are to monitor the sterilization process using physical, biological (BI) and chemical indicators (CI), and are to document results.

Sources

1. Health Protection and Promotion Act. Ontario Regulation 136/18 Personal Service Settings. Cited [2019 Sept 10] Available at: *https://www.ontario.ca/laws/regulation/180136*
2. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Guide to infection prevention and control in personal service settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2018. Cited [2019 March 11] Available at: *https://www.publichealthontario.ca/-/media/documents/guide-ipac-personal-service-settings.pdf?la=en*
3. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices. 3rd ed. Toronto, ON: Queen's Printer for Ontario; May 2013. Cited [2019 March 14] Available at: *https://www.publichealthontario.ca/-/media/documents/bp-cleaning-disinfection-sterilization-hcs.pdf?la=en*

This fact sheet is based on PSS best practices recommendations, current reprocessing standards and legislation. It is not an inclusive list of all requirements. Operators are responsible to ensure that all services are offered according to local requirements, best practices and legislation.