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

Sterilization Packaging & Monitoring

Equipment/devices that require sterilization are to be dismantled, physically cleaned and dried prior to packaging. Due to the invasive nature of some personal services (e.g., tattooing, body-modification procedures), some reusable items that are non-invasive but have a significant potential for exposure to blood and body fluid are to be treated as critical items and sterilized after each use (e.g., metal grips/tips, receiving tubes, clamps and reusable scalpel handles).

Infection Risks

Failure to properly package equipment/devices can compromise the sterility of critical items and potentially expose clients and operators to microorganisms that can cause infections and illness (e.g., vegetative bacteria, bacterial spores, fungi, fungal spores, viruses, etc.).

Packaging Considerations:

- All equipment and items to be sterilized are to be packaged prior to sterilization, including items sterilized in cartridge-type sterilizers, to ensure sterility of items until the point of use.
- Operators are to select packages and pouches that are intended for use with steam sterilizers and are appropriate for the item/equipment to be sterilized.
- Operators are to ensure that items to be sterilized are in the open and unlocked position and that packages/pouches are not overloaded to ensure effective steam penetration and sterilization of all items in the package.
- Paper-plastic peel pouches are a suggested option due to their ease of use, wide range of sizes and features such as self-sealing closures and chemical indicators.
- Packages/pouches are to be labelled with the date of sterilization, using a permanent, soft-tipped marker, and in a way that does not compromise the integrity of the package/pouch. I.e., the date can be written outside the sealed edge of the plastic side of the paper/plastic pouch, but should not be written on the paper side of the pouch.

Physical (Mechanical) Parameter Monitoring:

- Physical monitoring verifies that the conditions for sterilization were achieved in the chamber during each sterilization cycle.
- New sterilizers are to be equipped with either a printout or a display that provides the details of all three physical parameters (e.g., time, temperature and pressure).
- The sterilizer’s manufacturer’s instructions for use (MIFU) are to be followed regarding temperature and cycle length, these should be compliant with current standards.
- Operators are to review the MIFU for each item to be sterilized and ensure the sterilizer cycle parameters match the recommended time, temperature and pressure for each item.
- Operators are to review physical monitoring results (i.e., paper printouts or displays) and keep/document the results of physical monitoring for each sterilization cycle/load.

- Operators are to record the date of sterilization and the equipment/instruments processed in each load, in case these need to be recalled/held due to a failed (positive) spore test.

Chemical Indicator Monitoring:

- Chemical monitoring verifies that a packaged instrument/device has been processed through a sterilization cycle. Chemical monitoring reveals a change in one or more parameters following exposure to sterilization, but does not verify successful sterilization..
- Chemical monitoring involves the use of internal and external indicators. External indicators may be applied to the outside of packages or embedded in the package. Internal indicators are usually placed inside the packages and are visible from outside. An external CI is to be used on each package or pouch to be sterilized, unless the design of the package allows the internal CI to be viewed without opening the package.
- An internal CI (minimum Type 4) is to be placed inside each package/pouch to be sterilized.
- If a dynamic air removal sterilizer is used, an air removal test with a Type 2 CI (e.g. a Bowie-Dick test) is to be performed every day the sterilizer is used, before the first load.
- Operators may use a Type 5 CI (integrator), which responds to all of the critical parameters of steam sterilization, to further verify the effectiveness of sterilization, but these do not replace BIs. If items within a load are to be released and used prior to BI results being available, internal CIs are to be Type 5 or 6.

Biological Indicator (BI) Monitoring or Spore Testing:

- BI monitoring verifies the ability of the sterilizer to kill microorganisms and is to be performed at least every 2 weeks, although testing once each day the sterilizer is used, and for each type of cycle used, is best practice.
- BIs are to be included in every load with implantable devices and devices held until BI results are available.
- BIs are to be contained in a process challenge device (PCD) in a fully loaded sterilizer.
- BIs are to be sent to a lab capable of performing BI testing and certified to recognizable standards (e.g., International Standards Organization).
- Operators are to maintain records of spore tests. Ideally critical instruments/equipment are to be held until BI results for the respective load are verified to be negative (i.e., passed).
- If an operator receives notification of a positive (i.e., failed) BI, operators are to immediately notify the local public health unit and take any action recommend by the public health unit. Operators are to recall and hold any equipment/instruments reprocessed since the last negative (passed) spore test, assess potential risks to clients, and repeat the BI test.

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*

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.