

Sterilizing Medical Instruments in the Office - what physicians need to know -

The College began an Infection Prevention and Control Program for physician offices in 2008. Initial goals of the program were to:

- educate physicians about the cleaning, disinfecting and sterilizing of critical and semi-critical medical devices and instruments (hereinafter called medical equipment); and
- verify that practices in physicians' offices meet accepted standards.

So far, more than 150 medical offices have been inspected. The first audit cycle has given us confidence that flexible scopes are being adequately disinfected prior to re-use in medical offices. The second cycle reminds us that education is still required around the cleaning, disinfection and sterilization of common instruments such as specula of all types (vaginal, nasal and aural) and simple suture equipment.

Below are important principles physicians need to know about the cleaning, disinfecting and sterilizing of critical and semi-critical medical devices and instruments (hereinafter called medical equipment.)

In general:

- Use manufacturer's instructions for cleaning, disinfecting and sterilizing medical equipment. Manufacturers are required by Health Canada to have them. A physician must:
 - have or obtain manufacturers' instructions for any medical equipment currently being cleaned, disinfected and/or sterilized for re-use;
 - purchase only (re-useable) medical equipment for which the manufacturer provides detailed reprocessing instructions; and
 - avoid use of (re-usable) medical equipment for which reprocessing instructions are not available from the manufacturer.
- Do not store medical equipment in a liquid solution of any kind.
- Liquid detergents, cleaners and disinfectants must be prepared and used in accordance with each manufacturer's instructions.
- Policies and procedures for the cleaning, disinfecting and/or sterilizing of medical equipment must be written and followed in each office.
- Staff who clean, disinfect and/or sterilize medical equipment must have received training at the office for that function, and this training must be documented.
- Staff must wear personal protective equipment (PPE) while cleaning, disinfecting and/or sterilizing medical equipment. Protection is required from aerosolized microbes and from chemical splashes and fumes.
- Cleaning, disinfecting and/or sterilizing medical equipment should occur in areas separate from patient care areas and never where patients are present.

For cleaning:

- Contaminated medical equipment must be kept moist or be soaked or cleaned immediately to prevent hardening of organic contaminants.
- Meticulous physical cleaning with appropriate devices (e.g. brushes) is the first step in cleaning.

- Cleaning accessories (e.g. brushes) must be high-level disinfected or sterilized before they are re-used, lest they become a secondary source of contamination.
- Liquid detergents and high-level disinfectants used in reprocessing medical equipment must be formulated for that purpose by manufacturer.
- High-level disinfectants used in reprocessing medical equipment must have a Drug Identification Number from Health Canada.
- Rinsing (in clean tap water) and drying are the final steps before disinfecting or sterilizing.

For high level disinfection:

- Manufacturer's instructions for chemical products must be followed. Those instructions can apply to storage conditions, shelf-life, dilution, immersion time and rinsing.
- Test strips, which are specific to the manufacturer and to the product, must be used to confirm the adequate concentration of any new batch of disinfectant and then periodically for aliquots in current use. Test strip results must be documented as proof of quality control.
- Most liquid disinfectants are toxic; workers and patients must be protected.

For sterilization:

- A steam autoclave is the most efficient and non-toxic method of sterilizing medical equipment in a physician's office.
- The following parameters must be monitored and documented for each autoclave cycle:
 - Length of cycle (minutes)
 - Temperature during cycle
 - Pressure during cycle
- Chemical indicators must be used during all cycles.
 - External chemical indicators must be used on all wrapped packages, identifying that the package has been subject to heat.
 - Internal indicators should also be placed with the instruments inside the packaging, verifying heat penetration of the wrapping.
 - When instruments are autoclaved unwrapped, a chemical indicator must be placed in the autoclave in an area most difficult for steam to access, such as under the tray or between the instruments.
- Biological indicators must be used each day the autoclave is in use. They are placed outside of any wrapping. Results from the incubation of each biological indicator must be documented. Failed tests must be investigated and the causes resolved. Instruments autoclaved since the last successful cycle must be recalled. Actions taken must be documented. (Sterilization of implantable devices demands the even higher standard of *a biological indicator with every cycle* plus *quarantine* of the implantable device until results are confirmed.)
- Wrapping material for sterilizers must be approved. Autoclave manufacturers' instructions should be followed. Proper wrapping materials allow for adequate air removal, steam penetration, and steam evacuation inside the package. The material must also be an effective barrier to microorganisms, be strong enough to withstand handling, and be configured so as to allow for the aseptic removal of the sterilized equipment inside. Self-sealing sterilization pouches are the preferred choice and are available from many medical supply companies.

A "***Physician Toolkit for Reprocessing***" is now available on our website at:

<http://www.cpsa.ab.ca/collegeprograms/ipac.asp>

For more information on the College's Infection Prevention and Control Program, please contact Tracey Lubkey, Accreditation Coordinator, at 780-969-5002 or email tlubkey@cpsa.ab.ca.