International Federation of Perioperative Nurses

IFPN Guideline
for
Sterilization and Disinfection

Purpose:

To provide guidelines to achieve sterilization and disinfection of supplies and equipment. Positive patient outcomes of surgical interventions depend on the maintenance of an aseptic environment. Supplies and equipment should be free of contamination at the time of use. Sterilization and disinfection are methods to achieve this. Sterilization provides the greatest assurance that an object does not have viable microbes. Disinfection reduces the risk of microbial contamination but does not have the same level of assurance as sterilization.

RECOMMENDATIONS:

A. Sterilization
   1. All items to be sterilized should be thoroughly cleaned to reduce the bioburden.

      Rationale: Sterilization is affected by the number, type, and resistance of organisms on the item(s) to be sterilized. This is referred to as the bioburden. Any residual soil, oils, or other materials present may interfere with penetration of the sterilant.
   2. Items to be sterilized should be prepared in a clean, controlled environment.

      Rationale: Temperature, humidity, lighting, personnel attire, room design, and cleaning procedures are some of the factors to be considered to assure proper presterilization processing.
   3. Care must be taken to arrange items to be sterilized in a manner that will expose all surfaces to the sterilant. All jointed instruments should be open and unlocked. Instruments should be disassembled when possible. Instruments should not be held together with rubber bands. Any needed lubricant should be nontoxic and water soluble.

      Rationale: Reliable sterilization depends on good quality contact between the sterilant and all surfaces.
   4. Instrument sets should be placed in perforated trays or instrument container systems. The total weight of the metal mass should not exceed the recommendations made by the manufacturer of the sterilizer or the container system manufacturer.

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Rationale: Conditions necessary for sterilization are difficult to achieve in excessively heavy instrument pans/packs. Heavy pans/packs may require longer time to attain sterilization temperature and drying time may be extended due to condensation and pooling of moisture.

5. When instruments are nested inside the pack, they should be separated by absorbent towels or other moisture absorbing material.

   Rationale: Placing absorbent towels or other moisture absorbing materials between nested instruments enhances passage of steam to all surfaces during the sterilization cycle and facilitates drying by preventing pooling of the condensate.
6. All packs should be arranged on sterilization carriers/racks in a manner that does not interfere with air removal and infusion of the sterilant.

   Rationale: Proper placement of packs in the steam sterilizer facilitates displacement of air and contact of steam with all surfaces of the containers and their contents. It also facilitates drying time. In combined loads of fabrics and hard surface packs, place hard surface packs on the lowest shelves/racks to prevent any dripping that may occur from hard surface packs.
7. A chemical indicator should be clearly visible on the outside of packs to be sterilized.

   Rationale: Chemical indicators show that items have been exposed to physical conditions during a sterilization cycle to render the items sterile. Chemical indicators do not replace quality assurance measures such as time, pressure, and temperature monitoring; biological monitoring; proper packaging; proper sterilizer maintenance; and, proper storage and handling.
8. Chemical indicators may be placed in packages or in open trays to be sterilized.

   Rationale: Whenever chemical indicators are used, they should be placed in the position of the pack or tray which is the most difficult for the sterilant to reach.
9. Chemical indicator results should be tracked and interpreted according to the manufacturer's written instructions.

   Rationale: Each practice setting should formulate its own polices regarding the use of chemical indicators. Factors to be considered should include a cost/benefit analysis, performance limitations, and personnel knowledge of sterilization.

10. The sterilizing process should be monitored at regular intervals with reliable biological Indicators. Commercially manufactured biological indicators prepared in accordance with minimum performance criteria should be stored and used according to the indicator manufacturer's written instructions. Measurements should be performed with a biological indicator that employs spores of established resistance in a known population.

    Rationale: The biological monitoring process is the best method presently available to help confirm the effectiveness of the sterilizing process.
11. Saturated steam under pressure should be used to sterilize heat and moisture stable items. Sterilizers should be used according to manufacturer's written instructions. The time/temperature settings recommended by the device manufacturer should be followed.

    Rationale: The time and temperature required to achieve sterilization by steam varies with the type of sterilizer, cycle design, bioburden, packaging, and the size and type of items being sterilized.
12. Ethylene Oxide (EO) may be used to process heat and moisture sensitive items. EO sterilizers and aerators should be used and vented according to the manufacturer's written instructions. Items to be EO sterilized should be disassembled, cleaned, rinsed and wiped or air dried until no visible water droplets remain.

    Rationale: Heavily soiled items inhibit gas permeation. Excessive moisture inhibits sterilization and produces toxic byproducts that are not removed during aeration.
13. Items should be positioned in the EO sterilizer to allow free circulation and penetration of the sterilant.

    Rationale: EO sterilization depends upon a correct balance of essential parameters which include concentration of sterilant, relative humidity, temperature, and exposure time. The sterilizer operating manual should explain the required relationship between these parameters for proper operation.
14. All EO sterilized items should be aerated according to the device and aerator manufacturer's written instructions.

    Rationale: Aeration of EO sterilized items is essential to reduce the residue of EO which can be harmful to staff and/or patients. Length of aeration depends on many variables:
    a. Composition, form, density, and weight of items to be sterilized
    b. Type of EO sterilization system used

   c. Temperature and number of filtered air changes per hour of aeration chamber
   d. Intended use of item (used externally or implanted)
15. The sterilizer manufacturer's recommendations for door opening and transfer of items should be followed.

    Rationale: The carts or baskets used to transfer items from the EO sterilizer to the aerator should be pulled rather than pushed. Pushing causes air to flow over the contents of the cart and the potential for inhalation of EO by the operator is increased.
16. Personnel should avoid direct contact with items during the transfer from EO sterilizer to aerator. The EO sterilized items should remain on the cart or in the basket during transportation. Inhalation of EO should be avoided or minimized.

    Rationale: Excessive exposure to EO presents a health hazard to workers.
17. EO sterilizers and aerators should be vented to the outside atmosphere via an appropriate vent line.

    Rationale: EO sterilizer and aerator design and venting guidelines are extensive. Consult governmental regulations and the Sterilizer and aerator manufacturer's recommendations for requirements for use.
18. Every package should be labeled with a load control number that indicates the sterilizer used, the cycle or load number, and the date of sterilization. Load control numbers should be used for quality control to facilitate the identification and retrieval of supplies, inventory control and stock rotation.

    Rationale: Quality control records to insure sterility must be documented and records maintained by the facility.
19. Sterilized articles should be carefully handled, and only as necessary. They should be stored in a well-ventilated, limited access area with controlled temperature and humidity. All wrapped sterilized items should remain untouched on the sterilizer rack or carriage until adequately cooled.

    Rationale: Placement of warm wrapped sterilized items on a cold surface can induce condensate formation resulting in contamination of items.
20. The contents of any sterilized package should be considered contaminated if the integrity of the packaging is visibly damaged. All wrapped sterilized packages should be handled and stored in a manner which minimizes stress and pressure. The storage area should provide protection against dust, insects, vermin, and temperature and humidity extremes.

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Rationale: Cautious minimal handling of sterile packages reduces the possibility of microbial contamination.

21. Performance records should be maintained for all sterilizers. Mechanical control monitors such as time-temperature recordings, and temperature and pressure gauges should be monitored by the sterilizer operator at the beginning and end of each sterilizer cycle to verify function. Sterilizer records should include sterilizer identification number, date, cycle number, contents of each load, duration and temperature of exposure phase, identification of operator, results of biological tests and dates performed, time-temperature recording charts from sterilizers, and any other test results.

    Rationale: Sterilizer performance records may be used for documentation for product recall and for quality assurance.
22. Preventive maintenance should be performed according to the manufacturer's recommendations and individual facility policy. Sterilizers should be inspected and cleaned daily or at an interval recommended by the manufacturer.

    Rationale: Daily cleaning includes washing and rinsing all surfaces of the sterilizer to prevent accumulation of grease residue from materials being sterilized. The strainers located in the opening of the chamber discharge line should be removed and cleaned daily to insure that pores are free from lint and sediment.
23. The chamber discharge system should be cleaned at least weekly according to the manufacturer's instructions.

    Rationale: Periodic cleaning of the discharge system will prevent build up of grease residues and cogging substances that may retard air and condensate discharge from the chamber.
24. In prevacuum sterilizer, a Bowie-Dick test should be carried out each day prior to the first sterilization cycle. If the sterilizer is in use 24 hours a day, the test should be run at the same time each day. The Bowie-Dick test pack should be placed horizontally at the bottom front of the sterilizer near the door, in an otherwise empty chamber for 3.5 minutes.

    Rationale: The Bowie-Dick test evaluates the ability of prevacuum sterilizers to reduce air residuals effectively from the chamber space. If air has not been sufficiently removed, steam will drive air back into the load, air pockets will develop, and sterilizing conditions will not occur.

B. Disinfection

1. A high-level disinfectant should be used if an item is to be disinfected rather than sterilized. The manufacturer's written instructions should be followed for use.

   Rationale: Chemical disinfection differs from sterilization by its power to kill spores.
2. Items to be disinfected should be thoroughly cleaned, rinsed and dried to avoid interference with the disinfecting process of dilution of the disinfectant.

   Rationale: Disinfection is divided into 3 levels - high, medium, and low. A high-level disinfectant can be sporicidal as well as bactericidal and virucidal if contact time is sufficient. An intermediate-level disinfectant is not sporicidal but will kill the more resistant bacterial and viruses. A low-level disinfectant is not sporicidal and will kill only less resistant bacteria and viruses.
3. All surfaces, including lumens and channels, of items must be in contact with the disinfectant solution for the recommended exposure time.

   Rationale: The time required to achieve high-level disinfection varies depending on factors including the nature of the contaminating microorganisms, length of exposure to the agent, bioburden, and temperature.
4. An expiration date, determined according to the manufacturer's written instructions, should be marked on the container of the disinfectant currently in use.

   Rationale: All disinfectants will cease to remain effective after repeated use due to dilution, inactivation, and/or instability.
5. High-level disinfectant contact with skin, mucous membranes, and eyes should be avoided. Solutions should be kept covered and used in a well ventilated area.

   Rationale: Some high-level disinfectant solutions have been reported to be irritating to the skin and eyes.

C. Policies and Procedures

1. Policies and procedures for sterilization and disinfection should be written, readily available in the practice area, and reviewed annually. They should establish authority, responsibility, and accountability for sterilization and

disinfection processes.

Procedures for sterilization and disinfection processes may include:

a. Preparation of items for processing
b. Processing of limited use items
c. Loading of sterilizers
d. Use of chemical and biological indicators
e. Type of processes and length of time for sterilization and disinfection of individual items
f. Use of each type of sterilizer and disinfectant
g. Specific aeration requirements for each type of EO sterilized material
h. Maintenance records of sterilizers and aerators
i. Safety precautions associated with use of sterilizers, aerators, and disinfectants
j. Handling and storage of sterilized instruments and supplies
k. Designation of shelf life
l. Recall and/or disposal or reprocessing of outdates sterile supplies

Rationale: Documentation aids in communication, provides a mechanism for evaluation of nursing care, and serves as evidence of care in legal maters.

References:

- ACORN (2018) Australian College of Perioperative Nurses: **Standards for Perioperative Nursing in Australia.**

- AfPP (2016) Association for Perioperative Practice: Harrogate UK: **Standards and Recommendations for Safe Perioperative Practice.**

- AORN (2019) American Operating Room Nurses Association: Denver USA: **Guidelines for Perioperative Practice.**

- ORNAC (2017) Operating Room Nurses Association of Canada**: Standards for Perioperative Nursing Practice.**

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