Sterilization in the Perioperative Setting

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Franciscan Alliance

Perioperative Consortium

Objectives

Upon completion of this module, perioperative staff should:

Define sterility

Understand different types of sterilization including steam sterilization, gas plasma sterilization, hydrogen peroxide and ethylene oxide sterilization

Recognize physical, chemical and biological sterilization indicators

Perform flash (immediate use steam sterilization) correctly

Purpose:

The creation and maintenance of an aseptic environment has a direct influence on patient outcomes.

A major responsibility of all surgical and sterile processing staff is to minimize patient risk for surgical site infection (SSI).

One of the measures for preventing SSI is to provide sterile items that are free from contamination at the point of use.

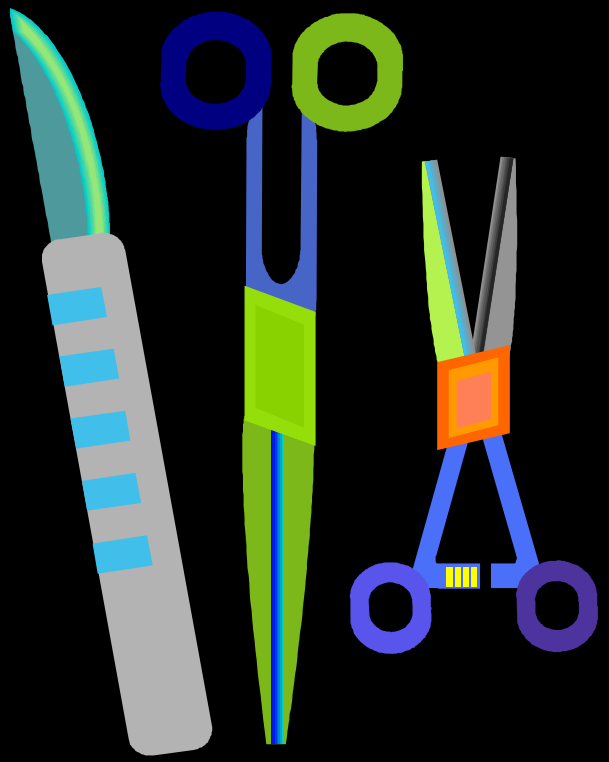
Sterility

….is the absence of microorganisms required for the use of any critical item

Sterilization is the final step of a process that renders equipment and supplies safe for use. The sterilization process consists of several steps including:

- decontamination,
- inspection and assembly,
- packaging,
- sterilization, and
- storage.

Steps in the Sterilization Process



Decontamination

The first and most critical step in the sterilization process. Effective sterilization cannot take place without effective cleaning.

The purpose of decontamination is to breakdown bioburden and make items safe to handle by:

- manual cleaning,
- ultrasonic cleaning,
- the use of cleaning agents (enzymatic detergents),
- and, automatic washers.

Manufacturer's instructions for use (IFU's) should be used for proper disassembly and cleaning.

Inspection and Assembly

- Manufacturer's instructions should be used for proper assembly of instrumentation
- Items should be inspected for proper operation and placed in appropriate tray
- This is the final check for cleanliness and operation of the item

Packaging

Items to be sterilized should be placed in containers that are appropriate for the sterilization process chosen - with the appropriate chemical indicators inside.

- Rigid trays
- Wrapped trays, items
- Pouches

The appropriate external chemical indicator should be placed on the outside of the package.

Items should be wrapped in a manner that allows ease of presentation to the sterile field.

Sterilization: Steam

- Steam under pressure is the preferred sterilization method because it is effective, inexpensive, and relatively rapid for most porous and nonporous materials.
- Gravity displacement steam cycles (usually used in the o.r.) and prevaccum, dynamic air removal steam cycles, (usually used in SPD) accomplish the same level of sterilization.
- Prevacuum cycles are considered more efficient for wrapped items because the autoclave uses a pump to remove air in a faster way.

Sterilizers vary in design…some only do gravity, some only do prevac, some do both. Autoclaves should be checked before use for the correct cycle selection.

Sterilization: Steam in SPD

SPD (Sterile Processing Department) will steam sterilize the majority of items using the more effective prevacuum cycle with wrapped items.

Minimum temperature is 270-275 degrees Fahrenheit or 132-134 degrees Celsius, with a 4 minute prevacuum exposure time and 20- 30 minute dry time.

Extended exposure and dry times are frequently used when the manufacturer recommends it…this happens with large, complicated trays. The SPD staff will adjust the exposure and dry times as recommended.

Sterilization: Hydrogen Peroxide

- Frequently referred to as Sterrad or V-Pro
- For items that cannot be steam sterilized
- Low temperature

Items must be verified by the manufacturer to be sterilized by hydrogen peroxide. This is a much shorter sterilization cycle and is appropriate for steam sensitive items.

Sterilization: Ethylene Oxide

- For items that cannot be processed by steam or gas plasma

ETO/EO is a longer sterilization cycle (12 hours) and is not available at every facility.

Items require a long aeration time to prevent EO exposure to personnel.

Other Processes

Steris – liquid paracetic acid – frequently used for flexible scopes in a GI setting*

Ozone – used mainly by commercial companies

*Other endoscope processors provide high-level disinfection, not sterilization

Storage

- Sterile items must be stored in a controlled environment (minimal traffic, appropriate air flow and humidity, closed cupboard)
- In house processed items -

  Sterility and shelf life are event related (is the wrapper intact with no holes or tears; is the item kept in a controlled environment)
- Commercially prepared items –

  usually have an expiration date

Handling Sterile Supplies

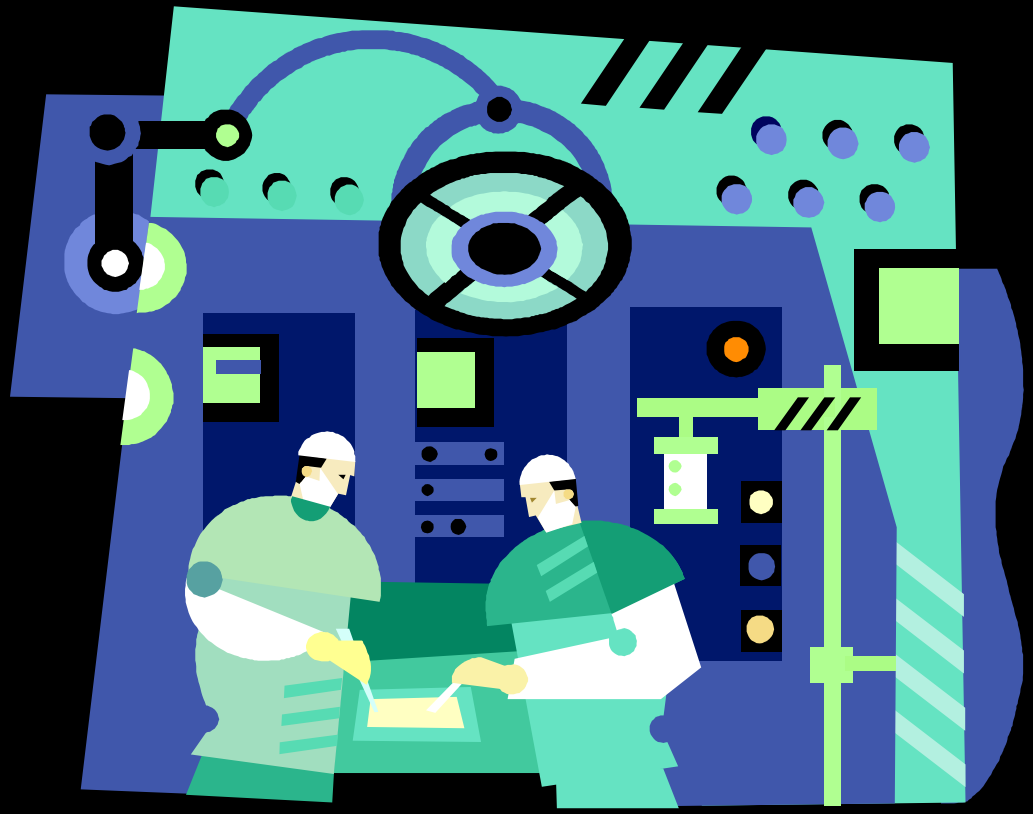
Handling of supplies shall be minimal and done with caution to reduce the possibility of microbial contamination.

All wrapped sterilized packages shall be handled in a manner which minimizes stress and pressure.

The contents of any sterilized package shall be considered contaminated if the integrity of the packaging is visibly damaged.

All trays/instruments will be visually inspected for sterility and integrity prior to placing in storage area or being sent to a department.

FLASH STERILIZATION



Flash Sterilization (Immediate Use-Steam Sterilization)

Flash sterilization is to be used in rare situations when an identical sterile item is unavailable and there is insufficient time to sterilize by the preferred wrapper or container method of steam sterilization.

Flash sterilization may be associated with increased risk of infection to patients because of pressure on personnel to eliminate one or more of the steps in the cleaning and sterilization process.

Flash Sterilization (Immediate Use-Steam Sterilization)

The issue with flash sterilization is that each item must be processed in the same way that it would be if it wasn't flash sterilized.

- Was it cleaned and disinfected appropriately?
- Was it disassembled before cleaning and sterilizing?
- Can it be transported to the o.r. in a sterile manner?

Flash Sterilization - Cleaning

- Items are disassembled and thoroughly cleaned with an enzymatic detergent (e. g. Aseptizyme) and water to remove soil, blood, body fats, and other substances
- This should be done in a decontamination area wearing PPE
  - Gowns, masks, eye protection and gloves should be available in this area.
- Lumens are brushed and flushed under water with the cleaning solutions and rinsed thoroughly
- Syringes and brushes of different sizes should be available in the decontamination area.

Flash Sterilization - Processing

Items are placed in a closed sterilization container (e.g. FLASH-PAK), that is validated for steam sterilization, in a manner that allows steam to contact all instrument surfaces. A chemical indicator (CI) is placed in tray. Multiple CI's should be used for large trays and trays with more than one level.

Appropriate sterilization parameters are selected. The device manufacturer's written instructions on cycle type, exposure times, temperature setting, and drying times (if recommended) should be available.

Sterilization: Immediate Use, Steam

Exposure times for Flash sterilization using a gravity autoclave with a minimum temperature of 270-275 degrees Fahrenheit or 132-135 degrees Celsius:

General recommendations:

3 minutes – for single items, all metal, no lumens (if using FlashPak, use a 5 minute exposure time)

10 minutes – for multiple items, trays, anything non-metal, anything with a lumen (if using a FlashPak, the exposure time is 10 minutes)

Documentation of Flash (Immediate-Use Steam) Sterilization

Every cycle run in a sterilizer needs to be documented.

A log should be kept near the sterilizer for this purpose. Documentation should include date, name of patient, item sterilized, load number, and signature of the person removing the item who has checked both the printout and chemical indicator for proper sterilization assurance.

Sterility Assurance –

How do you know if an item is sterile?

Sterilization Assurance – Indicators and Quality Control

Physical Monitors – sterilizer printouts

Chemical indicators

External indicators - tape

Internal Indicators – Class 5 integrators

Accept/Reject strips

Biological Indicators – Attest

Indicators and Quality Control

- Physical Monitors

  These are the settings for the sterilizers. The printout for each cycle will validate:

  - Exposure time
  - Temperature
  - Pressure

  Each cycle printout should be checked for valid parameters by the person removing the item(s).

Indicators and Quality Control

- External Indicators (Chemical indicator)

These are special strips or tapes that change color if the item is exposed to the particular sterilant. They do not validate sterilization.

This is the first line of sterilization assurance.

Indicators and Quality Control

- Internal Indicators (Chemical indicator)

Inside the sterilized item, there should be an indicator appropriate for the sterilant used (steam, EO, sterrad). These indicators are a higher level of sterilization assurance than the sterilizer printouts or the external indicator.

Indicators and Quality Control

- Biological indicators (BI)

This is the highest level of sterilization assurance. A biological indicator is run in each sterilizer, minimally, once a day and with every load containing implants. The BI assures the user that the sterilizer is capable of killing spores…the most difficult challenge for sterilization.

Indicators and Quality Control

Each type of sterilization process (steam, hydrogen peroxide, EO) has their own chemical and biological indicators.

For steam and hydrogen peroxide, a BI should be run, minimally, the first load of the day and any load containing implants.

For EO, a BI should be run for every load.

Documentation

The Sterile Processing and Surgery Departments maintain meticulous logs for every sterilization cycle, including printouts, chemical and biological indicator results, and load contents.

What to do if a BI is positive

A positive BI means that the sterilizer has not killed the spores included in the test vial, and consequently, all items included in the load are considered non-sterile.

If any biological indicator shows a positive result, the sterilizer should be immediately removed from service. The supervisor or manager should be contacted. All items processed since the last negative BI result should be retrieved. A repeat BI should be run. Maintenance, bio-med, or the autoclave service technician should be contacted. After service, 3 successful biological indicators should be run and validate 3 negative results before the sterilizer is put back into service.

Remember:

Items must be clean to be sterilized.

Sterility assurance means using physical, chemical and biological indicators to provide the maximum assurance that an item is sterile.

Documentation of every sterilization cycle run is mandatory.

Sterilization

Providing sterile products to the surgical patient is one of the most basic requirements for preventing surgical site infections. It is a continuous and ongoing effort involving both SPD and OR personnel. With adequate knowledge and consistent practice, patient safety can be assured.

Resources

- 2010, AORN, Perioperative Standards and Recommended Practices, “Sterilization in the Perioperative Setting”
- 3M Sterile U Network, Sterilization Assurance, Standards Practice
- CCI, Sterilization, Competency Assessment Module, 2004
- AAMI ST79