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Sterilization

FAQs

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What conditions are necessary for storage of sterile supplies?

Environmentally controlled conditions, which include a maximum temperature of 75° F (24° C), a maximum relative humidity of 60%, positive air pressure in relation to adjacent areas, and a minimum of four air exchanges per hour.

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Sterile items should be contained in an US Food and Drug Administration-approved

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sterile barrier system and stored under environmentally controlled conditions, which include a maximum temperature of 75° F (24° C), a maximum relative humidity of 60%, positive air pressure in relation to adjacent areas, and a minimum of four air exchanges per hour. The user should check the conditions specified by the manufacturers of the materials being stored and ensure parameters for the storage space meet the device and packaging system manufacturers' requirements. To comply with fire code regulations and reduce the risk of contamination, sterile supplies should be stored at least 8 to 10 inches from the floor, at least 18 inches from the ceiling, and at least 2 inches from outside walls. Fire codes specify minimum distances below the ceiling to ensure the effectiveness of sprinkler systems.

Resources

Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

Facility Guidelines Institute. Guidelines for Design and Construction of Hospitals.

Facility Guidelines Institute. Guidelines for Design and Construction of Outpatient Facilities.

Feedback

Venous Thromboembolism

AAMI ST79

NFPA 13: Standard for the Installation of Sprinkler Systems

Updated August 15, 2018

What is the weight limit for instrument sets to be sterilized?

AORN and the Association for the Advancement of Medical Instrumentation (AAMI) recommend that instrument sets and trays prepared for sterilization not exceed 25 lbs.

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AORN and the Association for the Advancement of Medical Instrumentation (AAMI) recommend that instrument sets and trays prepared for sterilization not exceed 25 lbs. This weight limit includes the combined weight of the pan and the instruments. In addition, the user should check the packaging system manufacturer's instructions for use for any product-specific weight restrictions. Sets exceeding this weight limit present an increased risk for ergonomic injury to personnel handling the sets and may result in failed sterilization cycles or wet loads.

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Resources

Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

AAMI ST79

Updated August 15, 2018

What is the best way to prevent contamination during transport of items sterilized using immediate use steam sterilization?

AORN recommends the use of sterile barrier systems designed and intended for immediate use steam sterilization.

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AORN recommends the use of sterile barrier systems designed and intended for immediate use steam sterilization. AORN and the Association for the Advancement of Medical Instrumentation (AAMI) state that items should be delivered to the point of use and the sterile field in a manner that maintains sterility.

Resources

Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

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AAMI ST79

Updated August 15, 2018

How should instruments with sharp points or edges and hinges (eg, towel clips) be sterilized?

All hinged instruments should be sterilized in the open position, unless the manufacturer's instructions for use advise against this practice.

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All hinged instruments should be sterilized in the open position, unless the manufacturer's instructions for use advise against this practice. If hinged instruments are on stringers, racks, or instrument pegs, the instruments should be kept open and unlocked. The rationale behind the practice is to expose all surfaces of the instrument to the sterilant.

To manage sharp points and edges, loose-fitting tip protectors for sharp and delicate instruments should be used if they have been validated for use with the method of sterilization and according to the manufacturer's instructions for use.

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Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

AAMI ST79

Updated August 15, 2018

What should be done if moisture is found within a pack?

Wet packs in a terminal sterilization cycle should be investigated and corrective measures taken.

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Wet packs in a terminal sterilization cycle should be investigated and corrective measures taken. Depending on the type of sterile barrier system, there may be no way to determine whether wicking has occurred during handling of the item which could contaminate the package. If moisture is to be expected according the packaging manufacturer's IFU, then corrective action may not be necessary. There is a growing body of evidence suggesting that moisture inside a closed container that has been subjected to a terminal sterilization cycle is sterile.

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Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

AAMI ST79

Updated August 15, 2018

How can we decrease the occurrence of wet packs?

The occurrence of wet packs can be minimized by the actions below.

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The occurrence of wet packs can be minimized by the following actions:

- Confirm steam quality supplied to the sterilizer.
- Precondition the load by placing instruments inside the steam sterilizer with the door closed for 10 to 15 minutes before starting the cycle.
- Place a towel on the bottoms of trays with wire mesh bottoms and between layers of instruments (unless contraindicated by the instrument and container manufacturer).
- Divide sets if they are excessively heavy or dense. Instrument sets that weigh

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more than 25 lb are difficult to dry without a lengthy dry time.

- Do not enclose peel pouches in instrument sets.
- Do not overload the sterilizer.
- Inspect steam line drains for clogs.
- Document and track wet packs according to the facility policy to identify any problems that may exist with the sterilizer and take steps to correct problems.

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Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

ST79 Annex O

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What should be considered when choosing a sterilization method?

Saturated steam under pressure is the preferred method of sterilization and should be used to sterilize heat- and moisture-stable items unless otherwise indicated by the device manufacturer.

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Saturated steam under pressure is the preferred method of sterilization and should be used to sterilize heat- and moisture-stable items unless otherwise indicated by the device manufacturer. When steam is not an option, an interdisciplinary team should evaluate sterilization options by determining:

What sterilization methods are allowed in the device manufacturers' instructions for use?

What packaging system(s) are available and are they compatible with the desired sterilization method and device?

What sterilizer(s) are available in the health care organization and are they compatible with the device and packaging system?

What is the environmental impact of the sterilant?

What is the toxicity of the sterilant to personnel processing and handling the device?

How much time is needed for the sterilization processes?

What is the cost?

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Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

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When is it acceptable to use immediate use steam sterilization (IUSS)?

Only under the conditions detailed below.

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It is only acceptable to perform IUSS if

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Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

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- the item will be used immediately;
- terminal sterilization is not an option;
- the device and sterilizer manufacturers' written instructions for use include instructions for IUSS;
- the device manufacturer's written instructions for cleaning, cycle type, exposure times, temperature settings, and drying times (if recommended) are readily available and followed; and

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- the IUSS rigid sterilization container manufacturer's written instructions for use are followed.

What should a health care organization consider when evaluating the quality of immediate use steam sterilization (IUSS) processes?

Immediate use steam sterilization can be an effective and reliable mode of sterilization only when each process step leading to the sterilization cycle is performed correctly.

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Immediate use steam sterilization can be an effective and reliable mode of sterilization only when each process step leading to the sterilization cycle is performed correctly. Instruments sterilized using IUSS are sterile, just as instruments sterilized using terminal sterilization are sterile, provided that all necessary cleaning steps are performed correctly before instruments are placed in the sterilizer and the necessary sterilization parameters are met during the complete sterilization cycle. The manufacturers' instructions for use for the device, sterilizer, and sterile barrier system provide guidance for performing the necessary cleaning, handling, and sterilization steps. Only personnel with

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documented competency in decontamination, packaging, and sterilization processes should perform these tasks.
Audits and analysis of the complete process (cleaning, inspection, assembly, packaging, sterilization) for items handled for immediate use can inform IUSS quality improvement efforts. Higher rates of IUSS may indicate a deficit in instrumentation inventory, and breaks in any aspect of the complete process pose an infection risk for affected patients.

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Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

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Why do wet packs occur?

Several variables contribute to wet packs, detailed below.

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Several variables contribute to wet packs, including

- problematic steam supply caused by

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    - poor steam quality (eg, insufficient dryness) that can lead to excessive condensate formation within the sterilizer;
    - buildup of condensate in the steam supply pipework (especially when it has not been used for a few days);
    - excessive demands on the steam supply that can lead to wet steam;
    - steam supply infrastructure issues, including pipework with dead ends, improperly trapped or insulated piping, or inadequate maintenance of steam traps;
    - a steam line that is far from the heating source so that condensate is more likely to form; and
    - a steam generator that does not have sufficient capacity for the sterilizer, causing a pressure drop at times of peak demand that can cause residual water (condensate) to enter the sterilizer;
- malfunctioning or improperly sized steam traps that cause excessive water formation that might overwhelm the sterilizer;
- improper loading of the sterilizer caused by

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    - overloaded and densely packed loads that cause excessive condensation and pose a challenge for steam circulation and evacuation during the sterilization cycle,
    - use of the wrong type of packaging materials,
    - a large metal density in each set,
    - an improper loading technique (eg, rigid containers should be spaced and not stacked unless this is allowed by the container manufacturer's instructions for use),
    - items touching the sterilizer wall,
    - items loaded when wet,
    - a load configuration that traps water, and
    - blocked condensate drains;
- a temperature differential between the sterilizer jacket, sterilizer door, and chamber;
- an open drain valve (leading to drain water being returned);
- a stainless steel carriage, which creates more condensate than an aluminum carriage; and

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- an inadequate preheating process.

Resources

Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

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Guidelines

At A Glance

- Anesthesia
- Aseptic Technique
- Hand-Over Tools
- Instruments
- Medication
- OR for Infection Preventionists
- Pediatrics
- Positioning
- Procedures
- Room Setup
- Scrub Role
- Skin Prep

Vetted Links

- Procedures in Action
- A Glimpse into Infection Prevention
- An Inside Look at OR Efficiencies

Tools

FAQs

Specialties

- ASC Infection Prevention Policies and Procedures
- Resources for Cardiac Catheterization
- Resources for Endoscopy
- Guidelines and Tools for the Sterile Processing Team
- NAON Books
- ARIN Books
- Core Curriculum for the RNFA
- Perioperative Care of the COVID-19 Patient

Accreditation

- Joint Commission

Devices

- Equipment and Supplies Finder

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