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Manual of Infection Control in ORTHOPAEDIC SURGERY

Operation Theater Protocols and Patient Optimization



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Ashok Shyam

Foreword
Javad Parvizi

SECOND EDITION

JAYPEE

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Section **1**

Operation Theater Norms and Protocols

Section Outline

1. Sterilization
2. Operation Theater Planning and Protocols
3. Surgeon Preparation and Scrubbing Protocols
4. Laminar Airflow and Air-handling Unit
5. Operation Theater Personnel

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1

Sterilization

Vaishali Tadokar, Bharat S Mody, Hemant M Wakankar

INTRODUCTION

Sterilization is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Since, sterilization of all patient-care items is not necessary; healthcare policies must identify primarily on the basis of the items intended to be used, whether cleaning, disinfection or sterilization is indicated.

Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods.

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects.

Chemical sterilants are disinfectants that kill spores with prolonged exposure times (3–12 hours).

High-level disinfectants are disinfectants that work at similar concentrations, but with shorter exposure periods (e.g. 20 minutes for 2% glutaraldehyde) will kill all microorganisms except large numbers of bacterial spores.

Low-level disinfectants can kill most vegetative bacteria, some fungi and some viruses in a practical period of time (< 10 minutes).

Intermediate-level disinfectants might be cidal for mycobacteria, vegetative bacteria, most viruses and most fungi, but do not necessarily kill bacterial spores.

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What is the most common method of sterilization used in orthopedic setup?

- **Steam** sterilizer is the most common method used for sterilization of instruments and linen as it is nontoxic, inexpensive, rapidly microbicidal and sporicidal.
- The pre vacuum type of steam sterilizer is most commonly used.

Explanation[1]

Sterilization is a process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods.
Sterilization methods include:

- High temperature sterilization:
  - Steam sterilization
  - Flash sterilization
  - Dry heat sterilization.

Description

High Temperature Sterilization

- **Steam sterilization:** It is nontoxic, inexpensive, rapidly microbicidal and sporicidal. Steam sterilization, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time. Moist heat in the form of saturated steam under pressure is the most widely used and the most dependable.
  - **Gravity type:** 30 minutes at 121°C (250°F) in a gravity displacement.
  - **Pre vacuum type:** 4 minutes at 132°C (270°F) in a pre vacuum sterilizer.
  - **Steam-flush pressure-pulsing process:** It is a process, which removes air rapidly by repeatedly alternating a steam flush and a pressure pulse above atmospheric pressure.

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- **Flash sterilization:** Sterilization of an unwrapped object at 132°C for 3 minutes at 27–28 lb of pressure in a gravity displacement sterilizer.
- **Dry heat sterilization:** This method should be used only for materials that might be damaged by moist heat or that are impenetrable to moist heat (e.g. powders, petroleum products, sharp instruments). The primary lethal process is considered to be oxidation of cell constituents.

Advantage

Steam sterilization is nontoxic, relatively low costs, penetrates materials, noncorrosive.

Disadvantage

Slow rate of heat penetration.

What is the use of ethylene oxide and plasma sterilizers in orthopedic setup?

Ethylene oxide (ETO) sterilization and hydrogen peroxide (H_2O_2) gas plasma sterilization has been the most commonly used process for sterilizing temperature and moisture-sensitive medical devices and supplies in healthcare institutions such as arthroscopy instruments, camera head and cables, fiber optic light cables, shaver handpieces, Stryker drill and saw system, endoscopes, corrosion-susceptible metal alloys.

Explanation[1]

Low Temperature Sterilization

- **Ethylene oxide sterilization:** Two types—mixed gas and 100% ETO. ETO is a colorless gas that is flammable and explosive. The four essential parameters are gas concentration (450–1,200 mg/L), temperature (37–63°C), relative humidity (40–80%) (water molecules carry ETO to reactive sites) and exposure time (1–6 hours).

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- **Hydrogen peroxide gas plasma sterilization:** Gas plasmas have been referred to as the fourth state of matter (i.e. liquids, solids, gases and gas plasmas). Gas plasmas are generated in an enclosed chamber under deep vacuum using radiofrequency or microwave energy to excite the gas molecules and produce charged particles in the form of free radicals. A free radical is an atom with an unpaired electron and is a highly reactive species that are capable of interacting with essential cell components (e.g. enzymes and nucleic acids) and thereby disrupt the metabolism of microorganisms. The type of seed gas used and the depth of the vacuum are two important variables that can determine the effectiveness of this process.
- **Peracetic acid sterilization:** Peracetic acid is a highly biocidal oxidizer that maintains its efficacy in the presence of organic soil. The diluted peracetic acid is circulated within the chamber of the machine and pumped through the channels of the endoscope for 12 minutes, decontaminating exterior surfaces, lumens and accessories.
- **Ozone sterilization:** Ozone is produced, when O_2 is energized and split into two monatomic (O_1) molecules. The monatomic oxygen molecules then collide with O_2 molecules to form ozone, which is O_3. This additional oxygen atom makes ozone a powerful oxidant that destroys microorganisms, but is highly unstable.
- **Formaldehyde sterilization:** The process involves the use of formalin, which is vaporized into a formaldehyde gas that is admitted into the sterilization chamber.
- **Ionizing radiations:** Sterilization by ionizing radiation, primarily by cobalt 60, gamma rays or electron accelerators, is a low-temperature sterilization method that has been used for a number of medical products (e.g. tissue for transplantation, pharmaceuticals and medical

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devices). There are no Food and Drug Administration (FDA) cleared ionizing radiation sterilization processes for use in healthcare facilities.

What is the use of flash/immediate-use steam sterilizer (IUSS) in orthopedic setup?

Flash sterilizer is not recommended to be used for sterilization of instruments.

Explanation[1]

Flash Sterilization

Flash sterilization is a modification of conventional steam sterilization (either gravity, pre vacuum or steam-flush pressure-pulse) in which the flashed item is placed in an open tray or rigid container to allow for rapid penetration of steam. It is not recommended because of the lack of timely biological indicators to monitor performance, absence of protective packaging following sterilization, possibility for contamination of processed items during transportation to the operating rooms and the sterilization cycle parameters (i.e. time, temperature and pressure) are minimal. Implants should never be flash sterilized.

How are the instruments and linen sterilized?

Instruments/linen before sterilization need to go through the process of:

- Decontamination: Manual or mechanical cleaning in water with detergents/enzymatic cleansers
- Packaging: After visual inspection of cleaned and dried instruments, they must be wrapped in ideal sterilization wrap or placed in rigid containers and kept in instrument trays/baskets
- Sterilization: High temperature/low temperature sterilization depending upon the instruments
- Sterile storage room.

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Explanation[1,2]

A controlled environment is intended to facilitate effective decontamination, assembly, sterilization and storage, and to minimize environmental contamination and maintain sterility of sterilized items. The Central Sterile Supply Department (CSSD) ideally should be divided into at least three areas:

- Decontamination
- Packaging
- Sterilization and sterile storage room.

Decontamination Area

Instruments must be cleaned using:

- Water with detergents: Water to be used for cleaning should be soft water or preferably demineralized water to protect the instruments from hard ion deposits.
- Stainless steel sinks with air pressure guns and water sprayer, and showers to be available for cannulated instruments.
- Enzymatic cleaners: They are of proteases/lipases/amylases working at neutral/near neutral pH. Dilution, time of contact should be followed according to manufacturer's instruction:
  - Manual cleaning: There are two essential components, friction and fluidics. Friction (e.g. rubbing/scrubbing the soiled area with a brush) is an old and dependable method. Fluidics (i.e. fluids under pressure) is used to remove surgical debris from internal channels after brushing and when the design does not allow passage of a brush through a channel.
  - Mechanical cleaning machines:
    - Ultrasonic cleaner
    - Washer-disinfector.

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Ultrasonic Cleaning

Ultrasonic cleaning is mainly recommended for cannulated instruments and others with crevices (hinges and serrations).

Mechanism: Ultrasonic cleaning removes soil by cavitation and implosion in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces.

Packaging

Once instruments are cleaned, dried and inspected, they must be double wrapped or placed in rigid containers and should be arranged in instrument trays/baskets.

An ideal sterilization wrap would successfully address barrier effectiveness, penetrability (i.e. allows sterilant to penetrate), aeration (e.g. allows ETO to dissipate), ease of use, drapeability, flexibility, puncture resistance, tear strength, toxicity, odor, waste disposal, linting, cost and transparency. There are many packing systems:[2]

- **Woven fabrics:** 100% cotton, cotton-polyester blends, synthetic blends
- **Non-woven materials:** Plastic polymers, cellulose fibers, paper pulp
- **Peel pouches:** Plastic/paper, cellophane, polyethylene
- **Rigid containers:** Plastic/metal.

Loading

All items to be sterilized should be arranged, so all surfaces will be directly exposed to the sterilizing agent.

There are several important basic principles for loading a sterilizer:

- Allow for proper sterilant circulation
- Perforated trays should be placed, so the tray is parallel to the shelf
- Non-perforated containers should be placed on their edge (e.g. basins)
- Small items should be loosely placed in wire baskets

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- Peel packs should be placed on edge in perforated or mesh bottom racks or baskets.

Storage

Heat sealed, plastic peel-down pouches and wrapped packs sealed in 3 mL (3/1,000 inch) polyethylene; overwrap have been reported to be sterile for as long as 9 months after sterilization.

Sterile supplies should be stored far enough from the floor (8–10 inch), the ceiling (5 inch) and the outside walls (2 inch) to allow for adequate air circulation, ease of cleaning and compliance with local fire codes.

How are the instruments/implants packed before sterilization?

Packing material used for wrapping of instruments depends upon the technique of sterilization (steam/ETO/plasma) and manufacturer's instruction:

- Steam sterilization: Woven/non-woven textile wraps, spunbond/meltblown/spunbond (SMS) wraps, paper–plastic peel pouches.
- Ethylene oxide sterilization: Polyethylene plastic bags, peel pouches of paper/polyethylene polyester laminate, paper/polypropylene polyester laminate.
- Plasma sterilization: Polypropylene wrap, polyolefin-plastic combination (Tyvek) pouches.

The shelf life of linen packing material is approximately 5–10 days.

The shelf life of paper-plastic peel pouches is approximately 3–6 months.

The shelf life of the packing material is event related and is valuable only when the appropriate storage conditions are maintained like humidity, temperature, dust-free environment and if there is no tear/holes in the packaging material.

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Explanation[3]

- Personnel should understand how the sterilization method and the items being sterilized affect the selection of the appropriate packaging method and how the packaging method affects sterilization parameters.
- While selecting a packaging system, personnel should obtain and keep on file the manufacturer's test data, instructions for use and care and handling instructions.

An effective packaging material for steam sterilization processing, as a minimum should:

- Allow adequate air removal from steam penetration of the package contents
- Provide an adequate barrier to microorganisms or their vehicles
- Resist tearing or puncture
- Allow a method of sealing that result in a complete seal that is tamper-evident and provides seal
- Integrity
- Be free of toxic ingredients and non-fast dyes
- Be nonlinting
- Cost-effective.

What are the factors affecting the efficacy of cleaning, disinfection and sterilization?

Factors that affect the efficacy of the sterilization.[1]

Table 1.1: Factors affecting sterilization processes

Factors	Effects
Cleaning	Failure to adequately clean instrument results in higher bioburden, protein load and salt concentration
Bioburden	The natural bioburden of used surgical devices is 10^2–10^3 organisms (primarily vegetative bacteria), which is substantially below the 10^5–10^6 spores used with biological indicators

Contd…

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Factors	Effects
Pathogen type	Spore-forming organisms are most resistant to sterilization and are the test organisms required for Food and Drug Administration (FDA) clearance However, the contaminating microflora on used surgical instruments consists mainly of vegetative bacteria
Protein	Residual protein decreases efficacy of sterilization
Salt	Residual salt decreases efficacy of sterilization much more than the protein load
Biofilm accumulation	Biofilm accumulation reduces efficacy of sterilization by impairing exposure of the sterilant to the microbial cell
Lumen length	Increasing lumen length impairs sterilant penetration
Lumen diameter	Decreasing lumen diameter impairs sterilant penetration
Restricted flow	Device designs that prevent or inhibit this contact (e.g. sharp bends, blind lumens) will decrease sterilization efficacy
Device design and construction	Materials used in construction may affect compatibility with different sterilization processes and affect sterilization efficacy Design issues (e.g. screws, hinges) will also affect sterilization efficacy

What are the monitors for validating the sterilization procedure?

The sterilization procedure should be monitored routinely by:

- Mechanical indicators: Time, temperature and pressure
- Chemical indicators: Class 1 to Class 6
- Biological indicators.

Explanation[1]

Mechanical Indicator

Mechanical monitors for steam sterilization include the daily assessment of cycle either by manual recording or computer printout and the records need to be maintained:

- Time
- Temperature
- Pressure.

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Chemical Indicators

Chemical indicators are convenient, inexpensive, and indicate that the item has been exposed to the sterilization process.

Chemical indicators have been grouped into six classes based on their ability to monitor one or multiple sterilization parameters:

- **Class 1:** They are process indicators, which show that the unit has been exposed directly to steam, e.g., indicator tapes, indicator labels that should be put outside every pack
- **Class 2:** This is Bowie Dick test used for equipment control to evaluate the efficacy of air removal and steam sterilization in dynamic air removal sterilizers
- **Class 3:** A single variable indicator is of not much use
- **Class 4:** Multivariable indicators are used for pack control monitoring and should be used inside each pack
- **Class 5:** They are integrating indicators to react to all critical variables used for pack control monitoring and placed inside each pack; they can be used to release loads, which do not contain implants
- **Class 6:** They are emulating indicators.

The class 1, 2 and 5 are important indicators that help in monitoring.

Chemical indicators usually are either heat- or chemical-sensitive inks that change color, when one or more sterilization parameters (e.g. steam sterilization—time, temperature and/or saturated steam; ETO sterilization—time, temperature, relative humidity and/or ETO concentration) are present.

Biological Indicators

Biological indicators are the only process indicators that directly monitor the lethality of a given sterilization process.

An ideal biological monitor of the sterilization process should be easy to use, inexpensive, not be subject to exogenous contamination, provide positive results as soon as possible after

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the cycle, so that corrective action may be accomplished and provide positive results only when the sterilization parameters (as mentioned above) are inadequate to kill microbial contaminates.

Biological indicators are to be used on daily basis or at least weekly basis and when implants are loaded.

Bacillus atrophaeus spores (10^6) are used to monitor ETO and dry heat sterilization and are incubated at 35–37°C.

Geobacillus stearothermophilus spores (10^5) are used to monitor steam sterilization, hydrogen peroxide gas plasma and liquid peracetic acid sterilizers, and are incubated at 55–60°C.

Steam and low temperature sterilizers (e.g. hydrogen peroxide gas plasma, peracetic acid) should be monitored at least weekly with the appropriate commercial preparation of spores. Each load should be monitored if it contains implantable objects.

What is the optimum method of sterilization of lumen (e.g. arthroscopy) instruments, which cannot be autoclaved?

The optimum method for arthroscopy instruments is sterilization with the following:

- **Ethylene oxide sterilization:**
  - **Advantages:** It is highly diffusive and excellent penetration. Items can be packed in plastic pouches, giving a long shelf life.
  - **Disadvantages:** It is a highly inflammable and explosive gas. Lengthy procedure (12–16 hours) and requires aeration to remove adsorbed gas from sterile articles.
- **Plasma sterilizer:**
  - **Advantages:** About 95% of the medical devices are compatible with hydrogen peroxide (H_2O_2) plasma, time taken is less (60–70 minutes), no aeration required.
- They can also be disinfected with high level disinfection, e.g., Cidex (glutaraldehyde).

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Formalin chambers are not to be used. Steam autoclave is also to be avoided, as extremes of temparature may cause loosening of lenses.

Explanation[1]

As with laparoscopes and other equipment that enter sterile body sites, arthroscopes ideally should be sterilized before used.

There still exists controversy with respect to use of high level disinfection versus sterilization for arthroscopes/laryngoscopes. Proponents of high level disinfection claim that only few organisms are introduced in the body by these instruments, the soft tissue damage is much less, the natural bioburden is quite less on these lumened instruments, incidence of infection is quite low in such cases and disinfection is enough to tackle common organisms. Proponents of sterilization claim risk of transmitting spores and sterlization as standard procedure for all instruments that enter sterile body cavities. This debate will continue till more robust evidence is available, however high level disinfectant can be considered as current standard.

How are the sterile instruments transported from CSSD to operation theater (OT) ward/casualty?

Sterility is event related and is dependent on the amount of handling, the conditions during transportation and storage, and the quality of the packaging material.[4]

Sterile items should be transported in covered or enclosed trolleys with solid-bottom shelves and brakes should be present. The trolley should be cleaned and disinfected after each use.

SUMMARY

1. Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients.

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2. Steam sterilizer (pre vacuum type) is the most common method used for sterilization of instruments and linen.
3. Ethylene oxide sterilization and H_2O_2 gas plasma sterilization has been the most commonly used process for sterilizing temperature and moisture-sensitive medical devices.
4. CSSD should not have a dirty/washing area, packing area and sterile store room for storing sterile instruments after sterilization.
5. The sterilization procedure should be monitored routinely by mechanical indicators, chemical indicators and biological indicators.

REFERENCES

1. Rutala WA,Weber DJ. Healthcare Infection Control Practices Advisory Committee (HICPAC). (2008). CDC-Guidelines for disinfection and sterilization in healthcare facilities. [online]. Available from http://www.cdc.gov/hicpac/Disinfection_sterilization/toc.html [Accessed] September, 2014.
2. Training Manual for Health Care Central Service Technicians, 5th Edition. American Society for Healthcare Central Services Professionals; November 2005.
3. Association for Advancement of Medical Instrumentation. ANSI/AAMI ST79:2010 and A1 and A2; 2011. p. 67.
4. Recommended practices for sterilization. Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc: 2013. pp. 513-40.

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Manual of Infection Control in ORTHOPAEDIC SURGERY

Operation Theater Protocols and Patient Optimization

Salient Features

The book is unique in terms of offering a concise account of every aspect of infection control and optimization of patient care and has specific focus on providing the following details:

- Guidelines for infection control in surgical practice modified as per Indian settings
- Protocol for optimization of patients, surgeons and hospital environment to minimize infection rates
- Detailed discussion on construction and running of an optimal operation theater
- Chapters on intraoperative and postoperative precautions that will help to reduce the surgical infection rates.



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