

Instrument Processing

LEARNER OBJECTIVES

1. Discuss the *responsibilities of the perioperative nurse* in *processing instruments* to prevent *patient injury* & *surgical site infection* (SSI).
2. Explain the *partnership between perioperative personnel & sterile processing department* in *instrument processing*.
3. Describe *responsibilities for cleaning surgical instruments at the point of use and transport to the sterile processing department*.
4. Explain the *relationship among cleaning, sterilization, and disinfection*.
5. Identify the *steps associated with inspecting, assembling & packaging items for *sterilization or disinfection**.
6. Describe *high- and low-temperature sterilization technologies*.
7. Discuss *responsibilities associated with sterilization monitoring*.
8. Explain *requirements for storage of sterile items*.

Lesson Outline

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B. *Transporting Items from Point of Use to Sterile Processing Department*

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B. *Mechanical Cleaning*

C. *Special Needs Instruments*

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I V. Preparation and Packaging

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I. Introduction

- ☒ Postoperative wound infection/surgical site infection (SSI) is a complication of surgery with potentially dire consequences for the patient, including delayed recovery, increased length of stay, increased cost of care, increased pain and suffering, and even death.
- ☒ According to the (CDC, 2015c), SSIs are a leading cause of hospital-associated infections (HAIs), accounting for 31% of all HAIs in hospitalized patients in a recent study.
- ☒ SSIs associated with 3% mortality rate & 75% of SSI-associated deaths attributable to SSI.
- ☒ SSI reduction identified as → Phase One priority → in Action Plan to Prevent HCAI.
- ☒ Intact skin is → first line of defense against infection. Pathogenic microorganisms are capable of causing disease when they invade human tissue.
- ☒ Surgical incisions interrupt skin integrity → portal of entry for microorganisms, which ↑ a patient's risk of getting infection by giving microorganisms a route into areas of body.
- ☒ Drains, catheters & monitors → alter skin integrity and contribute to risk for infection.
- ☒ Contaminated instruments are → a known source of infection.
- ☒ Every effort is made to remove microorganisms from items that contact human tissue.
- ☒ The nursing diagnoses of “increased risk for infection” and outcome statement “free from injury” are pertinent when caring for patients undergoing invasive procedures.
- ☒ Most instrument processing is performed in separate sterile processing department (SPD).
- ☒ Perioperative nurse is a partner in preparing instruments & assumes responsibility for cleaning, inspection, packaging, sterilization, and storage of sterile supplies.
- ☒ As patient's advocate, perioperative nurse strives to ensure that all instruments delivered to sterile field have been appropriately prepared & processed & are in good working order.
- ☒ Disinfection & sterilization accomplished within OT department, is nurses' responsibility.
- ☒ Device & equipment manufacturers' instructions for use (IFU) must be considered.

Definitions

Antiseptics: Chemicals used to destroy microorganisms on body surfaces. The number & type of organisms killed determined by composition & concentration of antiseptic & amount of time agent remains active.

Autoclave: A steam sterilizer.

Bioburden: A population of viable microorganisms on an item.

Biofilm: A collection of microscopic organisms that exist in polysaccharide matrix that adheres to a surface & prevents antimicrobial agents as sterilants, disinfectants, & antibiotics from reaching the cells.

Biological indicator: A sterilization monitor consisting of a known population of resistant spores that is used to test a sterilizer's ability to kill microorganisms.

Bowie-Dick test: An air-removal test designed to assure that autoclave can remove air & noncondensable gases from chamber of a dynamic air-removal autoclave & that steam can penetrate a specified pack.

Cavitation: in Ultrasonic washer, processes by which high-intensity sound waves generate tiny bubbles expand until collapse or implode → negative pressure on surfaces of instruments that dislodges soil.

Chemical indicator: A device used to monitor one or more process parameters in sterilization cycle. It responds with a visible chemical or physical change (color change). **Chemical indicators** are usually paper strip, tape, or label that changes color when parameter met. Chemical indicators go on the outside and inside of each package to be sterilized.

Contaminated:

(1) Items soiled or potentially soiled with microorganisms are considered to be contaminated. Items that were opened for surgery, (used during surgery & or not) are also considered to be contaminated.

(2) In regulatory arena, a term referring to an item that has been in contact with an infectious agent.

Decontamination: process that renders previously contaminated item safe for handling. Decontamination is usually accomplished by cleaning followed with a thermal or chemical disinfection process.

Definitions cont

Disinfectant: *antimicrobial agent* used to destroy microorganisms on inanimate surfaces. The composition and concentration of the disinfectant and amount of time an item is exposed to it determine the number and types of organisms that will be killed.

Disinfection: process *kills all living microorganisms*, with *exception of high numbers of spores*.

- Low-level disinfection kills → vegetative forms of bacteria, lipid viruses & some fungi.
- Intermediate-level disinfection kills → vegetative bacteria, mycobacteria, viruses, and fungi, but not spores.
- High-level disinfection kills → vegetative bacteria, mycobacteria, viruses, fungi, and some spores.

Event-related sterility: A *sterile item remains sterile* until an event happens to render it unsterile.

IFU: Manufacturer's instructions for use; (FDA) require manufacturer written instructions

Immediate-use steam sterilization (IUSS): A steam sterilization process for sterilizing heat- and moisture-stable items that are needed immediately; previously known as "flash sterilization."

Manufacturer's IFU: Written instructions by manufacturer of details appropriate use & process of device.

Prion: An *infectious protein particle* responsible for rare & fatal diseases of nervous system.

Spaulding's Classification: A system of categorization that *determines level of processing* of an item *based on its intended use*.

Spore: An *inactive or dormant, but viable, state of a microorganism*, which is notably resistant to heat, drying & chemicals & is difficult to kill.

Sterile: Free of all viable microorganisms, including spores.

Sterility assurance level (SAL): *probability of microorganism being present on item after sterilization*.

Sterilization: A process that *kills all living microorganisms, including spores*.

Strike-through: *Passage of a liquid through a barrier product*.

Treated water: Water from which additives as chlorine, dissolved salts, naturally occurring minerals, organic contaminants, bacteria, and endotoxins have been removed.

Washer-disinfecter, washer-decontaminator: Automated processing units used to decontaminate instruments. Cycles within these machines vary but always include washing and rinsing.

- ☒ Selecting appropriate method of processing instruments requires an *understanding of the scientific principles* involved in cleaning, inspection, packaging, sterilization, and storage of sterile instruments and supplies.
- ☒ When immediate-use steam sterilization (IUSS) or high-level disinfection is required, perioperative nurse may assume total responsibility for cleaning, inspection, & packaging, as well as for sterilization or disinfection process. For instance, perioperative nurse *must understand* why *no instruments—not even a single instrument* intended for IUSS — *should ever be cleaned in a scrub sink*.

II. Managing Instruments at the Point of Use

- ☒ All instruments opened for procedure are considered contaminated whether or not used.
- ☒ During a surgical procedure ⇒ instruments kept as clean as possible ⇒ wiped clean with sponge moistened or immersed in sterile water to prevent debris in serrations & crevices.
- ☒ Instrument lumens ⇒ flushed free of debris using syringe filled with sterile water. Irrigation ⇒ take place below surface of water to prevent aerosolization of particles.
- ☒ Sterile water (~~not saline~~) ⇒ used for cleaning items during surgery.
- ☒ Instruments ⇒ cleaned quickly after use to prevent blood & debris from drying.
- ☒ Bioburden that dry on instruments is difficult to remove & interfere with sterilization.
- ☒ Once instrument is opened, it is considered contaminated whether or not it is actually used.
- ☒ Instruments should be returned to their *original containers* so *sets are complete*.
- ☒ Before instruments leave the operating room:

- **Remove blades** and other **sharps** and **discard** them in a sharps container.
- **Remove drill bits & saw blades**; ⇒ if reusable, (wipe clean & segregate) prevent injury.
- **Segregate sharp instruments**, as scissors & osteotomes, from other instruments.
- **Open instruments** with box locks and joints.
- Unless contraindicated by manufacturer's IFU, disassemble devices with multiple components; keep parts together.
- Place **heavy instruments** in bottom of tray with **lighter ones** on top.
- ☒ **Preventing bioburden** from drying on instruments facilitates effective cleaning and helps to prevent corrosion, rusting and pitting.
- ☒ To prevent biofilms ⇒ instruments should not remain in water for lengthy periods of time.
 - ✓ Once formed, biofilm cannot be rinsed away & must be removed mechanically.
 - ✓ Biofilm will prevent sterilant from contacting all surfaces of instrument.
 - ✓ Biofilms can pose serious threat to health.
 - ✓ It compromising disinfection & sterilization ⇒ resulting in massive infusion of bacteria
 - ✓ Biofilm is 500 times resistant to antibiotics.
 - ✓ **Sterilant** cannot reach microorganisms protected glycocalyx.
 - ✓ To prevent formation of biofilms ⇒ instruments are kept moist until they are cleaned.

A. Instruments Exposed to Prions

- ☒ **Prion** ⇒ infectious **protein particle** responsible for transmissible spongiform encephalopathies as Creutzfeldt-Jakob disease, a rare & always fatal disease of central nervous system.
- ☒ Brain, spinal cord, dura mater & eye ⇒ **considered high-risk** tissue for transmission of prion.
- ☒ **Perioperative nurse** should follow policies & procedures & conduct patient assessment to identify those at high risk for prion disease & instruments contaminated with prions
- ☒ **Prions** are resistant to routine sterilization & disinfection procedures. Ideally, instruments used on tissue known or suspected to be contaminated with prions should be **discarded**.
- ☒ In patient suspected having **prion disease** ⇒ instruments not discarded should be cleaned & sterilized according to special protocols:
 - At point of use, avoid mixing instruments exposed to high-risk tissue with other.
 - Keep instruments moist until cleaned or decontaminated.
 - **Clean instruments** as soon as possible to minimize drying of tissue, blood, & body fluids.
- ☒ Use following protocols for decontaminating instruments:
 - Easily cleaned instruments ⇒ steam autoclave them after cleaning at (134°C) for 18 min in prevacuum sterilizer or at (132°C) for 60 min in a gravity-displacement autoclave/cycle.
 - For instruments that are difficult to clean or have small lumens:
 - ✓ Discard the instruments or
 - ✓ Immerse instruments in 1 NaOH for 60 minutes, then remove, rinse with water, & sterilize using one of the cycles already described

B. Transporting Items from Point of Use to Sterile Processing Department

- ☒ Transport items from the point of use to SPD as soon as possible.
- ☒ **Remove all trash & linen** from sets. Any items in SPD cannot be processed ⇒ discarded.
- ☒ **Contain all instruments** in durable, leakproof, labeled, or color-coded container that is closed before being removed from work area to prevent personnel from contacting contaminated items.
- ☒ A biohazard label should be affixed to cart before it is removed from work area.

III. Decontamination: Sterile Processing Department

A. Manual Cleaning

- ☒ Instruments received in *sterile processing department* in area to contain contamination
- ☒ The “decontam” area is a **negative air pressure environment**; this prevents microorganisms in air *from escaping into surrounding areas*. AAMI recommends a **minimum of 10 air exchanges per hour**; Facility Guidelines Institute recommends a minimum of **6 air exchanges per hour**.
- ☒ **Personnel working in decontamination area** should wear the following PPE for protection:
 - A liquid-resistant gown or apron with sleeves
 - Long-cuffed utility gloves
 - A mask
 - Eye protection (goggles or full-face shield)
- ☒ **All instruments returned to SPD is *cleaned whether they were used or not*.**
 - ✓ Cleaning is the ***first and most important step in preparing items for sterilization***.
 - ✓ If an item ***is not thoroughly clean, it cannot be sterilized***.
 - ✓ Any debris remaining on instrument will ***prevent sterilant from contacting surface***.
- ☒ Remember, **an item can be clean but not sterile**; but **no item can be sterile if it is not clean**.
- ☒ For instruments and devices that are **not sensitive to heat or moisture**, **mechanical cleaning** in an automated system ***is preferable*** because the process is consistent. **Manual cleaning** can be equally ***effective if performed correctly***.
- ☒ Some **powered instruments** & **heat sensitive, delicate**, or **items cannot tolerate mechanical washing**. These should be ***cleaned according to device manufacturer’s IFU***.
- ☒ When **instruments are manually cleaned**, it is important for the process to be **standardized**.
- ☒ Following supplies & equipment should be readily available wherever items are processed:

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| ○ Enzymatic detergent | ○ Eyewash station |
| ○ Soft-bristle brushes of various sizes | ○ Medical grade compressed air |
| ○ Syringes for irrigation of lumens | ○ PPE |
| ○ Adaptors and accessories for specific devices as required by the manufacturer’s IFU | |

- ☒ **Before washing with a detergent**, instruments should be ***rinsed in cold water*** to remove gross debris. **Hot water coagulates protein & makes the cleaning process more difficult**.
- ☒ **Detergent** should be ***specific for instrument cleaning***. Detergent should be ***used strictly according to manufacturer’s IFU***. For example, mixing detergents to higher concentration because of heavy debris is not appropriate and may, in fact, ***impede rinsing*** that will subsequently ***interfere with sterilization or disinfection***.
- ☒ **Immersible items** ⇒ **cleaned below surface of water** to prevent aerosolization of debris.
- ☒ **Lumens and cannulas** should be **flushed while submerged**.
- ☒ **Items that cannot be immersed** ⇒ cleaned in a manner that prevents aerosolization of debris.
- ☒ **Soft-bristle brushes or pipe cleaners** ⇒ can remove soil from hard-to-reach places such as hinges and serrations.
- ☒ **Abrasive cleaners, scouring pads, metal brushes, or steel wool** ⇒ should not be used on surgical instruments unless indicated in the device’s IFU.

B. Mechanical Cleaning

- ☒ For mechanical cleaning in a washer-disinfector/decontaminator, instruments are **arranged in trays** with an **open-mesh bottom** and **placed on shelves in the machine**.
- ☒ Washer-disinfector/decontaminators usually offer a variety of cycle options.

☒ **Phases in cycle may include:**

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|-----------------------------------|--|
| ✓ <i>Cool-water rinse,</i> | ✓ <i>Hot-water rinse (70–76°C),</i> |
| ✓ <i>Enzymatic soak or rinse,</i> | ✓ <i>Thermal or chemical disinfection,</i> |
| ✓ <i>Detergent wash,</i> | ✓ <i>Treated water rinse, and</i> |
| ✓ <i>Ultrasonic cleaning,</i> | ✓ <i>Drying.</i> |

- ☒ The washer-disinfector/decontaminator is built into wall between decontamination area and clean areas where instruments are assembled and packaged.
- ☒ Instruments are placed into machine in decontamination area & are removed from opposite end in the clean area.
- ☒ Instruments that have been processed in a washer-disinfector/decontaminator or are manually washed and disinfected according to the IFU are considered clean and safe to handle, and are ready to be inspected, assembled, packaged, and prepared for patient use.

C. Special Needs Instruments

1. Eye Instruments

- ☒ Although the principles for cleaning are similar for all instruments, eye instruments require special attention. They are delicate and cannot usually be cleaned in automated systems, so special care must be taken to ensure adequate cleaning.
- ☒ It is essential to clean eye instruments in accordance with the manufacturer's IFU. Eye instruments are delicate and have extremely small lumens. Thorough cleaning of lumens immediately following use is essential to ensure the removal of debris that may be responsible for toxic anterior segment syndrome (TASS).
- ☒ **Improper processing of eye instruments** has been ⇔ associated with TASS, a noninfectious inflammation of anterior segment of the eye that *can lead to permanent vision impairment*.
- ☒ Most cases of TASS occur when *foreign material* that was not removed during cleaning and sterilization is *introduced into the anterior chamber of the eye*.
- ☒ Endotoxins from Gram-negative bacteria in ultrasonic cleaners, viscoelastic solution used *during eye surgery* & detergent and disinfectant residue all associated with TASS

2. Flexible Endoscopes

- ☒ Flexible endoscopes are complex instruments; cleaning them is a multistep process. The manufacturers' IFU *provide the specific information required* to process each device.
- ☒ Personnel responsible for cleaning and disinfecting these devices should refer to following:
- American Society for Gastrointestinal Endoscopy (ASGE) and SHEA AORN (2015,p. 589)
 - Society of Gastroenterology Nurses and Associates (SGNA, 2013) CDC (2015b)
 - The endoscope manufacturer's IFU for cleaning and disinfection or sterilization
- ☒ Personnel responsible for endoscope reprocessing should have demonstrated competence.

3. Robotic Instruments

- ☒ **Robotic instruments** are complex and have lumens and difficult-to-clean components. It is essential to *follow the device manufacturer's IFU* for cleaning, inspection, and processing.
- ☒ Pay special attention to cleaning the *ports* and *articulating areas* on robotic instruments.
- ☒ Flush ports while rotating the articulating component of the device through its full range of motion. *Flush until the water runs clear*.
- ☒ **Failure to flush effectively** may result in in-complete removal of debris that can dry and harden, making cleaning more difficult and impeding effective sterilization.

D. Ultrasonic Cleaning (UC)

- ☒ The purpose of ultrasonic cleaning is to dislodge & remove tenacious debris from instruments with hard-to-reach nooks and crannies.
- ☒ The UC is not suitable for lensed instruments, powered instruments, or instruments that are chrome plated or made of plastic or rubber. Consult the instrument manufacturer's IFU to determine whether ultrasonic cleaning is compatible with a specific instrument.
- ☒ High-intensity sound waves generate tiny bubbles that expand until they collapse or implode (cavitation), creating negative pressure that dislodges soil from hard-to-reach crevices.
- ☒ The UC is beneficial for items with box locks, serrations, lumens & crevices.
- ☒ Follow both detergent and the ultrasonic manufacturers' IFU when adding detergent to water in ultrasonic cleaner. IFU will also indicate if and when water needs to be degassed.
- ☒ Before placing instruments in the ultrasonic washer, ensure that they are free of gross soil.
- ☒ Place instruments in specialty designed instrument basket or tray. Instruments should not rest on bottom of unit ⇒ will prevent cavitation on part of instrument not in contact with water.
- ☒ Attach adaptors that flush cleaning solution through lumens of cannulated instruments.
- ☒ Instruments of same kind of metal should be placed in ultrasonic machine at one time.
- ☒ If instruments of dissimilar metals are in ultrasonic cleaner ⇒ etching & pitting may occur.
- ☒ To prevent aerosolization of contaminants ⇒ lid on ultrasonic remain closed during use.
- ☒ If automated rinse phase is not included in ultrasonic cycle & instruments are not placed in automated washer using treated water, instruments ⇒ manually rinsed with treated water
- ☒ Solution in ultrasonic washer should be changed at least daily or if it is visibly soiled.
- ☒ Most facilities use UC post initial decontamination & prior manual cleaning
- ☒ Some use UC for most instruments; others for specialty or difficult-to-clean instruments.
- ☒ Some washer-disinfectors/ decontaminators include an ultrasonic cycle.

E. Lubrication

- ☒ Instruments with movable parts should be lubricated with an antimicrobial, water-soluble lubricant that ⇒ protects against rusting & staining according to device manufacturer's IFU.
- ☒ The lubricant must be water soluble ⇒ to allow penetration of steam during sterilization.
- ☒ The residue from oil-based lubricants ⇒ can prevent penetration of steam.

IV. Preparation and Packaging

A. Inspection

- ☒ When instruments arrive in clean area of SPD remaining moisture ⇒ is dried & instruments are inspected for cleanliness, integrity, alignment, sharpness of edges & proper function
- ☒ Items that do not function are removed from service & either discarded or sent for repair.
- ☒ It is imperative that careful inspection & checking for function occur prior to packaging.
- ☒ An instrument that fails in surgery can be the direct cause of an injury to the patient.

B. Assembly and Packaging

a. Selection Criteria for Barrier Protection

- ☒ Packaging materials & systems ⇒ maintain sterility of items until intended use.
- ☒ Packaging material must be ⇒ appropriate for both item and sterilization process.

- ☒ Not ***all packaging materials*** are ***compatible with every sterilization process***; however, all packaging materials must:
 - ***Provide a barrier*** to microorganisms.
 - Permit ***penetration and exit of the sterilant***.
 - Allow for ***adequate air removal***.
 - Be ***intact; resist tears, punctures, and abrasions***.
 - Permit ***complete and secure enclosure*** of the contents.
 - Be ***fluid resistant***.
 - Be ***free of toxic ingredients and non-fast dyes***.
 - Provide ***adequate seal integrity***.
 - Be ***large enough to evenly distribute the contained mass***.
 - Permit ***identification of the contents*** and/or ***labeling to identify contents***.
 - ***Maintain sterility of items until package is opened***.
 - ***Allow for aseptic delivery of contents to sterile field***. (AAMI, 2013; AORN, 2015)
- ☒ A ***wide variety of types of packaging systems*** is available:
 - Woven fabrics - Nonwoven materials
 - Paper - Rigid container systems
 - “Peel packs” (plastic/paper and plastic/Tyvek pouches)

1. Woven Fabric

- ☒ **Reusable wrappers constructed of cotton and polyester blend fabrics** that have been treated to be **water resistant** have been largely **replaced by disposable, nonwoven fabrics.**

Woven wrappers:

- May produce lint.
- Do not exhibit “memory” a characteristic that causes material edges, when the package is opened, to return to their original folded position.
- **Compatible** with steam & ethylene oxide sterilization but not (hydrogen peroxide or ozone)
- **Must be inspected between uses** for pinholes & tears.
- **Must be laundered between uses** to prevent ⇒ superheating & deterioration of fabric. They maintained for 2 hours at temperature (20–23°C) & at a relative humidity of (30% to 60%).
- **Lose their water-resistant properties over time** and must be retreated or discarded.
- Usually **require two wrappers** (four layers) to protect sterile contents.
- **Packages may be wrapped:**
 - ✓ **Sequentially** متعاقب ⇒ 2 wrappers folded one at a time to create package within package
 - ✓ **Simultaneously** معا: 2 wrappers at once: ⇒ folded into 2 wrappers to create single package
 - ✓ **Single-layer wrap**: Items wrapped in single layer of material when single-layer wrap meets the same barrier protection requirements as two layers of traditional material.
- **Manufacturer’s IFU** ⇒ describe number of layers required & method of folding
- **Facility’s policy for wrapping** ⇒ driven by ability of wrap to maintain items in sterile state

2. Nonwoven Materials

- ☒ **Nonwoven wrappers** are made of combination of cellulose and/or other synthetic materials.
- ☒ **Nonwoven, cellulose-based wrappers** are **compatible** with steam & EtO, but not compatible with **hydrogen peroxide** (H₂O₂) sterilization technologies. **Polypropylene wrappers** are designed for items to be sterilized with H₂O₂ & with EtO & steam.

- ☒ Nonwoven wrappers are single use, disposable, lint free & tear resistant; they provide excellent barrier protection against dust, airborne microorganisms, & moisture.
- ☒ Some nonwoven wraps require two layers; others require single wrap.
- ☒ Nonwoven wrappers eliminate need for washing, inspecting & patching (*used only once*)
- ☒ Nonwoven wrappers may display undesirable memory, because *wrapper edges try to return to their original fold* when packages are opened.
- ☒ Some nonwoven packaging products may require a longer sterilization time.
- ☒ Packages are secured with pressure-sensitive tape that also *serves as a process indicator*.

3. Pouches: Plastic/Paper, Plastic/Tyvek

- ☒ Pouches (called “peel packs”) constructed from plastic & paper or plastic & Tyvek (*made from high-density polyethylene fibers*) used for packaging items for sterilization.
- ☒ The plastic/paper combination is appropriate for steam or EtO sterilization.
- ☒ Tyvek/plastic combinations contain no cellulose & compatible (H_2O_2 & EtO), but not steam
- ☒ The plastic film is fused to paper or Tyvek $\Rightarrow$ so that one side is clear & other opaque.
- ☒ The sterilant penetrates opaque paper or Tyvek portion of the pouch, while the plastic portion permits visualization of the item inside.
- ☒ Advantages of peel packs:
 - *Inexpensive* - Permit visualization of the contents - *Lint free*
 - Provide an *effective barrier against airborne microorganisms*
 - *Suitable for packaging multiple small items and individual lightweight items*
- ☒ Disadvantages of peel packs:
 - Provide *little resistance to punctures*
 - *Tendency to display memory*
 - *Limited to packaging items* that can be delivered aseptically to the sterile field
- ☒ Items can be packaged in a single pouch; or sealed pouch is placed within another pouch.
- ☒ When double pouching, inner pouch should fit inside outer pouch *without being folded*, and the pouches should be oriented in same direction (plastic faces plastic, and paper faces paper). The *contents of the inner pouch will be visible*.
- ☒ Pouch material is available in many sizes and pouches are manufactured as individual pouches or on a continuous roll that *can be cut into desired lengths*.
- ☒ Pouches are either self-sealing or can be fused with a *heat sealer*. Self-sealing often provides *most secure seal*. When *heat sealers* are used, consult manufacturer’s IFU to establish *appropriate temperature setting*.



Fig. 2: Single and double-packaging with paper/plastic pouches

- ☒ Remove as much air as possible from pouch before sealing. Air expands & can burst pouch
- ☒ *Once a pouch has been opened, item may not be resealed without being reprocessed.*
- ☒ Package seal must *not permit resealing* once pouch has been opened.
- ☒ Pouches positioned for sterilization on edge (vertically) & all *facing in same direction* to promote penetration & evacuation of sterilant. Occasionally, *racks are used*.

- ☒ Peel packs should never be placed inside instrument sets because they cannot be maintained in a **vertical position**. Paper bags, foam pouches, and other supplies have been validated for use within sets to contain multiple small items & protect delicate instruments (Fig. 3).



Fig.3 Arrange small items in sets in paper bags, foam, and small containers validated for that purpose.

4. Rigid Container Systems

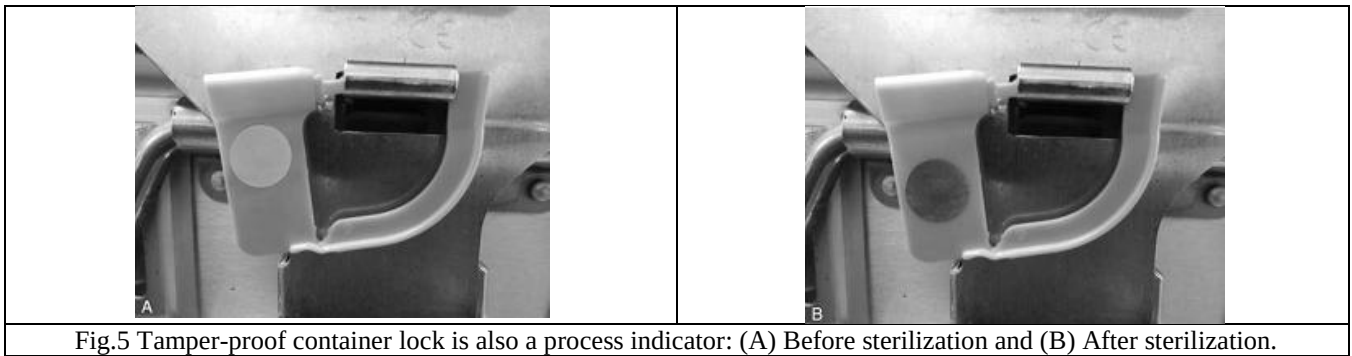
- ☒ Rigid container systems are *packaging receptacles* that have an outer case (called a *casket*) constructed of aluminum, stainless steel, heat-resistant plastic, or combination of materials. Each system has *one or more* wire mesh baskets that fit inside to hold instruments (Fig.4).



Fig.4 Rigid Containers and Accessories

- ☒ Information about compatibility with sterilization technologies & cycles, arrangement of instruments within containers, sealing, labeling, temperature, exposure times, and cleaning instructions must be obtained from the manufacturer's IFU.
- ☒ Container systems have gaskets to promote a secure seal and either a valve or filter system to permit penetration and evacuation of sterilant.
- ☒ After rigid containers have been manually or mechanically cleaned, the gaskets, valves, and filter retainers must be inspected for integrity.
- ☒ Unless the *IFU indicates that filters* are intended to be used multiple times, a new filter(s) is placed in a container each time one is prepared for use.
- ☒ The lid & base of container are held together by a latch mechanism.
- ☒ The container is locked with tamper-evident seal (Fig-5). Once opened, contents of the container should be used immediately.
- ☒ The container **cannot be resealed**. The seal may also contain a process indicator.
- ☒ Advantages of rigid containers:
 - Durable; provide more protection for instruments than wrapped packages
 - Baskets often have pegs or posts to protect instruments and organize them efficiently

- **Do not require wrapping**
- **Can stack** for efficient storage



- ☒ **Rigid containers can be heavy**; an empty container can weigh as much as 10 pounds.
- ☒ If **condensation occurs within container** (“wet pack”). The instruments **are not considered sterile** and must not be used.

b. Packaging Items for Steam Sterilization

- ☒ **Instruments** & **other items** are arranged in **container baskets** or a **perforated** or **mesh bottom** tray that **permits steam to penetrate** and also **prevents air from being trapped** (Fig.6).

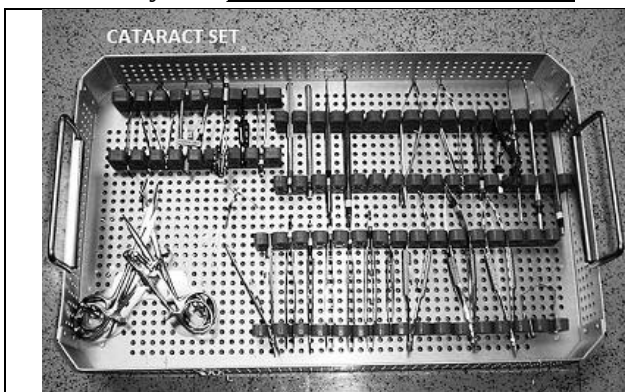


Fig. 6 Instrument set arranged for sterilization.

- ☒ Unless contraindicated by container manufacturer, **lint-free absorbent towel** or **tray liner** may be placed in bottom of tray **to help absorb condensate** that is **formed during sterilization** and to **help speed the drying process** (Fig.7).
- ☒ **Instruments** must be positioned⇒ **every surface of each item** exposed to sterilant (Fig.8).
- ☒ **Joints & hinges of instruments** must be **opened** & **detachable parts** disassembled unless the manufacturer provides validated instructions for sterilization when device is assembled.
- ☒ **Heavy instruments** are **placed on bottom** of tray & **delicate instruments** are **placed on top**.

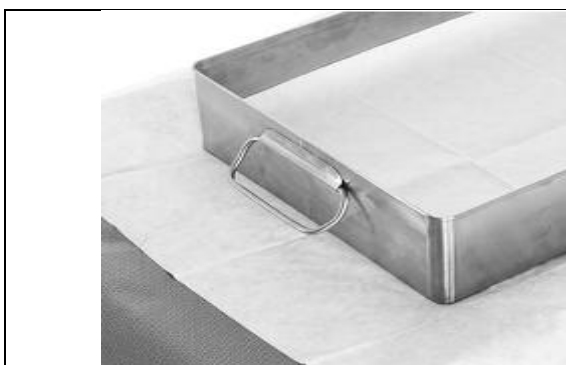


Fig.7 Tray liner in instrument tray

- ☒ Basins, bowls & cups can be nested one inside, other separated with gauze or an absorbent towel. Porous material permits entry of sterilant, sterilant contact with all surfaces, and exit of the sterilant, and it facilitates drying process.
- ☒ Basins, bowls & cups should be positioned vertically in steam sterilizer to prevent water from pooling in them and to prevent wet packs.

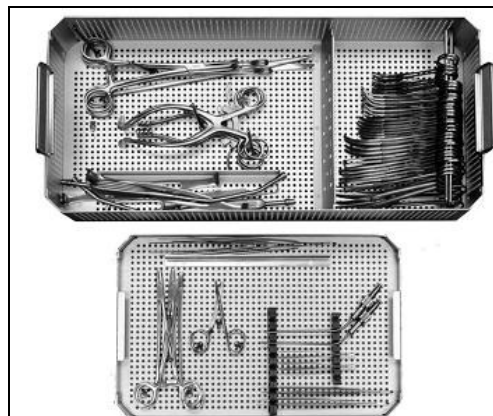


Fig.8: Instrument set arranged for sterilization. Note that
Ringed instruments are held open on stringer;
Pins hold larger instruments in place.
Heavy instruments are in larger bottom tray; more delicate instruments are arranged in a separate tray that fits on top.

- ☒ Nested items placed facing in same direction to prevent air pockets, allow circulation of steam, and permit condensate to drain out.
- ☒ Rubber sheeting (e.g., Esmarch bandage) or other impervious material cannot be folded on itself or wrapped tightly in a roll for sterilization. The resulting density of item prevents adequate circulation of sterilant.
- ☒ Open item & cover with porous material (e.g., gauze) of same size, roll or fold loosely, then wrap. This approach promotes sterilant contact with the entire surface of the rubber or other impervious material. Esmarch that is supplied sterile by the manufacturer is preferred.
- ☒ Lumened items, such as cannulas & ventricular & irrigation needles, ⇒ must be cleaned, rinsed, and dried thoroughly before packaging for sterilization.

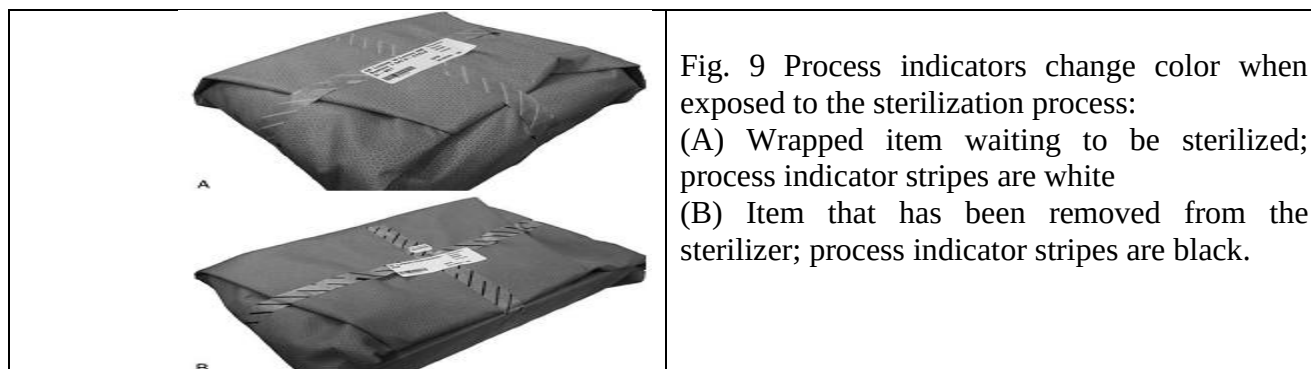
c. Packaging Items for Low-Temperature Sterilization

- ☒ For H₂O₂ or H₂O₂ /ozone sterilization systems:
 - All items must be thoroughly dry; lumens should be blown dry with compressed air.
 - If any moisture is present on objects ⇒ sterilizer cannot achieve vacuum & cycle aborts.
 - Appropriate packaging includes ⇒ polypropylene wrap or rigid container systems. The sterilizer manufacturer's & device manufacturer's IFU must be followed when selecting trays & containers.
 - Cellulose-based materials (e.g., paper, gauze, linen, or towels) absorb hydrogen peroxide and cannot be included within the load.
- ☒ For EtO sterilization:
 - Materials used to package items are also appropriate for EtO sterilization.
- ☒ Items prepared for gas sterilization must be thoroughly dry. Lumens ⇒ blown dry with compressed air. EtO in contact with water ⇒ forms ethylene glycol (a toxic residue).
 - Oil-based lubricants may not be used, because ethylene oxide cannot penetrate film left by these lubricants.

C. Monitoring: Chemical Indicators and Integrators

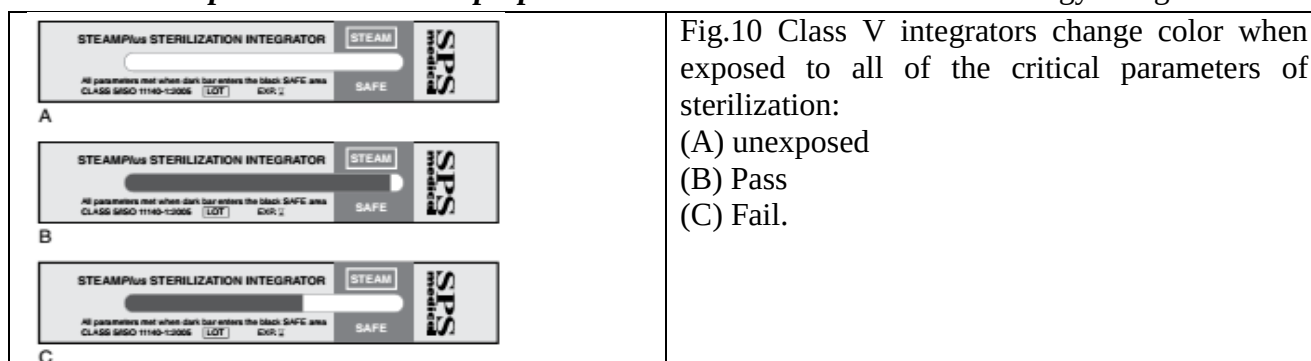
- ☒ Parameters of sterilization process are conditions that must be met for sterilization to occur:
 - Steam sterilization: time, temperature, and steam quality

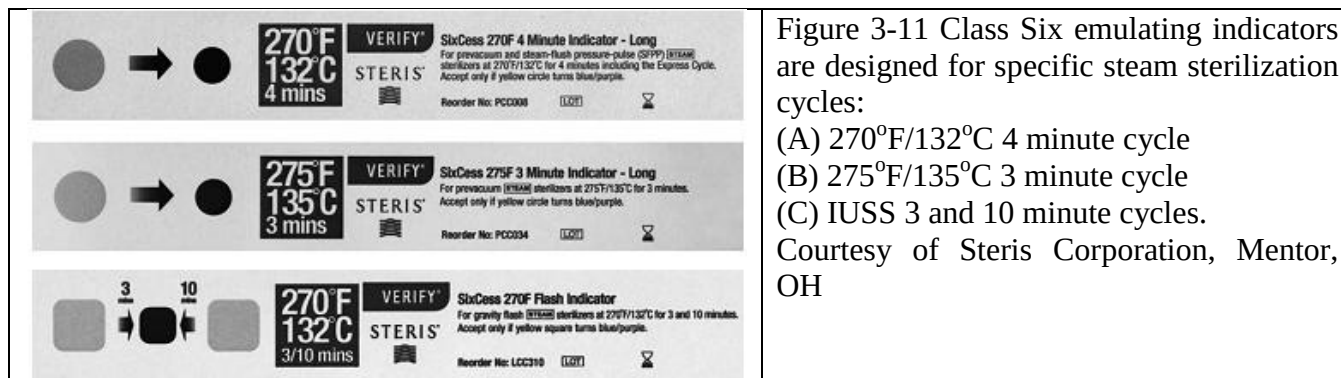
- EtO sterilization: time, temperature, gas concentration, & relative humidity
- H_2O_2 sterilization systems: H_2O_2 concentration, pressure, time & temperature
- ☒ **Chemical indicators** demonstrate visible change when exposed to parameters of sterilization; indicators differ in the parameter(s) to which they are sensitive.
- ☒ Process, or Class 1, indicators demonstrate only that items have been exposed to the physical conditions within the chamber that are monitored by the indicator.
- ☒ **Process indicators** include $\Rightarrow$ heat-sensitive tape, labels, or strips that are placed outside of a package to distinguish between processed and unprocessed units (Fig.9).



Packaging materials such as peel packs and rigid container locking devices often have an *integrated process indicator*.

- ☒ When there is no visible indicator, $\Rightarrow$ *package must be considered contaminated*.
- ☒ *In addition to process indicator on outside of each item, one or more chemical indicators should be placed inside of each package or set (AORN, 2015, p. 655).*
- ☒ Manufacturer's IFU will identify the most challenging location(s) within a set or container to determine the most effective placement of the internal indicator. An **indicator** should be placed in each layer of multilevel sets.
- ☒ Single-variable indicators (Class 3) and multivariable indicators (Class 4) respond to one or more of the critical parameters of sterilization.
- ☒ Class 3 and Class 4 indicators are *rarely used in the surgical setting*.
- ☒ Integrators (Class 5) react to all critical parameters of the sterilization process. This is the most common internal indicator used in the healthcare setting (Figure 3-10).
- ☒ Emulators (Class 6) react to all critical parameters of the sterilization process & are cycle specific; each steam sterilization cycle has specific emulator; that not interchangeable (Fig.11)
- ☒ Chemical indicators are designed specifically for either high-temperature or low-temperature sterilization or are not interchangeable.
- ☒ It is *important to select the proper indicator* for the sterilization technology being used.



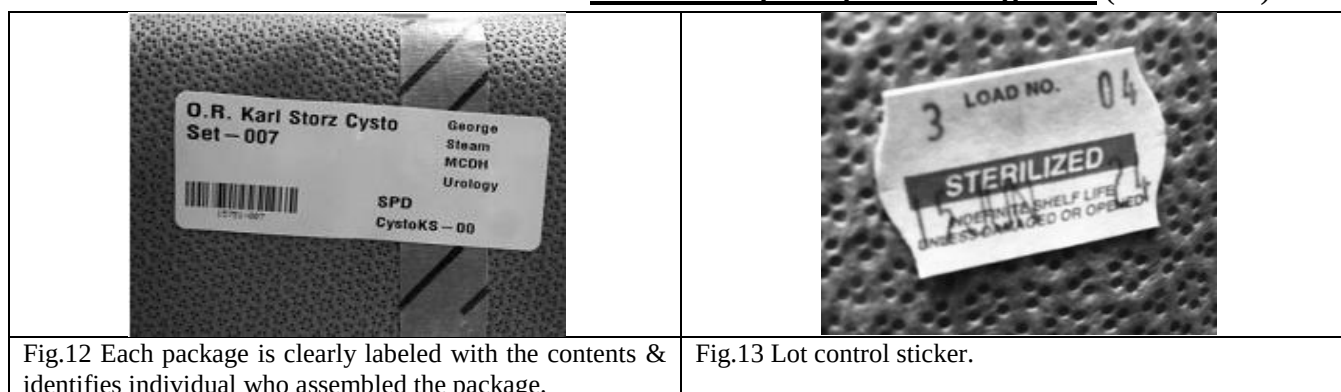


D. Labeling

- ☒ Items packaged for sterilization should be clearly labeled with the contents and initials of the package assembler (Fig.12).
- ☒ Indelible, nonbleeding, and nontoxic markers may be used to mark packages. Marking on peel packs should be on the plastic side of the pouch (AORN, 2015, p. 658).
- ☒ Before being placed into the sterilizer, a **lot control sticker** is placed on each package (Fig.13). Lot control number indicates **sterilization date**, **sterilizer used** & **cycle** or **load number**. Lot control numbers, in conjunction with computerized instrument tracking systems, facilitate inventory control, stock rotation & retrieval of items in sterilization event or sterilizer failure

V. Sterilization and Disinfection

- ☒ **Sterilization & disinfection** processes **destroy microorganisms** & are among cornerstones of infection prevention.
- ☒ Advances in surgical techniques & technology have created a **proliferation** of **complex**, **sophisticated** & **expensive surgical instrumentation**, **including endoscopic**, **fiberoptic**, and **robotic instruments** that require special handling.
- ☒ The appropriate method of **cleaning**, **disinfecting**, and **sterilizing** an item is determined by its **composition & configuration**, its **compatibility with the sterilization & disinfection** methods.
- ☒ Whether an item is **disinfected or sterilized** depends on its **intended use**. The Spaulding classification of devices categorizes devices as **critical**, **semicritical**, or **noncritical** & determines whether an item must be **sterilized or if disinfection is sufficient** (Exhibit 3-1).



A. Sterility Assurance Level (SAL)

- ☒ Process of sterilization provides the **greatest assurance** that ***items are sterile*** (free of known and unsuspected microorganisms).
- ☒ **Critical items** used in surgery must be sterilized with **sterility assurance level** of 10⁶.

- ☒ This expression means that there is equal to, or less than, **one chance in 1 million** that any viable microorganism will be present on item after sterilization. This is very high SAL compared to industries where an SAL of 10^3 (**one chance in 1,000**) might be acceptable.
- ☒ A **sterilizer** must be capable of killing 1 million spores in half time for which the sterilizer is programmed for hospital use. Example, **if exposure phase** in sterilization cycle is 4 minutes, sterilizer manufacturer must demonstrate that 1 million spores are killed in 2 minutes.
- ☒ **Certain pathogenic bacteria** such as *Clostridium tetani* (tetanus), *Clostridium peridens* (gas gangrene), & *Clostridium difficile* ⇒ developing spores. **Spores** are hardest bacterium; more resistant to heat, drying & chemicals, & can remain alive for many years.
- ☒ **Disinfection kills all living microorganisms** ⇒ exception of high numbers of bacterial spores. **Disinfectants** are classified according to their cidal activity (ability to kill microorganisms).
- ☒ **Only sterilization** can render an item free of all microorganisms, including spores.

Exhibit 3-1 Spaulding Classification System.

Minimum preparation of items is determined by the risk of infection involved with use

Critical Item

- Device enters normally sterile tissue or the vascular system
- Device should be sterilized to destroy all microbial life.
- Examples: surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities

Semicritical Item

- A device that contacts intact mucous membranes and does not ordinarily penetrate sterile tissue.
- Minimum level of processing is high-level disinfection to destroy all vegetative microorganisms, mycobacterium, small or nonlipid viruses, medium or lipid viruses, fungal spores, and some bacterial spores.
- Examples: respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades, 24 esophageal manometry probes, cystoscopes

Noncritical

- A devices that does not ordinarily touch the patient or touches only intact skin.
- Such devices should be low-level disinfected.
- Examples: blood pressure cuffs, OR bed safety strap, positioning equipment, computers, environmental surfaces

B. Methods of Sterilization

- ☒ The **choice among methods of sterilizing** an item depends on its compatibility with sterilization technology, configuration of item, packaging of item, available technologies, length of time of the sterilization process, and safety factors.
- ☒ **Steam** is high-temperature technology that is least expensive & most common sterilization.
- ☒ 2 other accepted methods of sterilization dry heat & ionizing radiation, are not found in U.S. healthcare facilities.
- ☒ Equipment, safety & cost considerations confine ionizing radiation to industrial settings where it is used for bulk sterilization of commercially prepared items.
- ☒ **Dry heat** is appropriate for powders, oils, & petroleum products that cannot be penetrated by steam or ethylene oxide or other sterilizing agents.
- ☒ **Heat- & moisture-sensitive items** require low-temperature sterilization technologies.
- ☒ **Hydrogen peroxide gas plasma** was introduced in 1990s; H₂O₂ vapor & H₂O₂ vapor plus ozone introduced in early 2000s.

- ☒ EtO, approved for medical device sterilization in late 1950s, was first low-temperature technology. Because of toxicity of EtO & stringent restrictions for installation & use, it has largely been replaced with H₂O₂ sterilization technologies.

a. High-Temperature Sterilization

1. Steam Sterilization (autoclave)

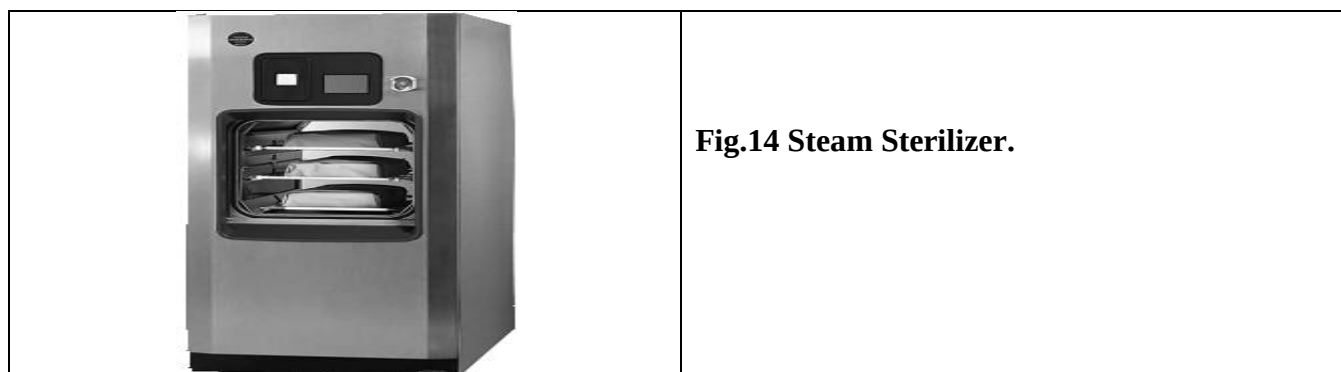
- ☒ Moist heat in the form of saturated steam under pressure is an economical, safe, and effective method of sterilization used for the majority of surgical instruments.
- ☒ For an item to be sterilized, steam must penetrate every fiber of packaging & contact every surface of the item inside. Critical parameters of moisture, temperature & time must be met.
- ☒ Saturated steam contains the greatest amount of water vapor possible. Heated to a sufficient temperature, it is capable of destroying all living microorganisms, (including spores), within a relatively short period of time.
- ☒ Saturated steam destroys microorganisms through a thermal process that causes denaturation & coagulation of proteins or enzyme protein system contained within microorganism's cell.
- ☒ Steam at atmospheric pressure has a temperature of (100°C), (inadequate for sterilization). Addition of pressure to ↑ temperature of steam is necessary for destruction of microorganisms.
- ☒ ↑ in pressure of 15-17 pounds/ square² will ↑ steam temperature to (121–123°C). Twenty seven pounds of pressure per square inch will ↑ steam temperature to 270°F (132°C).
- ☒ Minimum generally accepted temperature required for sterilization is (121°C). Typical temperatures for operation of steam sterilizers are in range of (132–135°C), although (121°C) is also used. Steam sterilization is a function of time & temperature. Sterilization at (121°C) requires more time than sterilization at (132°C).
- ☒ Steam sterilization has many advantages.

Steam:

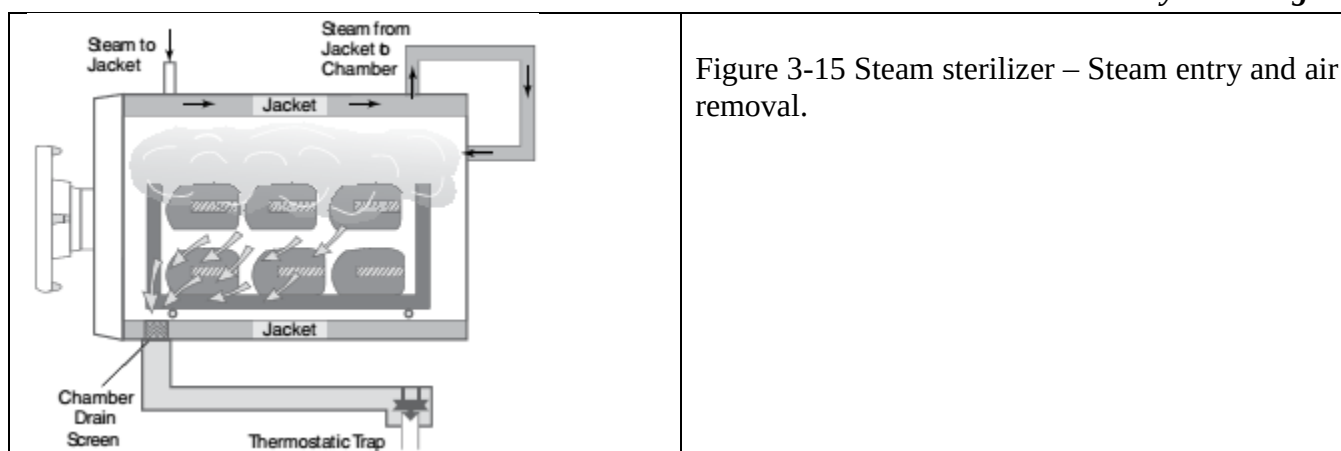
- Is readily available - Is economical.
- Enables fast sterilization ⇒ destruction of most resistant spores occurs quickly.
- Is compatible with most in-house packaging materials.
- Leaves no toxic residue and is environmentally safe.
- Is suitable for a wide range of surgical instrumentation.
- ☒ Steam sterilization is also associated with several disadvantages, though preset cycles on more modern autoclaves minimize these challenges.
 - A variety of instruments & devices cannot withstand high-temperature sterilization.
 - A temperature of 270°F is not appropriate for all items. A reduced temperature of 250°F may be necessary for a specific item being sterilized. A temperature higher than 270 o may be needed to comply with the manufacturer's IFU.
 - Timing of sterilization cycle adjusted based on ⇒ type of cycle, variances in materials, device configuration, and size of load.
- ☒ Improper preparation of items or improper placement within autoclave can interfere with steam circulation, draining of condensate, or proper drying ⇒ all can cause process to fail.
- ☒ A steam sterilizer consists of metal chamber & shell & enclosed space (jacket). When autoclave is ready to use steam & heat fill jacket & maintained at constant pressure (Fig.14)
- ☒ Items placed in chamber, door is shut tightly & sterilization cycle is initiated. Steam enters the chamber and displaces all the air from both the chamber and the items in the load. As the

pressure rises, steam penetrates packaging & contacts all surfaces within. The steam forces air out of chamber through a discharge port outlet at the bottom front of the autoclave.

- ☒ Proper loading of the autoclave is critical.
- ☒ Items must be placed so that steam can circulate freely. Placement of items must also promote drainage of condensate. For example, items as cups or basins placed on their side.



- ☒ The discharge port outlet is the beginning of a filtered waste line. Beneath the filter is a thermometer. This is the coolest part of autoclave.
- ☒ If air not trapped & parameters of time, moisture & temperature met, microbial destruction occur
- ☒ When **exposure time is complete**, steam is exhausted through outlet port & a drying cycle follows. A drying cycle is required for wrapped items.
- ☒ Wrapped packages & instrument containers should be allowed to cool on sterilizer rack.
- ☒ They should not be touched while they are cooling.
- ☒ A **minimum drying time** of 30 minutes is recommended, although *some instrument sets* may require as much as **2 hours to cool adequately** (AAMI, 2013, §8.8.1).
- ☒ **Warm packages** ⇒ must not be placed on **cool surfaces** because condensate will form, causing package to become damp. Microorganisms are capable of penetrating wet materials; therefore, moist packages that contact an unsterile surface must be considered contaminated.
- ☒ **Two types of (autoclaves)** are in use today: older gravity displacement & newer dynamic air removal technologies (*high vacuum, prevacuum & pulse pressure*).
- ☒ **Nature of items & container** ⇒ determine necessary time & temperature for sterilization.
- ☒ The **manufacturers' IFU for items** and for **autoclave** ⇒ determine the correct cycle settings.



2. Gravity Displacement

- ☒ In a **gravity-displacement cycle** or **autoclave**, steam replaces air in chamber by gravity.
- ☒ As **steam enters from port located near top** & rear of chamber, it is deflected upward.

- ☒ Air is heavier than steam ⇒ by gravity air is forced to bottom while steam on top of air. Steam rapidly displaces air under it & forces air out through discharge outlet port (Fig-15).
- ☒ Gravity autoclaves are operated at temperatures (121–134°C) with 10- 30-minute. For ex, wrapped instrument set requiring 30 minutes (121°C), or require 15-minute at (134°C).
- ☒ Certain equipment may require more times of as much as 55 minutes.
- ☒ Sterilization at higher temperature requires less time. All recommended cycles achieve an SAL of 10–6
- ☒ Disadvantages of gravity autoclaves ⇒ length of time & gravity to remove air.
- ☒ Gravity autoclaves common in dentist & physician offices, clinics & small surgicenters.
- ☒ Gravity autoclaves still found in healthcare facilities; for hospitals & large ambulatory surgery centers run dynamic air-removal cycles.

3. Dynamic Air Removal (Prevacuum Sterilizer)

- ☒ Prevacuum autoclave used vacuum pump that evacuates almost all air prior steam injection. The evacuation process takes ⇒ 5 minutes. When steam enters chamber ⇒ vacuum causes instant steam penetration & contact with all surfaces of contents (all package size or load).
- ☒ Following prevacuum phase, exposure time of 3-4 minutes (132–135°C) is recommended.
- ☒ Manufacturer's instructions for use are consulted before selecting cycle time & temperature.
- ☒ A dynamic air-removal (prevacuum sterilization) cycle has several advantages:
 - Incorrect placement of objects within chamber will have less effect upon air removal.
 - Entire load heat rapidly & more uniformly than with a gravity autoclave; time is shorter.
 - Loading autoclave is more efficient, allowing more supplies to be sterilized within time.
- ☒ The disadvantage prevacuum sterilizer is that event of leak, as in door seal, an air pocket can form that will inhibit sterilization.

4. Extended Cycles

- ☒ Proliferation of number & types of surgical devices, ⇒ variety of cycle times has likewise ↑.
- ☒ Cycles are commonly referred to extended cycles. Temperatures vary from (132–135°C).
- ☒ The manufacturer's IFU for sterilization ⇒ determine correct cycle length & temperature.
- ☒ Extended cycle of 18 min. at 134°C minutes is required for instruments exposed to prions.

5. Steam-Flush-Pressure-Pulse Sterilizer

- ☒ Instead of creating a vacuum to remove air from chamber, a sterilizer may use a repeated sequence of steam, flush, and pressure pulses above atmospheric pressure.
- ☒ Bowie-Dick test or daily air-removal test is not required for this type of sterilizer.
- ☒ A variety of cycle times can be selected based on nature of items to be sterilized.
- ☒ Advantage: is sterilization is not affected in event of air leak into sterilization chamber.

b. Immediate-Use Steam Sterilization (IUSS)

- ☒ IUSS has replaced the term flash sterilization ⇒ quick way to sterilize unwrapped item.
- ☒ IUSS is appropriate only ⇒ for processing item needed urgently. IUSS used to sterilize ⇒ one-of-a-kind item ⇒ contaminated during surgery & essential to complete procedure
- ☒ IUSS not used for routine sterilization & never intended to sterilize whole sets instruments.
- ☒ IUSS used only in carefully selected, urgent situations & not used in implantable devices.
- ☒ According to CDC, IUSS is not intended to be used for convenience.
- ☒ Cleaning is absolutely critical to proper instrument processing.
- ☒ An item intended for IUSS must be cleaned in same manner that it would be cleaned in SPD.

- ☒ Items subject to IUSS should be ***sterilized in containers specifically validated for IUSS***.
- ☒ These containers facilitate aseptic delivery of the item to personnel at the sterile field.
- ☒ There are ***new rigid containers designed*** that allow for item stored for short period of time.
- ☒ IUSS may be done in a gravity-displacement or a dynamic air-removal sterilizer.
- ☒ Exposure times vary by more than 30 minutes & are **determined by** factors as nature and configuration of item, type of sterilizer, & whether dedicated container is available. For example, at 134°C, a 3-minute exposure is appropriate in both a gravity-displacement and a prevacuum sterilizer for most metal or nonporous or nonlumened items only.
- ☒ For **metal items with a lumen** 10-minute cycle in gravity displacement sterilizer is required.
- ☒ In a **prevacuum sterilizer**, **metal items** with lumen might require only 4 minutes.
- ☒ If a dedicated IUSS container system is used, exposure time & temperatures may vary.
- ☒ It is critical that sterilizer, container & device manufacturer guidelines be followed.
- ☒ With an IUSS cycle, items may be wet or moist at the end of the process.
- ☒ When a device manufacturer does not provide instructions for IUSS, should not be sterilized in this manner. **Perioperative nurses** always refer to manufacturer's IFU.
- ☒ If IFU are not available within OT, **nurse should consult** with personnel from SPD.
- ☒ In the absence of instructions, IUSS should not be used to sterilize the item.
- ☒ Refer to most recent manufacturer's IFU ⇒ instructions for sterilization continue to evolve.
- ☒ **Disadvantage** of IUSS is that, **aseptic transfer may be challenging**.
- ☒ Sterilizers are often located at a distance from OT, ↑ **risk of contamination during transport**.
- ☒ Using special containers designed for IUSS ⇒ reduces risk of contamination during transfer.
- ☒ Ideally, a sterilizer used for IUSS would open directly into OT.

c. Low-Temperature Sterilization Technologies

1. Hydrogen Peroxide Plasma

- ☒ **Plasma** is a state of matter produced through action of strong electric or magnetic field.
- ☒ In **low-temperature** hydrogen peroxide plasma sterilization, a plasma state is created by action of radiofrequency or electrical energy on hydrogen peroxide vapor within vacuum (F16)



Fig.16 Hydrogen peroxide plasma sterilizer – Sterrad 100NX.

- ☒ **Items to be sterilized** are ⇒ placed in sterilizing chamber, vacuum is established, & liquid hydrogen peroxide is injected into a cap & enters chamber in vaporized or gas form.
- ☒ Hydrogen peroxide vapor is effective in killing microorganisms.
- ☒ The hydrogen peroxide gas is charged with radiofrequency energy that **creates plasma**.
- ☒ Levels of residual hydrogen peroxide are removed, & at end of cycle reactive species recombine to form O₂ & water vapor. Water vapor is in form of humidity & cannot be felt.
- ☒ Monitoring includes a special chemical indicator designed to change color in presence of H₂O₂ & a biological indicator containing spore Geobacillus stearothermophilus.
- ☒ **Packages** are dry at end of cycle & may be used immediately or stored for future use.
- ☒ **Advantages of low-temperature hydrogen peroxide gas plasma sterilization** include:

- Offers **efficient alternative** to *EtO*, ***no toxic chemicals & no aeration required***.
- Sterilization short (***30 minutes to > 1 hour*** depending up sterilizer model).
- The sterilant is ***compatible with most metals and plastics***.
- Sterilizer is simple. ***Cycle times are preset & temperature does not require adjustment***
- There is ***no plumbing, no drain, nor other fixed requirements***.
- ☒ **Disadvantages of low-temperature hydrogen peroxide gas plasma** include:
 - Hydrogen peroxide gas plasma is ***not compatible with powders, liquids, textiles, and other cellulose-containing items*** such as ***linen, gauze, and paper***.
 - **Packaging materials** are ***limited to nonwoven polypropylene wraps, Tyvek and Mylar pouches & specific container systems***.
 - In some **hydrogen peroxide gas plasma** sterilizer models, ***lumen restrictions*** may ***prevent long, narrow-lumened devices***, as ***ureteroscopes*** from being processed by this method.

2. Vapor-Phase Hydrogen Peroxide

- ☒ H_2O_2 is added to **sterilization** through ***vaporizer under low pressure*** $\Rightarrow$ creating vapor.
- ☒ As the H_2O_2 **diffuses & contacts surfaces** $\Rightarrow$ oxidative process ***inactivates*** microorganisms
- ☒ **Byproducts** of process $\Rightarrow$ O_2 & ***water vapor*** in the form of ***humidity*** no aeration is required.
- ☒ **Programmed cycles** address specific parameters for ***sterilizing instruments*** of different types: ***instruments with & without lumens & instruments with diffusion-restricted spaces*** (e.g., ***hinges, ratchets, box locks***) & ***single- or dual channel flexible endoscopes*** or other features.
- ☒ For **vapor & plasma H_2O_2** , all items $\Rightarrow$ ***clean, rinsed & dried*** before ***packaged & loaded***.
- ☒ Items $\Rightarrow$ arranged in a ***single layer, minimal overlap*** $\Rightarrow$ to ensure ***diffusion of sterilant vapor***.
- ☒ **Cycle phases include:**
 1. **Conditioning:** ***Sterilant fills reservoir & vacuum pulse removes air & moisture*** from chamber, ***filtered dry air*** $\Rightarrow$ introduced & load is tested electronically for ***moisture content***.
 2. **Sterilization:** ***4 pulses*** $\Rightarrow$ ***vacuum & introduces sterilant vapor & filtered air*** into chamber
 3. **Aeration:** ***sterilant vapor*** $\Rightarrow$ ***evacuated from chamber***. When complete $\Rightarrow$ ***chamber pressure*** is brought to atmospheric level & ***chamber door unlocks***.
- ☒ **Monitoring includes:** ***chemical indicator*** $\Rightarrow$ ***change color*** in presence of H_2O_2 & ***biological*** $\Rightarrow$ ***indicator*** containing ***spore Geobacillus stearothermophilus***.
- ☒ **Advantages** of low-temperature hydrogen peroxide vapor sterilization include:
 - ✓ Vaporized H_2O_2 $\Rightarrow$ ***alternative to EtO***; ***no toxic byproducts, only H_2O vapor & O_2***
 - ✓ **The sterilant** is $\Rightarrow$ ***compatible*** with ***most metals & plastics, glass & silicone***.
 - ✓ **Simple to operate:** $\Rightarrow$ ***Cycle times are preset & temperature does not require adjustment***.
 - ✓ There is ***no plumbing, no drain, nor other fixed requirements***.
- ☒ **Disadvantages** of vaporized hydrogen peroxide include:
 - ✓ It is ***not compatible*** with ***liquids, linens, powders, & cellulose*** (as ***linen, gauze & paper***).
 - ✓ **Packaging materials:** $\Rightarrow$ limited to ***nonwoven polypropylene, Tyvek & Mylar pouches, or specific container systems***.

3. Ethylene Oxide Gas (EtO)

- ☒ EtO is a **toxic gas** $\Rightarrow$ used to sterilize ***items that cannot tolerate temperature & moisture***. EtO achieves sterilization by **interfering** with ***protein metabolism & cell reproduction***.
- ☒ EtO as a **human carcinogen** $\Rightarrow$ sterilizers housed in location (***closely monitored & vented***)
- ☒ OSHA requires ***specific training, PPE, exposure monitoring & warning signs***.

- ☒ Exposure to EtO can cause⇒ eye irritation, nausea, dizziness, vomiting, nasal & throat irritation, shortness of breath, tissue burns, & hemolysis.
- ☒ Insufficiently aerated items ⇒ may cause *patient* or *personnel injury* (OSHA, 2012b).
- ☒ Safety issues & longer aeration time⇒ most healthcare reduced or eliminated use of EtO
- ☒ Items must be ⇒ thoroughly aerated following sterilization to remove vestiges of chemical from packaging & sterile items.

4. Liquid Chemical Sterilant Processing System

- ☒ Peracetic acid is acetic acid (vinegar خل) plus hydrogen peroxide ⇒ provides *extra O₂ atom*. Peracetic acid ⇒ disrupts protein bonds & extra O₂ atom ⇒ inactivates cell systems & causes immediate cell death.
- ☒ Liquid peracetic acid is a low-temperature, nonterminal process ⇒ can be used to *prepare reusable heat-sensitive devices* as endoscopes & their accessories.
- ☒ Processed Items ⇒ placed in dedicated container ⇒ then placed into tabletop unit (Fig.17). *Sterilant circulates* through container & tray, contacting all surfaces of items. Items are then rinsed with filtered & UV-treated water.
- ☒ Items with internal lumens ⇒ connected to irrigator adapters to ensure sterilant contact within lumens. It is important to ensure that devices with lumens are fitted with appropriate irrigator adaptors prior to processing.



Fig.17 Steris Liquid Chemical Sterilant Processing System 1E.

- ☒ Both **manufacturer of device** & chemical sterilant manufacturer's IFU **should be consulted**.
- ☒ **Contact time** is ⇒ **6 minutes** at (45.5-60°C). A rinse period ⇒ depends on *water temperature* & *fill time*. An entire cycle takes ⇒ less than 30 minutes.
- ☒ Circulating nurse opens lid, retrieves tray, transports it to OT & opens it. The sterile scrub person removes items (which are wet) from tray & places them on sterile field.
- ☒ Processed items must be ⇒ used immediately; they cannot be packaged & stored.
- ☒ The system uses **microprocessors** to ensure that ⇒ required parameters are met.
- ☒ **Monitoring** includes: chemical indicator designed to change color in presence of peracetic acid. **Biological monitoring**⇒ spore strip containing *Geobacillus stearothermophilus*.
- ☒ **Advantages** of liquid chemical peracetic acid processing include:
 - The cycle is *less than 30 minutes* and offers *quick turnaround time*.
 - It is combined with anticorrosive & buffering agents ⇒ *prevent corrosion* of *instruments* & render sterilant nontoxic to *personnel* & *environment*.
 - **Compatible** with many materials ⇒ that cannot *withstand* high-temperature sterilization
- ☒ **Disadvantages** of liquid chemical peracetic acid processing include:
 - *Size of tray* ⇒ does *not permit large loads*. Only *one flexible scope* be processed at a time.
 - Only *immersible items* that fit within *dedicated tray* may be processed.
 - Items are *wet at the end of cycle*.
 - Processed items ⇒ must be *used immediately*.

5. Vaporized Hydrogen Peroxide and Ozone

- ☒ Combined *vaporized hydrogen peroxide & ozone sterilization* recently introduced to market. Ozone is an emerging *low-temperature technology*.
- ☒ Manufacturer's IFU should be consulted to determine appropriate application of technology.

VI. Sterilization Monitoring: Quality Control

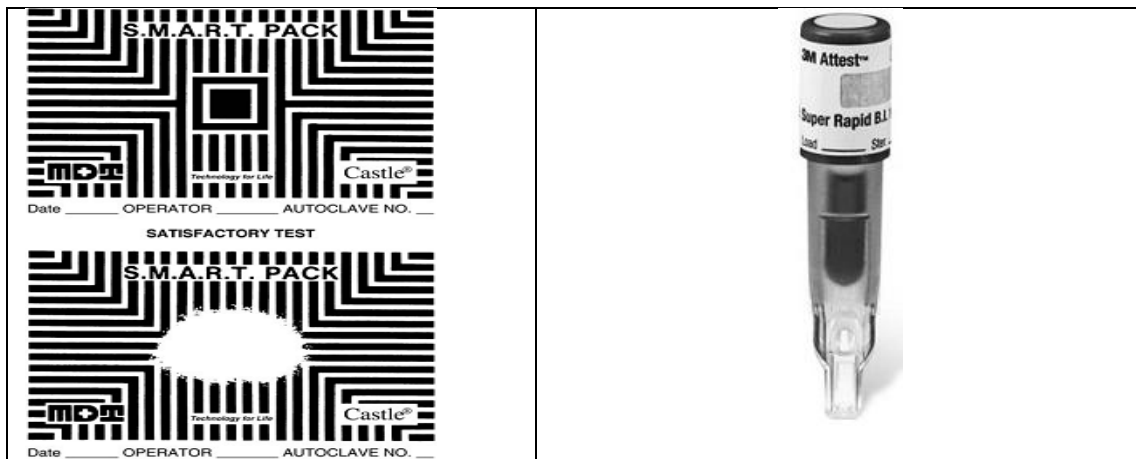
- ☒ **Assumption of sterility** is based on the following:
 - **Chemical & mechanical** indicators ⇒ insure that *all of required parameters of met.*
 - **Biological** indicators ⇒ provide proof that *microorganisms are destroyed.*
- ☒ Depending upon where sterilizer monitoring is done, the circulating nurse, the scrub person, and SPD personnel all share responsibility for checking these monitors.

A. Physical Monitors

- ☒ **Physical monitors** include ⇒ *temperature* & *pressure recorders*, *digital printouts* & *gauges* that *record activities within the chamber* during *sterilization cycle*.
- ☒ **Digital printout record** ⇒ correlates *exact times*, *temperatures* & *pressures* achieved during *conditioning*, *exposure* & *exhaust phases* of *sterilization cycle*. The *operator* who *opens* sterilizer at end of load *should verify* that *cycle was complete* & *correct*. Printout includes *space for operator to initial* & *include load identification* (Fig-18).
- ☒ **Gauges on autoclave** ⇒ *register* *pressure* & *temperature* within *jacket & chamber*. Gauges on EtO sterilizer may *register* *temperature*, *gas concentration*, & *humidity*.
- ☒ With **liquid peracetic acid** ⇒ *diagnostic cycle* is run to *check electricity supply*, *filters*, *temperature*, *pressure*, & *system integrity* at beginning of day & printout of results is filed.
A microprocessor system ⇒ will *abort cycle if parameters are not met*.

B. Chemical Indicators

- ☒ A Class 2 chemical indicator, **BowieDick** or **daily air-removal test (DART)**, is run each day before first processed load to *demonstrate air eliminated* from chamber of each dynamic air-removal autoclave effectively enough *to achieve steam penetration of standard load*.
- ☒ Class 2 indicator **contains** ⇒ *commercially prepared sheet of paper* with various patterns of *heat-sensitive ink* that is *contained in a commercially prepared package* or placed in a *specially constructed pack of towels*. The **Bowie-Dick** or **DART** ⇒ is *placed over drain* in an otherwise *empty autoclave*.
- ☒ Following cycle, *uniform color change* ⇒ *indicates successful air-removal process* (Fig-19).



C. Biological Monitors (B.M.)

- ☒ **Biological monitoring** ⇒ determines whether or not microorganisms destroyed & it is, the most accurate method of ensuring that conditions necessary for sterilization achieved.
- ☒ **Biological indicators (BI)** ⇒ capsules contain known, living & highly resistant spore population; spore strips; & ampoules with spores suspended in culture medium (Fig.20+21).
- ☒ ***Geobacillus stearothermophilus* spores** ⇒ used to test steam autoclaves & H₂O₂ sterilizers. Ethylene oxide sterilizers are ⇒ tested with *Bacillus atrophaeus* spores.
- ☒ **Both types of spores** are ⇒ highly resistant nonpathogenic microorganisms.
- ☒ A BI should be run ⇒ in steam sterilizer at least weekly & every day that sterilizer is in use
- ☒ It is run ⇒ in every sterilizer load containing implant (نسيج مزروع). BI is run with each load.
- ☒ Implants not released for implantation until ⇒ results of (B.M.) negative for growth.
- ☒ **EtO sterilizers** ⇒ should be tested with every load (AORN, 2015, p. 674).
- ☒ **Hydrogen peroxide sterilizers** ⇒ should be tested daily & preferably with every load.
- ☒ To routinely test ⇒ one or two strips, ampoules, or capsules containing spores are placed at specific location within chamber (by manufacturers' IFU) & sterilizer cycle is run.
- ☒ For cycles of **terminal sterilization** ⇒ BM should be contained within process challenge device (PCD). PCD represents a defined challenge to sterilization process. Most PCDs used are commercially prepared, but PCD may be assembled by user. Commercially prepared PCDs are equivalent in performance to an AAMI BI test pack (Fig.13)
- ☒ For **IUSS cycles** ⇒ biological monitor is placed directly in tray/container to be used, because the tray/container is considered to be the PCD.
- ☒ **Rapid-readout BIs** whose growth is visible in 3 hours, 1 hour, or 30 minutes, have replaced traditional BI that took 24-48 hours before bacterial growth was visible (Fig-22)
- ☒ It is essential to select biological monitor specific to each sterilizer technology & cycle.
- ☒ The **traditional biological indicator** must be incubated before results can be read.
 - ✓ Before BI is placed in incubator ⇒ it is crushed to expose spores to growth medium in capsule
 - ✓ A control BI ⇒ must be incubated at same time.
 - ✓ Microorganisms in control BI ⇒ are alive & will grow when exposed to growth medium.
 - ✓ As bacteria grow ⇒ medium exhibits distinct color change.
 - ✓ Microorganisms in BI from sterilizer should be destroyed & therefore will not grow when exposed to growth medium & no color change will occur.
 - ✓ At the end of incubation period ⇒ distinct difference in color between control & test BI ⇒ indicates "negative BI" & successful sterilization.
- ☒ **Rapid-readout BIs** must also be incubated.
 - ✓ They detect *Geobacillus stearothermophilus* by ⇒ recognizing activity of alpha-glucosidase, enzyme present within organism.
 - ✓ The **presence of enzyme** is detected by ⇒ reading fluorescence produced by enzymatic breakdown of a nonfluorescent substrate.
 - ✓ This creates a **fluorescence change**, which is detected by auto-reader.
 - ✓ A **fluorescence change** indicates ⇒ a steam sterilization process failure.
- ☒ **Positive BI reading** ⇒ (demonstrating bacterial growth) indicates ⇒ sterilizing failure
- ☒ A **positive BI** should be ⇒ reported immediately to appropriate supervisor.



Fig-21 Biological indicator spore strips - dual (steam, EtO, dry heat, and chemical vapor):

A) Hospitals sometimes send spore strips to an outside validation lab for third party verification;
 B) Clinics & office-based surgery often use a biological indicator mailing system.



Fig-22 Rapid readout biological indicator incubation system (A) Incubator and (B) The +sign in well #1 indicates growth (the spores in the ampoule have not been killed); the -sign in well #2 indicates that there has been no growth after incubation for the required time (the spores in the ampoule have been killed); the 11, 23, and 27 in wells #3, 4, and 5 indicate the number of minutes left before incubation time is reached. At the end of that time, the numbers will be replaced by a + or a - sign.

- ☒ With **rapid-readout BIs**, time is short ⇒ items not used for patient care.
- ☒ **Sterilizer malfunction**, a **positive reading** indicate ⇒ incorrect packaging, an incorrect cycle, items incompatible with process, or incorrect placement of items within sterilizer.
- ☒ When **cause of sterilizer failure identified** ⇒ **corrective action is taken** & **load is reprocessed**
- ☒ When **cause of failure is unknown** ⇒ all items from failed load must **recalled** (يلغى).

VII. Sterilization: Documentation

- ☒ The following records for **each sterilizer** ⇒ filed daily & kept as permanent record (Fig-23):
 - Results of **Bowie-Dick/DART**
 - Results of **biological monitoring**
 - For **each sterilizer load**:
 - ✓ **List of all contents** of the load
 - ✓ **Load lot control sticker** (sterilizer No & load, date) Chemical monitor included in load
 - ✓ Biological monitor results if implant included in load
 - ✓ **Sterilizer printout**, initialed by operator for verification (if one person puts in a load & another removes it, **both persons** should initial document)
 - **Sterilizer failure results** (if applicable)
- ☒ IUSS records should be **fully traceable** (تتبعه) to patient on whom **sterilized item was used**.

VIII. Disinfection

- ☒ It is process that **destroys pathogenic microorganisms** using liquid chemical germicide.
- ☒ They destroy vegetative forms of harmful microorganisms, disinfectants kill some spores.

- ☒ Liquid chemical disinfectants used to ⇒ destroy pathogens on inanimate objects such as walls, tables, small equipment, & surgical instruments.
- ☒ Disinfectants suitable for housekeeping purposes ⇒ cleaning walls & surfaces are **not** suitable for disinfection of surgical instruments.
- ☒ Examples of disinfectants include:

○ Alcohol	○ Glutaraldehyde	○ Formaldehyde	○ Chlorine compounds
○ Chlorine	○ Hydrogen peroxide	○ Iodophors	○ Ortho-phthalaldehyde
○ Phenolics	○ Quaternary ammonium compounds		

- ☒ Disinfectants ability to destroy microorganisms as high level, intermediate level & low level.
- ☒ Factors that influence the efficacy of a disinfectant include

✓ <u>Type of chemical</u> ,	✓ <u>Concentration & temperature of chemical</u> ,
✓ Adequacy of <u>prior cleaning</u>	✓ <u>Amount & types of microorganisms</u> ,
✓ <u>Exposure time</u> .	✓ <u>Configuration of item</u> to be disinfected,

- ☒ **High-level disinfectants (HLD)** ⇒ kill all microorganisms ⇒ vegetative bacteria forms, tubercle bacilli, viruses & fungi. They do not kill large numbers of spores, although some high-level disinfectants can achieve sterilization after prolonged exposure of 8 hours or more.
- ☒ **Intermediate & low level disinfectants** ⇒ used on environmental surfaces only
- ☒ **Intermediate-level** ⇒ inactivate most vegetative bacteria, Tb, fungi & viruses, but not spores
- ☒ **Low-level** ⇒ kill most vegetative bacteria, some fungi & some viruses; do not kill Tb.
- ☒ For **instrument disinfection** ⇒ only high-level disinfection is appropriate.
- ☒ **Frequently used HLD** ⇒ 2%-3.2% alkaline glutaraldehyde or 0.55% ortho-phthalaldehyde.
- ☒ **Following exposure**, device thoroughly rinsed in sterile water. It is important to refer to the manufacturer's IFU, because some disinfectant products require as many as 3 separate rinses.
- ☒ **To avoid dilution** ⇒ all items thoroughly cleaned, rinsed & dried prior to immersion.

A. Glutaraldehyde

- ☒ Glutaraldehyde is **commonly used high level disinfectant achieved in minutes**, although **exact number of minutes** varies with concentration & temperature of solution. **Manufacturer's IFU & institutional policy** ⇒ describe **exact required immersion time**.
- ☒ It is **irritating to mucous membranes & can irritate skin, eyes, throat, & nasal passages**.
 - ✓ It should be mixed in a well-ventilated room with a minimum of 10 air exchanges /hour.
 - ✓ **Local exhaust ventilation** at level of point of discharge is preferred to prevent vapor escap
 - ✓ **Self-contained workstations** with fume hood should installed where glutaraldehyde used.
 - ✓ Glutaraldehyde should always be stored in a closed container.
- ☒ **Protective eyewear, nitrile gloves or double latex gloves, mask, & repellent gown** should be worn during use of glutaraldehyde. **Exposure varies with activity. Mixing & discarding solution & immersing & retrieving items** from solution **poses greatest risk of exposure**.
- ☒ **Glutaraldehyde** must be mixed & used strictly according to manufacturer's IFU & standards of practice. **Information** regarding mixing instructions, temperature, use, immersion time, toxicity, and length of effectiveness can be ⇒ **found on product's label**.
- ☒ The current **OSHA ceiling** ⇒ threshold limit value for exposure to glutaraldehyde is 0.5 part glutaraldehyde - 1 million parts air during any part of work day. **Monitoring** of work area & employee exposure is not required by OSHA; however, **monitoring should be employed** when high levels of exposure are suspected (OSHA, 2015).
- ☒ **Heated Glutaraldehyde** ⇒ will achieve microbial killing faster. When **glutaraldehyde** is heated, **vapor pressure** is **raised**, which in turn ↑ amount of vapor released into air.

B. Ortho-phthalaldehyde

- ☒ Ortho-phthalaldehyde (OPA) is a ***nonglutaraldehyde disinfectant*** used in ***OT*** & ***endoscopy*** suites. Because it ***achieves disinfection faster than glutaraldehyde*** & does not release any ***irritating odors***, ***OPA has replaced glutaraldehyde*** in many facilities.
- ☒ OPA is ***rarely irritating to staff***. Although there are no ***OSHA requirements*** & ***no monitoring requirements for OPA***, high-level disinfectant monitoring systems are available.
- ☒ OPA will ***stain protein*** & items that are ***not thoroughly cleaned*** & ***rinsed prior to immersion***. It will ***stain gray in spots*** where there are protein residuals.

C. Quality Control

- ☒ Disinfectant solutions have ***expiration date*** that ***represents length of anticipated effectiveness***, as indicated on label. Date of mixing & expiration date indicated on container.
- ☒ Some disinfectant instructions for use call for a ***specific quality control test prior to use*** to ensure that the required effective concentration is present. In addition ***concentration testing*** should be conducted ***before use***. A disinfectant can lose its minimum effective concentration (MEC) before the expiration date. The ***frequent use*** & any ***dilution*** that occurs when items are washed, rinsed & not dried before immersion can all affect MEC & cause a solution to fail.
- ☒ ***Never rely entirely on label for proof of expiration of solution***. MEC of disinfectant solutions should be ***monitored before each use*** with ***indicators designed*** that are ***dipped into solution*** & then ***observed for appropriate color change*** as indicated on label.
- ☒ Chemical properties and appropriate hazard warnings should be posted.

D. Documentation

- ☒ When ***liquid chemical germicides*** are used for ***high-level disinfection***, document:
 - Results of ***quality control testing*** ⇒ performed ***according to manufacturer's*** instructions
 - ***Results of testing for minimum effective concentration***
 - ***Date solution is mixed/activated/opened/prepared***
 - ***Expiration date***—should be ***visible*** on the container
 - ***Person responsible for mixing***
 - ***Item disinfected***
 - ***Patient for whom the disinfected item was used***

IX. Reuse of Single-Use Devices

- ☒ Under current FDA (2000) regulations, ***any hospital that chooses to reprocess single-use Class 3 devices*** (devices that carry a significant risk in event of failure) that have been opened and used ***will be held to the same standard*** as the ***original manufacturer of that item***. The ***requirements for original manufacturer*** are ***extremely stringent*** and ***virtually impossible*** for a hospital to replicate.
- ☒ The perioperative nurse in the OT ***should never attempt to reprocess a single-use device***. When a question arises about whether a single-use device will be reprocessed, a group including ***infection preventionists*** and ***risk management*** should refer to FDA's (2000) "Guidance Document: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" ***to determine the facility policy***.

X. Storage of Sterile Items

- ☒ Sterilized items should be stored in a well ventilated, limited-access area, with controlled temperature & humidity, at least 4 air exchanges /hour, & that is clean & dust free.
- ☒ To reduce dust accumulation ⇒ wire mesh shelving is preferable to closed shelving.
- ☒ Cabinets and shelves should permit ⇒ adequate cleaning & air circulation.
- ☒ Closed cabinets are ⇒ best for items that are used infrequently.
- ☒ Storage cabinets and shelves should be ⇒ far enough away from floors, ceiling fixtures, vents, sprinklers & lights to prevent contamination. Shelves should be ⇒ 18 inches below ceiling or sprinkler head, 2 inches from outside walls & 8-10 inches above floor.
- ☒ Sterile items ⇒ stored separately from clean items. Sterile on uppermost & clean on lower.
- ☒ Sterile items ⇒ should not be stored under or next to sinks or areas where might become wet.
- ☒ Wrapped packages should not be ⇒ bent, crushed, crammed, or stacked.

Shelf Life (العمر الافتراضي للتعقيم)

- ☒ Shelf life is amount of time following sterilization that an item may be considered sterile.
- ☒ Event-related sterility: if an item is not contaminated during transport & storage, it will remain sterile indefinitely. Shelf life is related to ⇒ events occur that cause contamination.
- ☒ Proper packaging, handling & storage can ⇒ prevent contamination. Poor quality wrappers, poor storage conditions & improper handling of sterile items ↑ potential for contamination.
- ☒ Before any package is opened for surgery, it must be visually inspected to determine if package is compromised. Stains, pinholes & tears are examples of potential contamination.
- ☒ Shelf life is determined by many factors:
 - Type and configuration of packaging material: Items packaged in rigid container systems may have a longer shelf life than items packaged with woven and nonwoven materials.
 - Use of dust covers: Plastic pouches designed to prolong shelf life of sterilized items.
 - Conditions of storage: Dust, temperature, humidity & traffic can affect shelf life.
 - Number of times package is handled: more handling ⇒ greater risk for contamination
- ☒ Expiration dates on commercially prepared items ⇒ indicate integrity of device or material will be compromised after indicated date & item should not be used if this date reached.

Competency Checklist: Instrument Processing

Under “Observer’s Initials,” enter initials upon successful achievement of competency. Enter N/A if competency is not appropriate for institution.

Name	Observer's Initials	Date
Point of Use 1. Items are rinsed/wiped/irrigated during the procedure. 2. Disposable sharps and trash are discarded appropriately. 3. All instruments are returned to proper sets for return to SPD. 4. Enzymatic soak solution, spray, or gel is applied before transport to the decontamination area. 5. Contaminated instruments are contained during transportation to the decontamination area.		
Cleaning 6. Personal protective equipment is worn during cleaning. 7. Items requiring cleaning by hand are separated from those going to the washer/disinfector. 8. Manual cleaning: a. Detergent is prepared according to IFU. b. Spray nozzle is held close to instruments in sink to avoid splashing. c. Manual cleaning is performed under the surface of the water to avoid aerosolization. d. Proper approach is selected for decontamination of equipment according to IFU. 9. Washer/disinfector is properly used. a. Appropriate items are selected for washer/disinfector. b. Machine is loaded properly. 10. Ultrasonic cleaner is loaded properly (single layer; same type of metal). 11. Appropriate instruments are lubricated. 12. Instruments are inspected for cleanliness & good condition; all components are present.		
Packaging 13. Rigid containers are inspected and assembled appropriately: a. Caskets and inner baskets are thoroughly cleaned between uses. b. Gaskets, valves, and filters are checked prior to placement of instruments. c. Following assembly, the lock is placed and contents are identified. 14. Instrument sets are assembled properly. a. Items are placed in a tray/container compatible with the sterilization method. b. Multi-part instruments are disassembled. c. Hinged instruments are opened. d. Small, multi-part & delicate instruments are organized in appropriate containers (no peel packs). e. Heavy items are on bottom; more delicate on top. f. Items with broad surfaces are placed on edge. g. Nested items are separated with porous material and placed facing the same direction. 15. Appropriate chemical indicator(s) are in place. 16. Set is wrapped properly in packaging material appropriate to the method of sterilization. 17. Package is sealed with the appropriate process indicator. 18. Package is labeled with contents and initials.		
Sterilization 19. Appropriate method of sterilization is identified for each item. 20. Appropriate process indicator is confirmed on outside of package. 21. Load lot sticker is placed on each item in the load. 22. Chamber is loaded properly so that sterilant can contact surfaces of all items. a. Heavy trays lie flat in a single layer. b. Small wrapped packages are loosely stacked. c. Peel packs are placed on edge and all facing in the same direction. d. Basins (anything that can trap moisture) are placed on edge to promote draining. 23. Appropriate sterilization cycle is chosen. 24. Sterilizer is operated according to the manufacturer’s instructions. 25. When sterilization is complete: a. Printout/to is reviewed to insure all parameters achieved. b. Package is allowed to cool before it is removed from autoclave and distributed.		
Immediate-Use Steam Sterilization (IUSS) 26. Items are cleaned properly (IFU) before sterilization. 27. Appropriate container is selected for sterilization.		

28. Correct sterilization cycle is chosen for item.		
29. Inspection of printout:		
a. Patient information is included.		
b. Printout is signed or initialed.		
30. Sterile item is transported aseptically to sterile field.		
Sterilization Monitoring		
31. Demonstrates or verbalizes process for running a Bowie-Dick/DART sterilization monitor:		
a. Correct autoclave (dynamic air removal)		
b. Correct monitor		
c. Correct placement of monitor (IFU)		
d. No other items in autoclave during test run		
e. Documentation correct		
32. Demonstrates or verbalizes the process for running a biological monitor:		
a. Appropriate monitor		
b. Correct placement of monitor (IFU)		
c. Prepares ampoule and incubates monitor correctly		
d. Documents results correctly		
e. Verbalizes the process following a failed monitor		
33. Demonstrate or verbalizes the documentation process for each sterilizer load:		
a. Envelope for each sterilizer to contain sterilization documentation for a 24-hour period		
b. Results of Bowie-Dick testing		
c. Results of biological monitoring		
d. Documentation of each load		
✓ Sterilizer printout for each load		
✓ Load lot sticker		
✓ Load list		
✓ Chemical indicator (if run in load)		
✓ Biological indicator (if run in load)		
High-Level Disinfection		
34. Demonstrates or verbalizes the process for high-level disinfection.		
35. Appropriate items are identified for high-level disinfection.		
36. Appropriate personal protective equipment (PPE) is donned during preparation and use of disinfectant.		
37. Disinfectant is properly prepared (IFU).		
38. Minimum effective concentration (MEC) test is performed & results are documented		
39. Items are disinfected properly:		
a. Appropriately washed and dried before being disinfected		
b. Rinsed after being disinfected and before use		
c. Handled so as to prevent contamination		
40. Documentation is appropriate.		
Storage		
41. The fire safety/AAMI criteria for locating shelving in sterile storage is verbalized.		
42. Sterile items are protected from being compressed, dropped, ripped, or getting wet.		
43. Sterile items are shelved so that those sterilized first are first in line for use.		
44. Heavy sets are placed on center shelves; stacking heavy packages is avoided.		
45. Peel packs are stored in a container to protect and organize them.		
Observer's Signature	Initials	Date
Orientee's Signature		