Virtual Tour of Central Processing

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DISCLOSURES

2024

- **Consultations**
  - PDI (Professional Disposables International)
- **Honoraria**
  - PDI
- **Other**
  - Kinnos, Ideate Medical

Reprocessing Reusable Medical Devices

Learning objective-understand the key steps in the sterilization process

- Point-of-use treatment
- Preparing dirty instruments for transport
- Cleaning and decontamination
- Inspection
- Packaging
- Sterilization

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CDC Guideline for Disinfection and Sterilization

Rutala, Weber, HICPAC. November 2008. www.cdc.gov

Accessible version: https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Update: June 2024

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Medical/Surgical Devices

WA Rutala, DJ Weber, and HICPAC, www.cdc.gov

EH Spaulding believed that how an object will be disinfected depended on the object's intended use (developed 1968).

CRITICAL-medical/surgical devices which enter normally **sterile tissue** or the vascular system or through which blood flows should be **sterile**.

SEMICRITICAL-medical devices that touch **mucous membranes** or skin that is not intact require a disinfection process (**high-level disinfection** [HLD]) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL-medical devices that touch **only intact skin** require **low-level disinfection**.

Clarifying Infection Control Policy Requirements-The Joint Commission

https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/infection-prevention-and-hai/ic-hierarchical-approach-to-scoring-standards-april-2019-perspectives.pdf

- JC standards and elements of performance written to allow each HCF determine methods and best practices
- TJC finding many HCF build policies on evidence-based guidelines alone
- TJC recommends HCF apply a hierarchical method to address the IC requirements
- The following graphic illustrates the hierarchy of various references organizations should use as they draft and/or revise their IC-related policies

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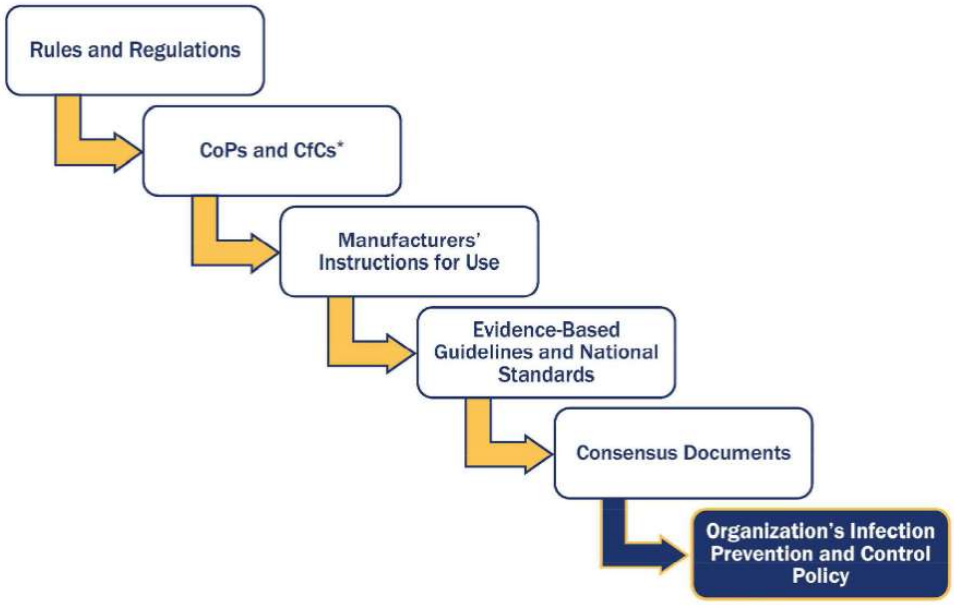
Hierarchy of Various References that Organization Needs to Include in Policies



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Clarifying IC Policy Requirements

(must comply with first three groups in illustration to comply with JC)

- Rules and regulations (e.g., BBP)
- CoPs and CfCs-CMS conditions of participation or conditions of coverage (CMS)
- Manufacturers Instructions for Use-deviation may result on biological, chemical or functional incompatibility
- Evidence-based guidelines (EBG) and National Standards. Organizations may choose to follow a variety of EBG (IDSA)
- Consensus Documents (AAMI)

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Central Processing

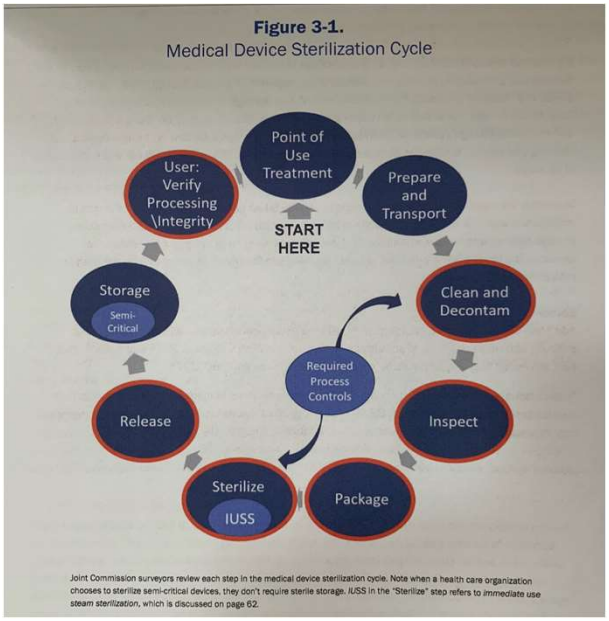
- Goal
  - Orderly processing of medical and surgical instruments to protect patients from infections while minimizing risks to staff and preserving the value of the items being reprocessed
  - Ensure consistency of sterilization practices requires a comprehensive program that ensures operator competence and proper methods of cleaning and packaging instruments, loading the sterilizer, operating the sterilizer, and monitoring the entire process

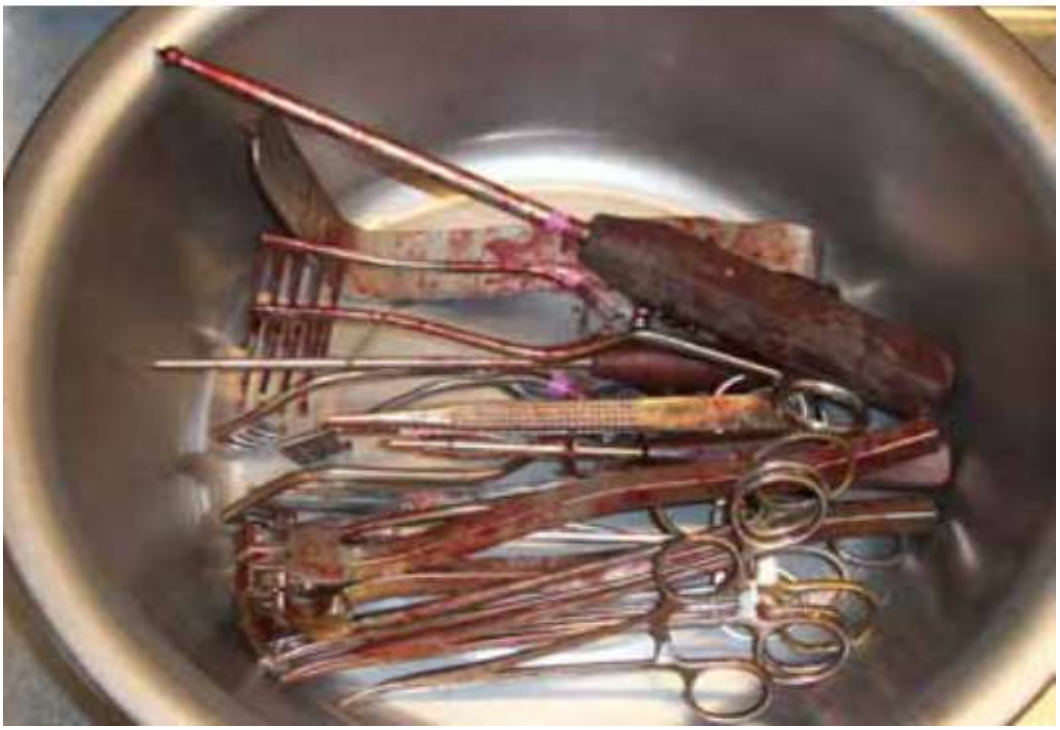
Central Processing
Physical Facilities

- Facility ideally divided into three (or four) areas:
  - Decontamination-reusable items are received, sorted, and decontaminated; negative pressure; 10AC/hr. Personnel wear gloves when handling contaminated instruments; face masks, eye protection, and gowns/aprons when splashing may occur.
  - Packaging-used for inspecting, assembling, and packaging clean, but not sterile, material.
  - Sterilization and storage-limited access area with a controlled temperature and relative humidity.

Medical Device Reprocessing Cycle

Garcia-Houchins, Olmsted. TJC Guide. 2023





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Point-of-Use

(takes place at the procedure site)

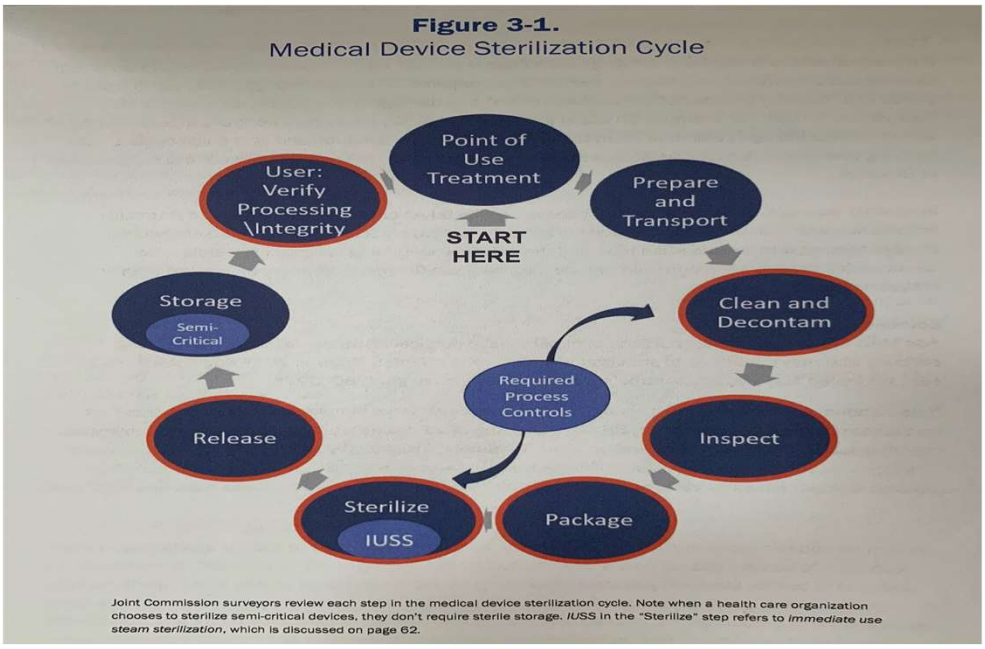
- May include (per MIFU)
  - Flushing lumens with sterile water or wiping tissue and blood from instruments during the procedure to remove gross soil
  - Placing items in transport product to prevent drying or start the breakdown of soil
  - Options for keeping used instruments and devices moist
    - Applying or soaking devices in compatible spray, gel, foam or liquid detergent
    - Placing instruments in a container or bag designed to maintain moisture
    - Covering the devices with a cloth moistened with water

Pre-Cleaning

- Surgical instruments are pre-cleaned in the OR. Ideally, instruments should arrive in Central Processing free on visible contamination
- To keep instruments wet from OR to CP, many hospitals spray instruments with an enzymatic solution
- Wipe instruments clean and keep lumens flushed throughout surgery. Soiled instruments that will not be reused should be allowed to soak in a basin of sterile water for the remainder of the procedures
- Keep instruments moist (e.g., damp towel, foam) as it prevents hardening of soil

Medical Device Reprocessing Cycle

Garcia-Houchins, Olmsted. TJC Guide. 2023



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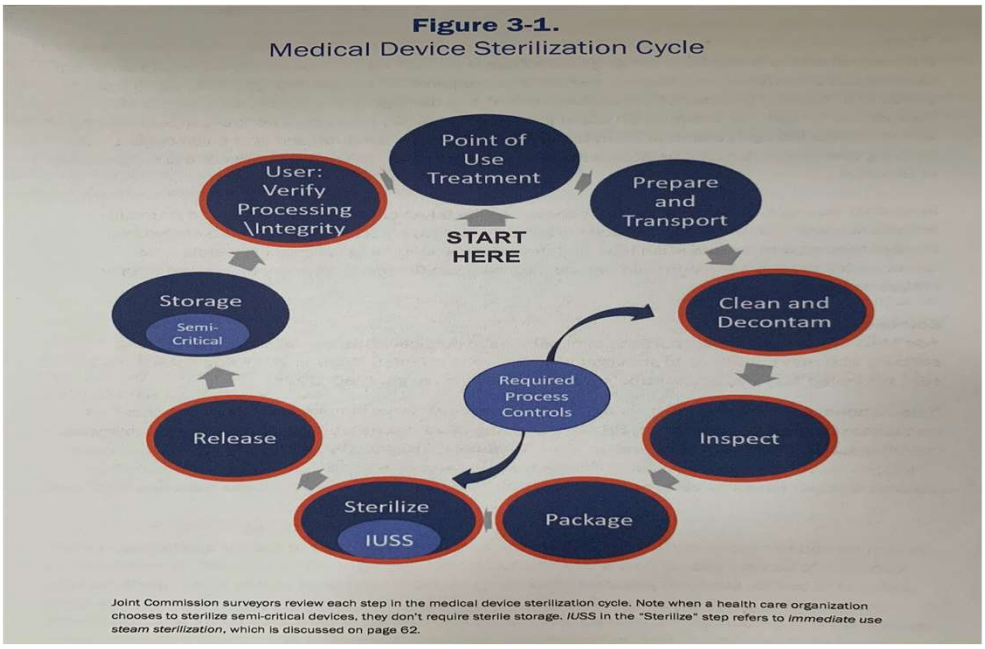
Preparing Dirty Instruments for Transport

- Consider presence of sharps, distance, route, PPE
- Transport ASAP to the decontamination area
- Additional steps may be necessary if transporting the devices off-site for reprocessing

Medical Device Reprocessing Cycle

Garcia-Houchins, Olmsted. TJC Guide. 2023



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Cleaning/Decontamination

- Cleaning is defined as the process to physically remove organic material, such as blood, secretions, excretions, and microorganisms to prepare the medical device for decontamination
- Decontamination refers to the use of physical or chemical means to remove, inactivate or destroy BBP on a surface or item so it is no longer capable of transmitting disease and rendered safe for handling. Decontamination area allows work to flow from dirty to clean, sinks, countertops, airflow, temp, RH

Disassembly

- Many medical devices may need to be disassembled before cleaning, especially those that are complex or have a number of parts
- Check the MIFU to see if the device requires disassembly.
- Some devices may require reassembly after cleaning but before sterilization; other may not.

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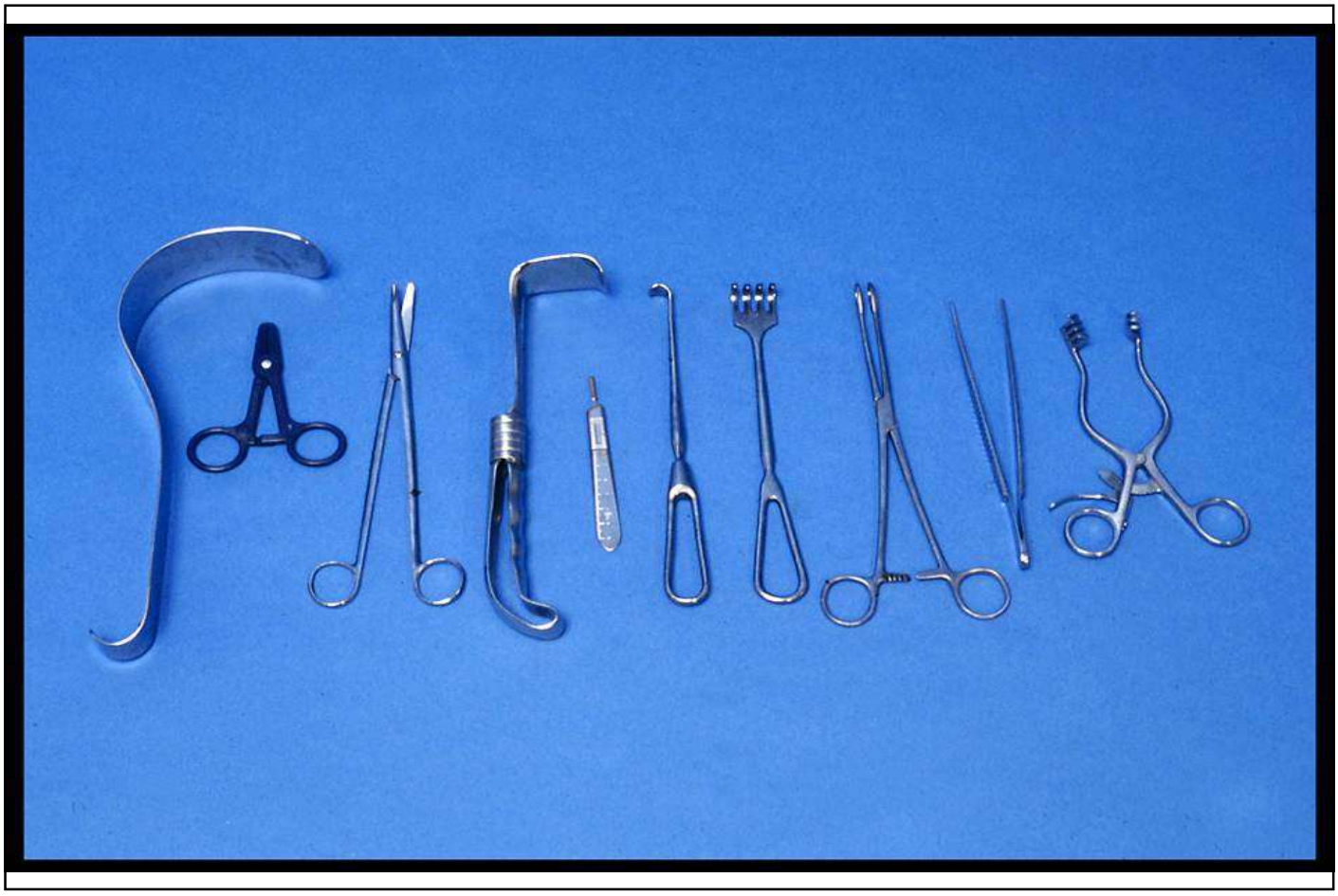
Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners before processing.
- Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process.
- Cleaning and decontamination should be done as soon as possible after the items have been used as soiled materials become dried onto the instruments.

Efficacy of Disinfection/Sterilization
Influencing Factors

- Cleaning of the object
- Organic and inorganic load present
- Type and level of microbial contamination
- Concentration of and exposure time to disinfectant/sterilant
- Nature of the object
- Temperature and relative humidity



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Bioburden on Surgical Devices

Surgical Instruments Carry a Low Microbial Load (<100 CFU, 85%)

- Bioburden on instruments used in surgery (Nystrom, J Hosp Infect 1981)
  - 62% contaminated with $<10^1$
  - 82% contaminated with $<10^2$
  - 91% contaminated with $<10^3$
- Bioburden on surgical instruments (Rutala, Am J Infect Control 1997)
  - 72% contained $<10^1$
  - 86% contained $<10^2$
- Bioburden on surgical instruments (50) submitted to CP (Rutala, AJIC 2014)
  - 58% contained <10
  - 20% contained $\leq 10^2$
  - 16% contained $\leq 5x10^2$
  - 6% contained $<10^3$

Cleaning

- Mechanical cleaning machines-automated equipment may increase productivity, improve cleaning effectiveness, and decrease worker exposure
  - Utensil washer-sanitizer
  - Ultrasonic cleaner
  - Washer sterilizer
  - Dishwasher
  - Washer disinfector
- Manual

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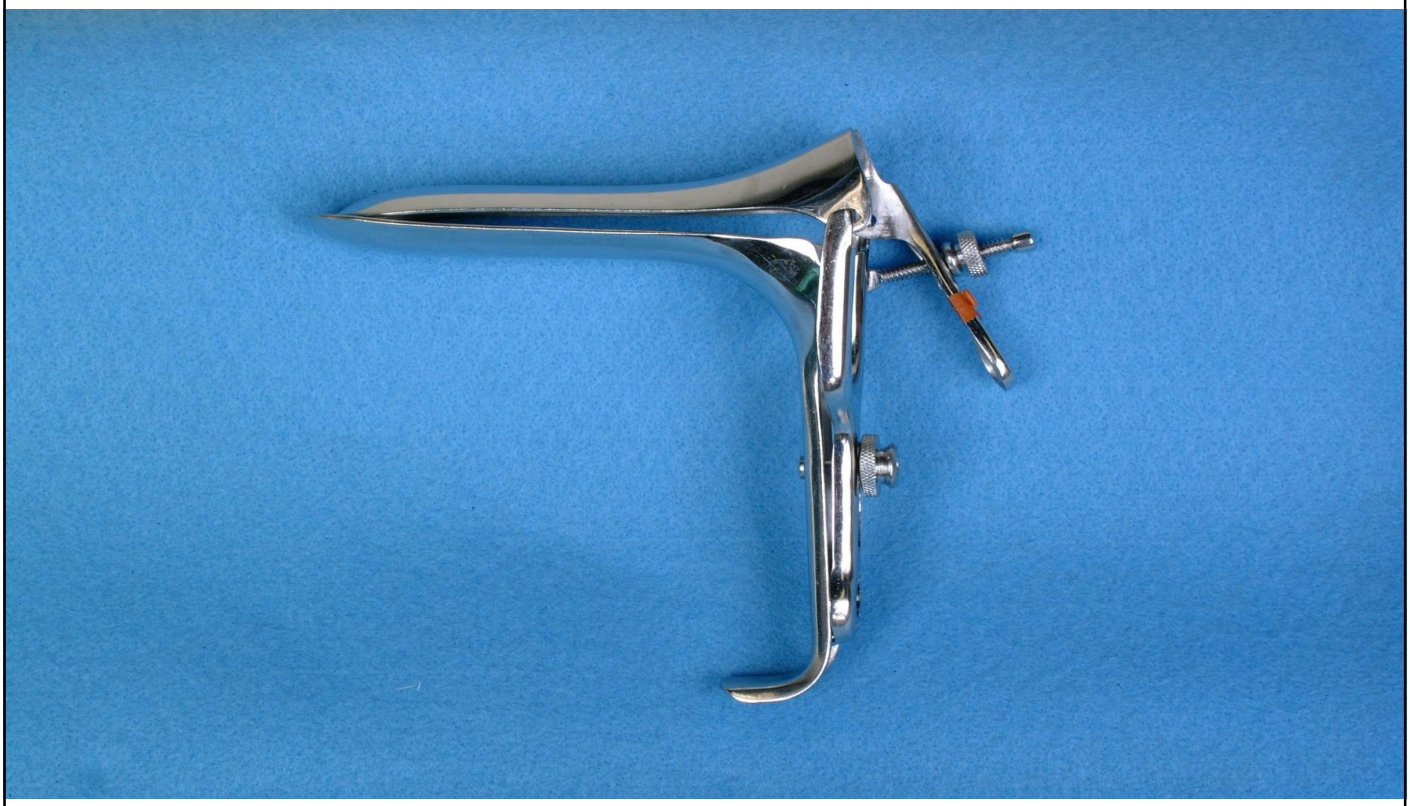
Washer-Disinfector

Rutala WA, Gergen MF, Weber DJ. ICHE 2014;35:883-885

- Five Chambers (Reliance 777 automated multichamber washer-disinfector was used). The programmed cycle included 5 phases.
  - **Pre-wash**: water/enzymatic is circulated over the load for 1 min
  - **Wash**: detergent wash solution (150°F) is sprayed over load for 4 min
  - **Ultrasonic cleaning**: basket is lowered into ultrasonic cleaning tank with detergent for 4 min
  - **Thermal and lubricant rinse**: hot water (180-200°F) is sprayed over load for 1 min; instrument milk lubricant is added to the water and is sprayed over the load
  - **Drying**: blower starts for 4 min and temperature in drying chamber at 180-240°F



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Washer-Disinfector

Physical Removal/Thermal Inactivation of Inoculum (Exposed) on Instruments

Rutala WA, Gergen MF, Weber DJ. ICHE 2014;35:883-885

WD Conditions	Organism	Inoculum	Log Reduction	Positives
Routine	MRSA	$2.6x10^7$	Complete	0/8
Routine	VRE	$2.6x10^7$	Complete	0/8
Routine	*P aeruginosa*	$2.1x10^7$	Complete	0/8
Routine	*M terrae*	$1.4x10^8$ (8.1)	7.8	2/8
Routine	GS spores	$5.3x10^6$ (6.7)	4.8	11/14
No Enz/Det	VRE	$2.5x10^7$	Complete	0/10
No Enz/Det	GS spores	$8.3x10^6$ (6.9)	5.5	8/10

Washer-disinfector was extremely effective (>7-$\log_{10}$ reduction) in eliminating contamination with both exposed and nonexposed test bacteria (MRSA, VRE, *P. aeruginosa* and *M. terrae*)

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Verifying Cleaning Processes

- AAMI recommends incorporating test methods that verify the functionality of the automated washer
- Washer indicators have been in use in Europe and Canada and some US hospitals
- Washer indicators are chemical indicators imprinted with a dried test soil formula and a dye.

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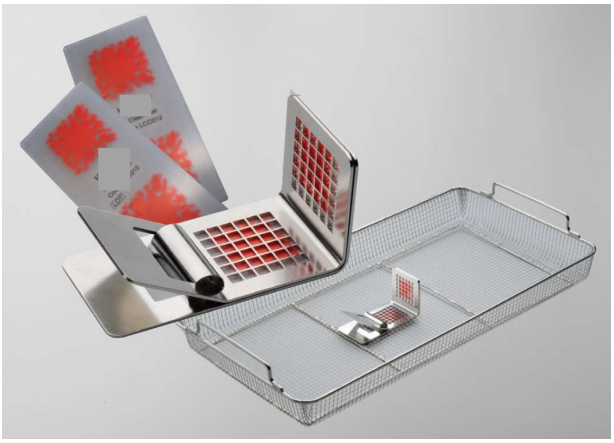
Cleaning Indicators for Washer-Disinfectors

- Verify cleaning process
- Monitor the automated washer and instrument cleaning chemistry functionality at least weekly (preferably daily)
- Complete soil removal of the dried test soil pattern is a “pass”
- Indicator includes proteins, lipids, and polysaccharides to mimic common challenging test soils



IS THERE A STANDARD TO DEFINE WHEN A DEVICE IS CLEAN?

- There is currently no standard to define when a device is “clean”, cleanliness controlled by visual
- Potential methods: level of detectable bacteria; protein (6µg/cm^2) based on Bradford’s reagent or ninhydrin; endotoxin; ATP; lipid; carbohydrate; hemoglobin
- This is due in part to the fact that no universally accepted test soils to evaluate cleaning efficiency and no standard procedure for measuring cleaning efficiency
- At a minimum, a cleaning process should: reduce the natural bioburden; remove organic/inorganic contaminants; provide devices that when sterilized have a SAL 10^{-6}

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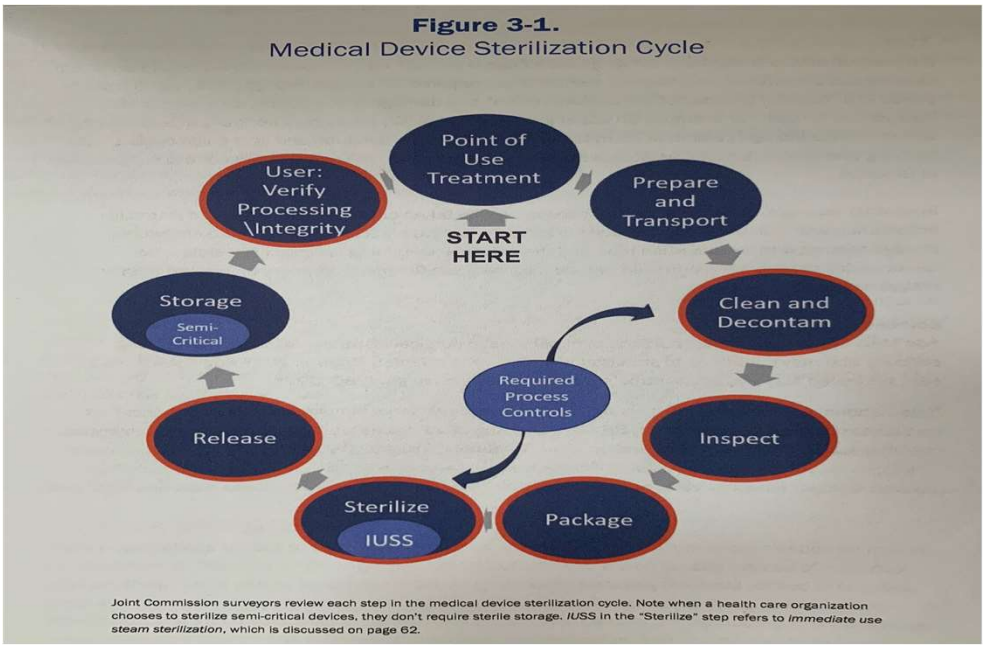
Cleaning Verification Tests

AAMI Summit September 2023

- No cleaning verification products cleared by FDA
- Tests criteria-easy-to-perform (e.g., go-no go color change), rapid, sensitive, accurate, robust, relevant, not damaging
- Options:
  - Protein <6.4µg/cm^2
  - Carbohydrate <1.8µg/cm^2
  - Hemoglobin <2.2µg/cm^2

Medical Decice Reprocessing Cycle

Garcia-Houchins, Olmsted. TJC Guide. 2023



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Inspection

- The identification and naming of defects on surgical instruments is not consistent among healthcare providers
- This can lead to varied assessment on when an instrument or tray is safe for use
- A multi-disciplinary group from surgical services, OR, infection control should create a uniform instrument defect glossary
- A specialty group should identify representative defects (if present) and what subsequent actions would be with regards to the instrument and the tray if the defect were seen in the OR

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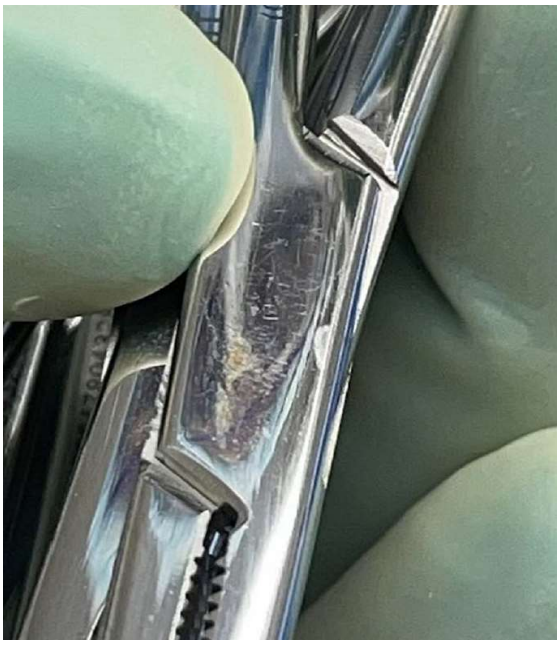
This instrument has rust.



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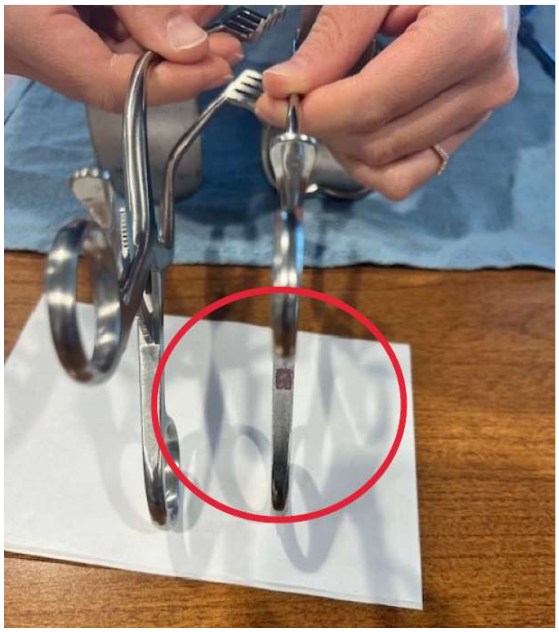
The instrument on the right has adhesive.

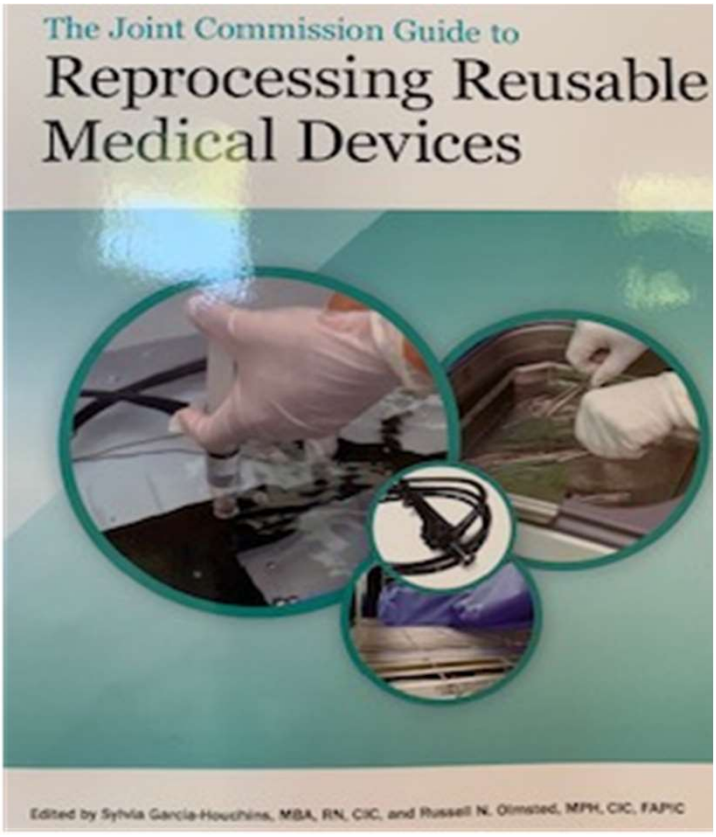


This is bioburden.

Inspection

Recommendation-A multi-disciplinary group from surgical services, OR, infection control will create a uniform instrument defect glossary using organization guidance (TJC, AORN)

Name (what was identified)	Action staff member will take	Example	Standard
Water spots that are clear and cannot be removed with a gloved hand	Instrument and tray can be used		No AORN or AAMI standard. Consensus of group (1)


The Joint Commission Guide to
Reprocessing Reusable Medical Devices
Edited by Sylvia Garcia-Houchins, MBA, RN, CIC, and Russell N. Olmsted, MPH, CIC, FAPIC

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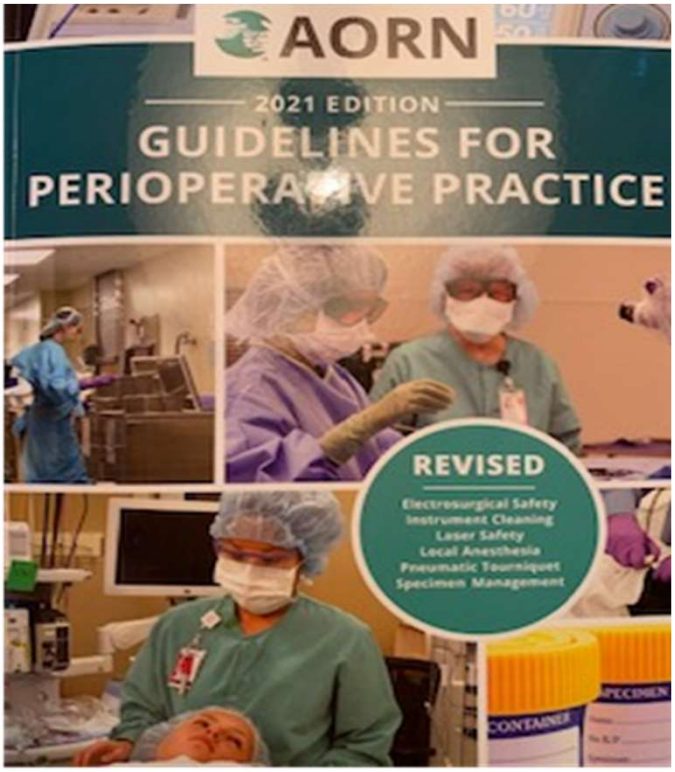
AORN
2021 EDITION
GUIDELINES FOR PERIOPERATIVE PRACTICE
REVISED
Electrosurgical Safety
Instrument Cleaning
Laser Safety
Local Anesthesia
Pneumatic Tourniquet
Specimen Management
CONTAINER
SPECIMEN

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Inspection

- Instruments and devices in disrepair or with compromised surfaces such as oxidation, pitting, rusting, cracking or damage from instrument marking, may not be able to be effectively sterilized
- Damaged, flaking or chipped instrument identification tape may be left behind in a wound as a foreign body
- In addition, instruments with structural damage may not function as intended

Inspection

- Scissor blades or forceps tips or teeth may be misaligned or ratchet performance affected
- Adequate lighting and magnification equipment can aid the inspection process
- Should be process for accessing maintenance/refurbishing resources so staff is empowered to take instruments out of circulation
- Stained instruments may indicate a problem with process such as detergent residues, salts and other elements, poor water or steam quality or lack of sterilizer/washer maintenance

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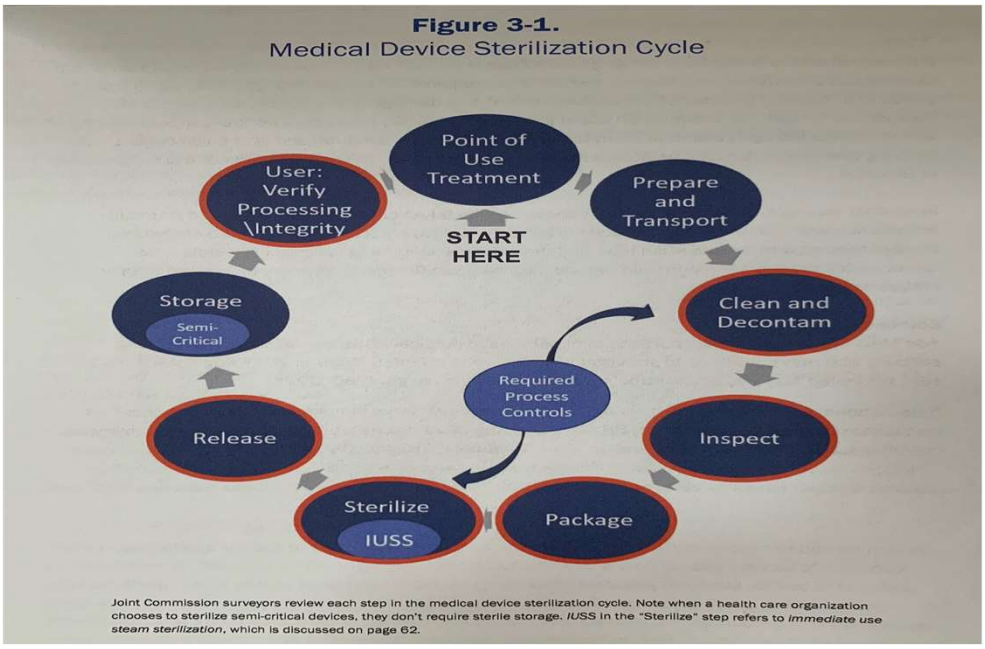
AORN Guidance

AORN Guideline for Perioperative Practice. 2021

- **6.2.4.** When an item or items are found to be contaminated, take the following corrective actions, at a minimum:
  - remove the contaminated item(s),
  - remove any other items that may have come in contact with the contaminated item(s),
  - change the gloves of any team member who may have touched the contaminated item(s), and
  - take any additional corrective actions required after thoughtful assessment and informed decision making based on the specific factors associated with the individual event.

Medical Device Reprocessing Cycle

Garcia-Houchins, Olmsted. TJC Guide. 2023



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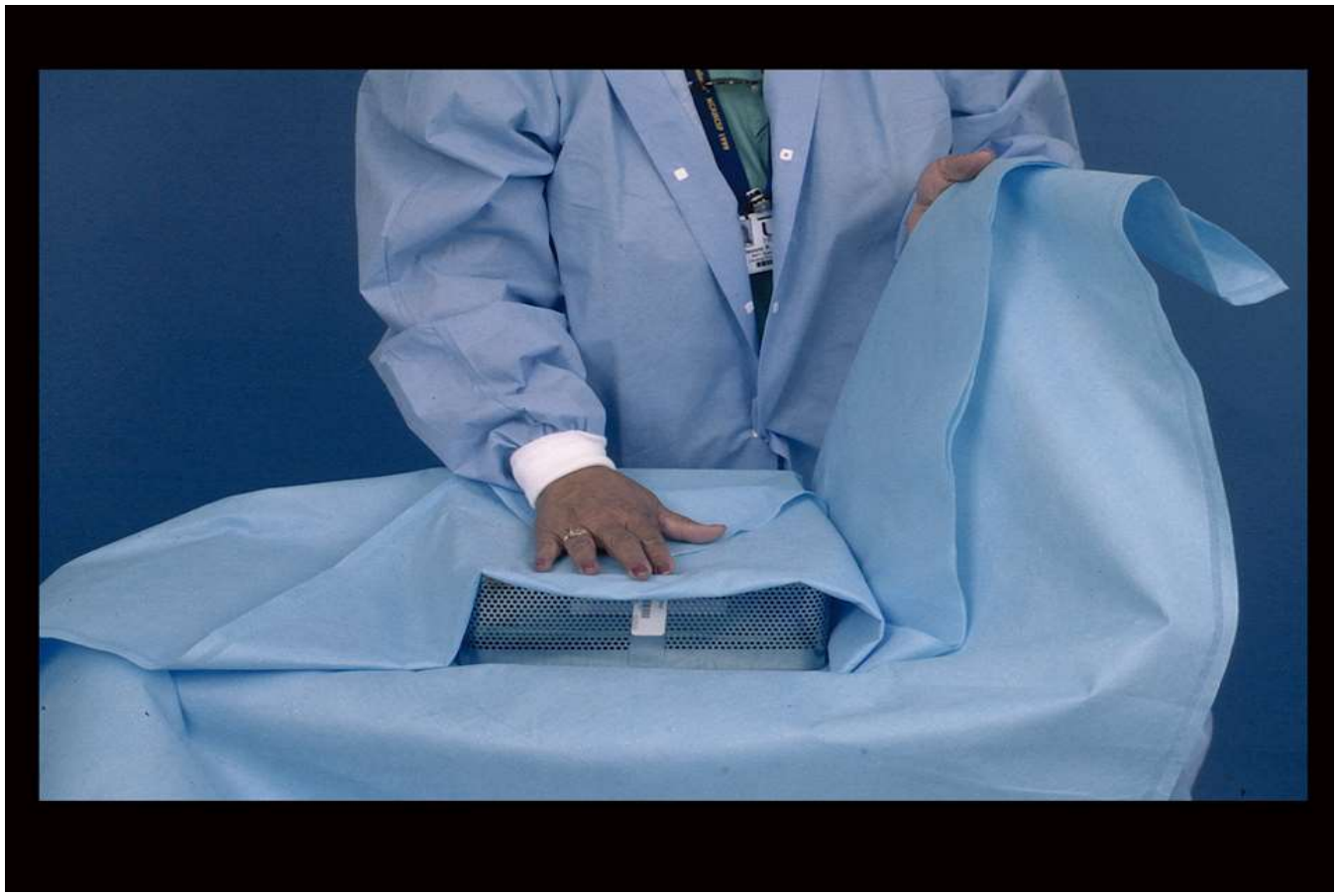
Packaging

- Once items are cleaned, dried, and inspected, items are wrapped or placed in a rigid container
- Arranged in tray/basket according to guidelines
  - Hinged instruments opened
  - Items with removable parts should be disassembled
  - Heavy items positioned not to damage delicate items
- Several choices to maintain sterility of instruments: rigid containers, peel pouched; sterilization wraps

Packaging
Sterilization Wraps

- An effective sterilization wrap would:
  - Allow penetration of the sterilant
  - Provide an effective barrier to microbial penetration
  - Maintain the sterility of the processed item after sterilization
  - Puncture resistant and flexible
  - Drapeable and easy to use
- Multiple layers are still common practice due to the rigors of handling



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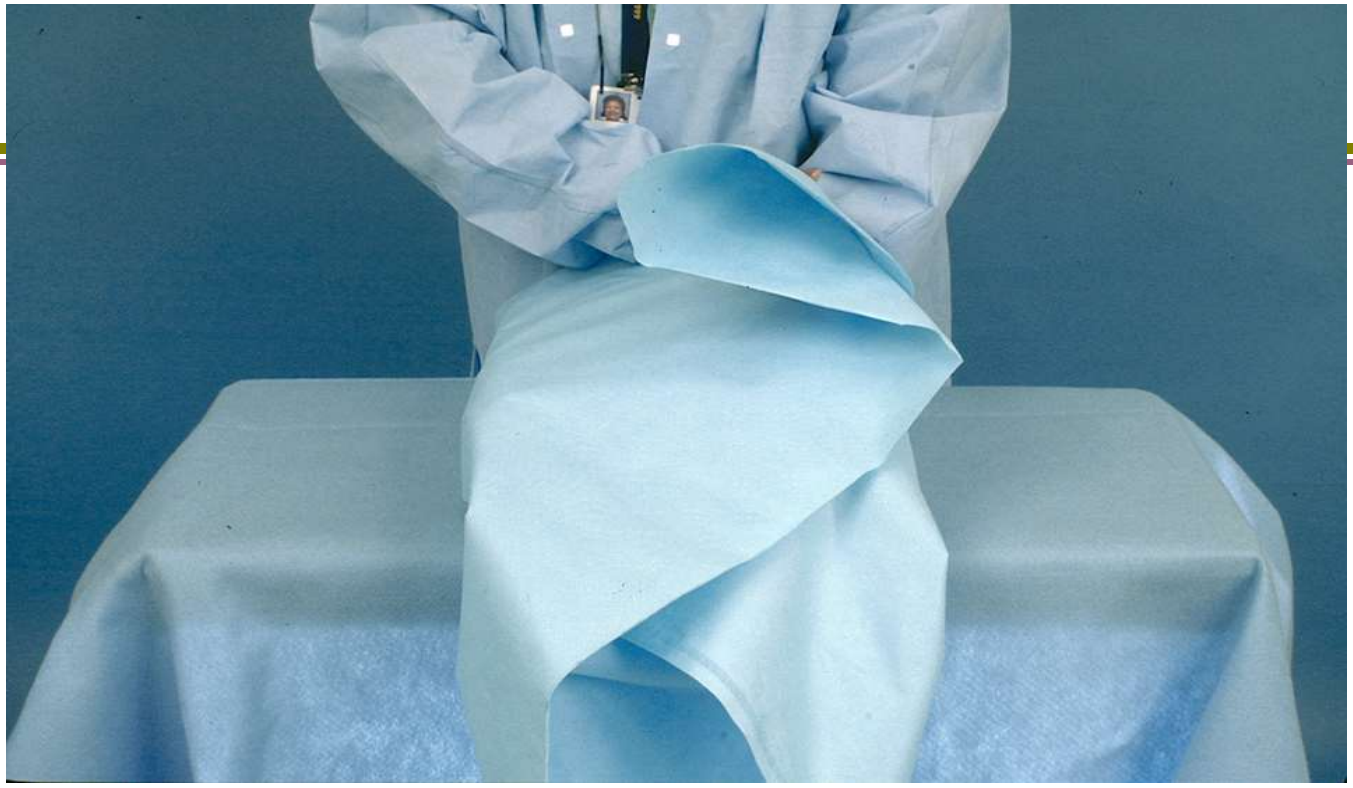

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Loading

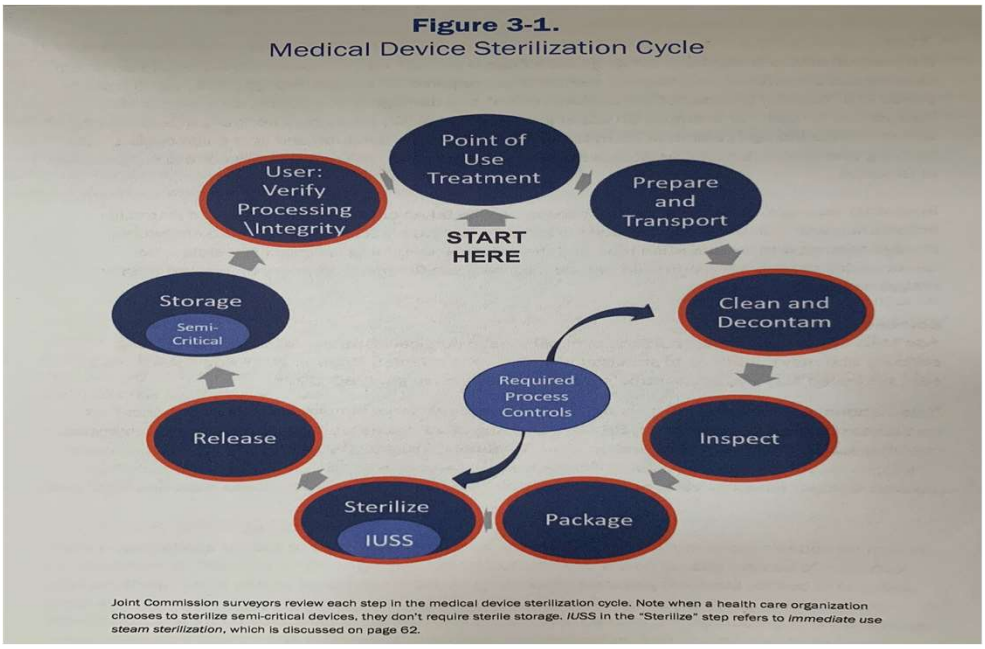
- All items to be sterilized should be arranged so all surfaces will be directly exposed to the sterilizing agent
- Other basic principles:
  - Allow for proper steam circulation
  - Nonperforated containers should be placed on their edge
  - Peel packs should be placed on edge

Packaging/Load Configuration

- Packaging materials should be compatible with the sterilization process
- Packaging (rigid containers, peel pouches, wraps) should provide a barrier to microorganisms and moisture and should be sufficiently strong to resist punctures and tears.
- Items should be placed loosely into the basket, shelf, or cart so as not to impede contact between the sterilant and the microorganism.

Medical Device Reprocessing Cycle

Garcia-Houchins, Olmsted. TJC Guide. 2023



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Sterilization

Complete elimination or destruction of all forms of microbial life. It is accomplished by physical or chemical processes.

Sterilization of "Critical Objects"

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala et al. AJIC 2019;47:A3-A9

Heat resistant

- Steam sterilization

Heat sensitive

- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

Steam Sterilization

Rutala, Weber AJIC 2019;47:A3-A9

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Least affected by organic/inorganic soils
  - Rapid cycle time
  - Penetrates medical packing, device lumens
- Disadvantages
  - Deleterious for heat labile instruments
  - Potential for burns

Minimum Steam Sterilization Times

Time at 132°C in Prevacuum Sterilizer

Rutala, Weber, HICPAC. November 2008. www.cdc.gov

Item	Minimum exposure	Minimum drying time
Wrapped instruments	4 min	30 min
Textile packs	4 min	5 min

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Immediate Use Steam Sterilization

- "Flash" originally defined as sterilization of an unwrapped object at 132°C for 3 min at 27-28 lbs pressure in gravity
- "Flash" used for items that must be used immediately and sterilized unpackaged (not sterile once removed from sterilizer)
- "Flash" is an antiquated term and replaced by "immediate use steam sterilization"

Immediate Use Steam Sterilization

- "Immediate Use" is defined as the shortest possible time between a sterilized item's removal from sterilizer and aseptic transfer to sterile field; now same time-temp (132^{o}C, 4min)
- The same critical reprocessing steps (such as cleaning, decontaminating, and transporting) must be followed
- A sterilized item intended for immediate use is not stored for future use.
- Sterilization process monitoring is essential
- Instruments inventories should be adequate to meet surgical volumes and permit the time to complete all critical elements of reprocessing

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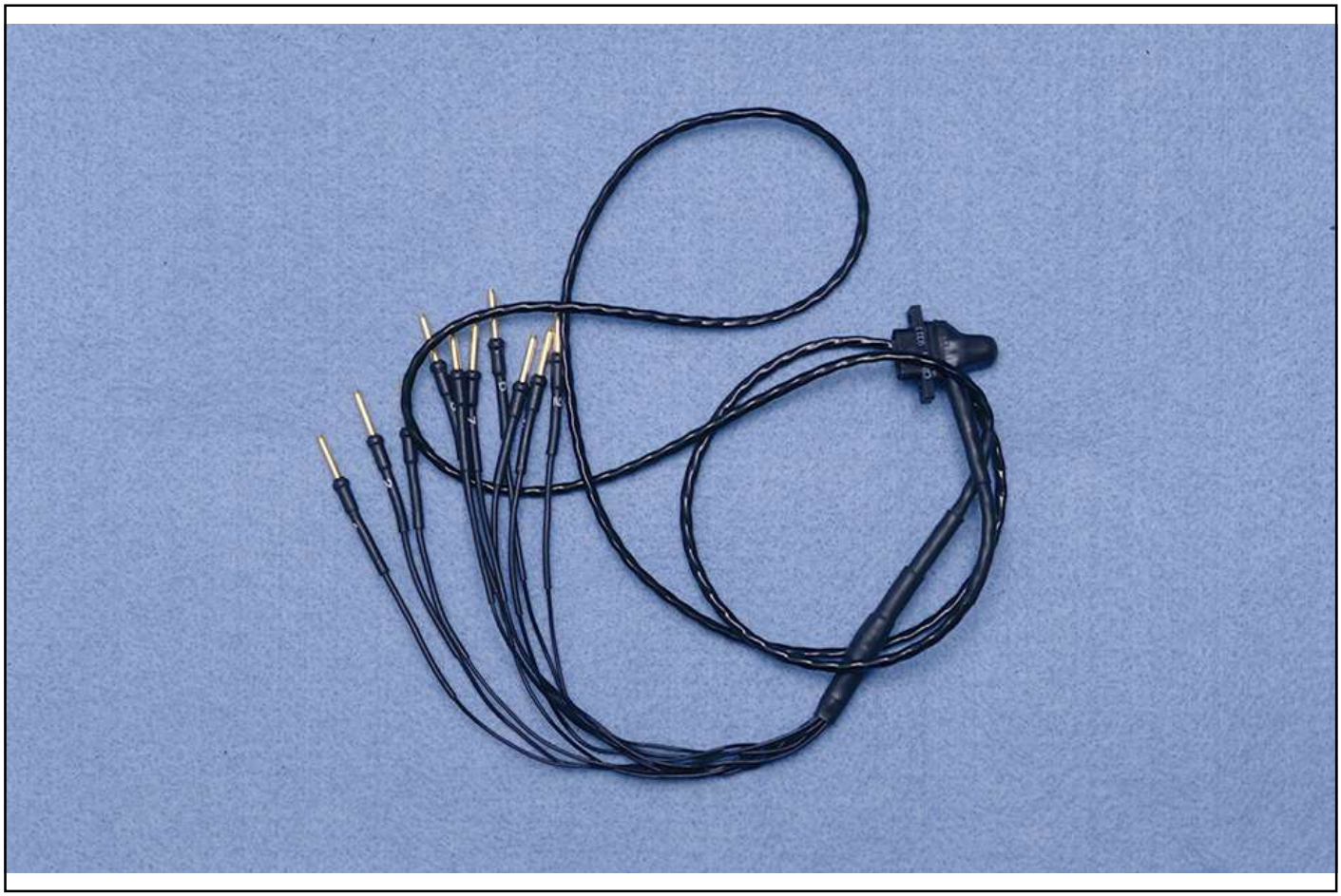

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Sterilization of "Critical Objects"

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala et al. AJIC 2019;47:A3-A9

Heat resistant

- Steam sterilization

Heat sensitive

- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

Conclusions

- All sterilization processes effective in killing spores
- Cleaning removes salts and proteins and must precede sterilization
- Failure to clean or ensure exposure of microorganisms to sterilant (e.g. connectors) could affect effectiveness of sterilization process

Sterilization Practices

Sterilization Monitoring

Rutala, Weber, CDC Guideline 2008. www.cdc.gov

Sterilization monitored routinely by combination of physical, chemical, and biological parameters

- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters present
- Biological - *Bacillus* spores that directly measure sterilization

Objectives of Monitoring the Sterilization Process

- Assures probability of absence of all living organisms on medical devices being processed
- Detect failures as soon as possible
- Removes medical device involved in failures before patient use

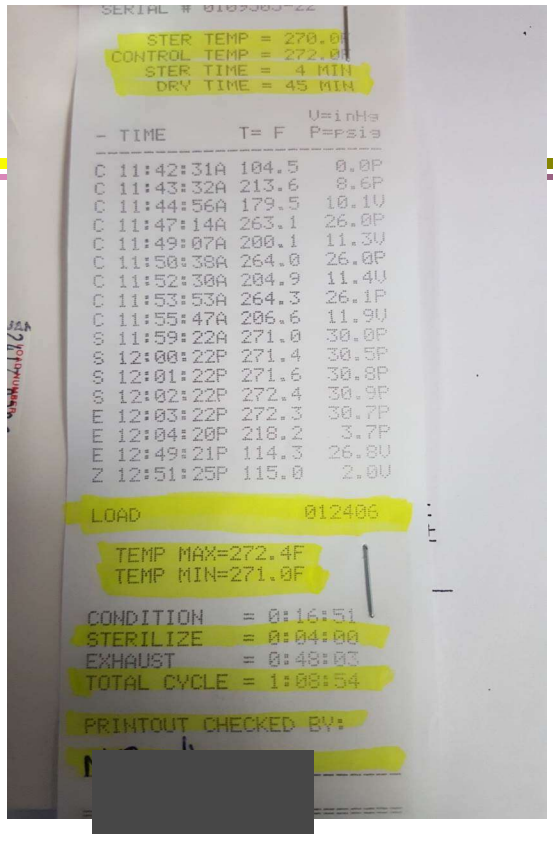
Monitoring of Sterilizers

- Use physical, chemical and biological monitors to ensure the effectiveness of the sterilization process
- Each load should be monitored with physical and chemical indicators
- If the physical, chemical or biological indicators suggest inadequate processing, the items should not be used
- Biological indicators should be used at least weekly with spores intended specifically for the type of sterilizer

Monitoring of Sterilizers

- Internal Chemical Indicator
  - Validates the sterilant penetrated the pack or tray
  - Advantage of the pack control monitor is that it is inside each pack in multiple locations
  - Detect local problem

Sterilizer Receipt



STER TEMP = 270.0F
CONTROL TEMP = 272.0F
STER TIME = 4 MIN
DRY TIME = 45 MIN

-	TIME	T= F	V=inHg P=psig
C	11:42:31A	104.5	0.0P
C	11:43:32A	213.6	8.6P
C	11:44:56A	179.5	10.1V
C	11:47:14A	263.1	26.0P
C	11:49:07A	200.1	11.3V
C	11:50:38A	264.0	26.0P
C	11:52:30A	204.9	11.4V
C	11:53:53A	264.3	26.1P
C	11:55:47A	206.6	11.9V
S	11:59:22A	271.0	30.0P
S	12:00:22P	271.4	30.5P
S	12:01:22P	271.6	30.8P
S	12:02:22P	272.4	30.9P
E	12:03:22P	272.3	30.7P
E	12:04:20P	218.2	3.7P
E	12:49:21P	114.3	26.8V
Z	12:51:25P	115.0	2.0V

LOAD 012406

TEMP MAX=272.4F
TEMP MIN=271.0F

CONDITION = 0:16:51
STERILIZE = 0:04:00
EXHAUST = 0:48:03
TOTAL CYCLE = 1:08:54

PRINTOUT CHECKED BY:

[redacted]

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Six Classes of Indicators Are Recognized by International Organization of Standards (ISO)

Table 2. Chemical Indicator Classifications

Class I Process indicators	Process indicators are attached to or printed on the outside of all packs to discern which packages have been processed from those that have not been processed in a sterilizer.
Class 2 Bowie-Dick test	The Bowie-Dick test is used to reveal the pass/fail rate in dynamic air removal steam sterilizers. This Class 2 chemical indicator should be used in an empty chamber daily, preferably before any loads are processed at the beginning of the day.
Class 3 Single parameter indicator	The single parameter chemical indicator is placed inside each package and provides data on time or temperature, revealing if one of these sterilization parameters has been met during a cycle.
Class 4 Multi-parameter indicators	Multiparameter indicators react to two or more sterilization parameters, such as time and temperature or time and pressure.
Class 5 Integrating indicators	React to all critical parameters of sterilization cycle over a range of temperatures; performance must equal that of the biological indicators.
Class 6 Emulating indicators	Cycle specific; react to all critical parameters for a specified sterilization level; used at the pack/tray level.

Dimensions of Dental Hygiene, March 2009

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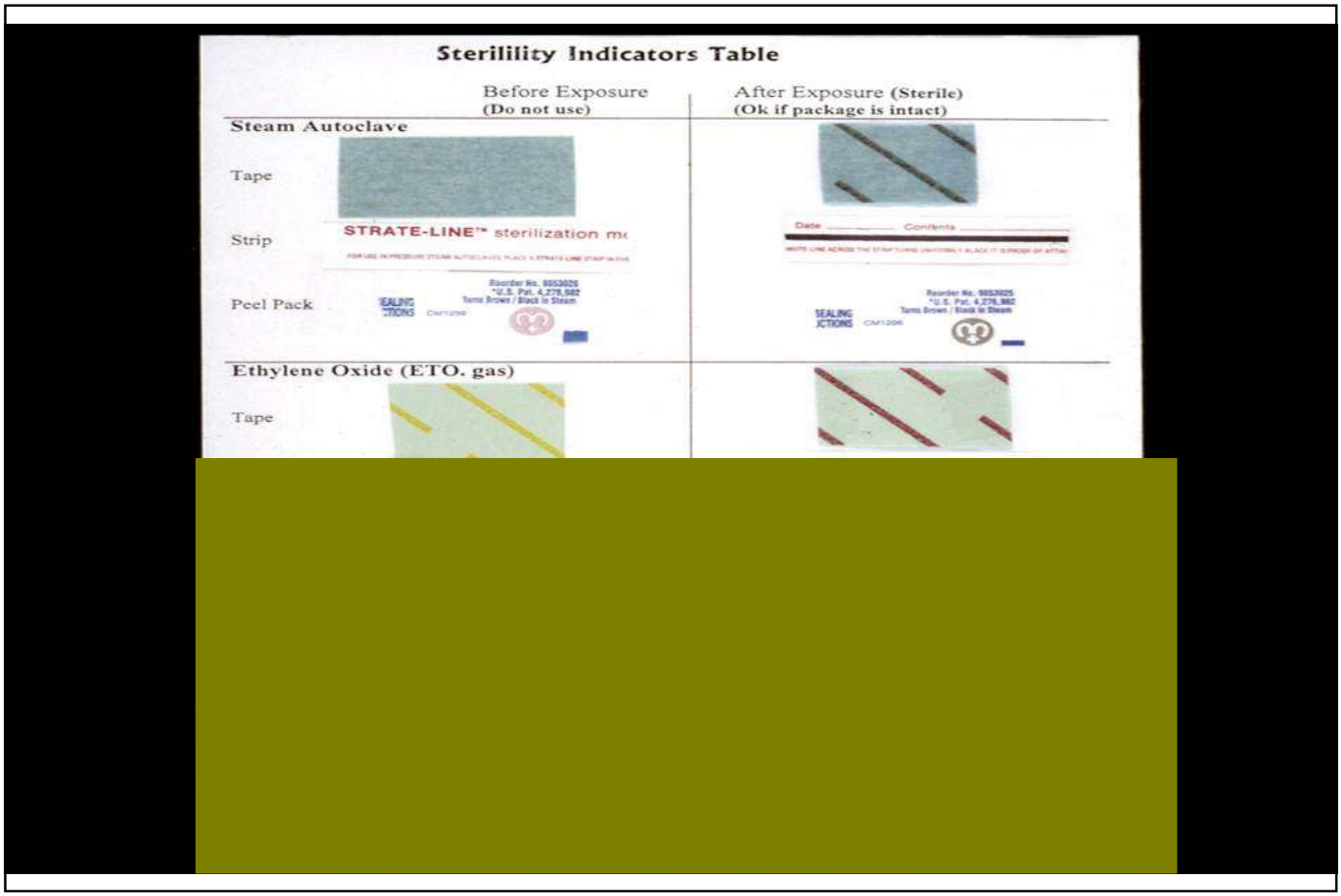
Sterilility Indicators Table
Before Exposure
(Do not use)
After Exposure (Sterile)
(Ok if package is intact)
Steam Autoclave
Tape
Strip
STRATE-LINE™ sterilization m
Peel Pack
Date
Contents
Ethylene Oxide (ETO. gas)
Tape

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PREVAC
START AT 12:00:33A
ON 10/04/11
COUNT 10513
HUR
STERILIZER VAC 01
SERIAL # 0322706-07
STER TEMP = 270.0F
CONTROL TEMP = 272.0F
STER TIME = 4 MIN
DRY TIME = 1 MIN
LOAD NUMBER
0411 0101
STERILIZED S1
INDEFINITE SHELF LIFE UNLESS DAMAGED OR OPENED
Date
Ster. No.:
Init.:

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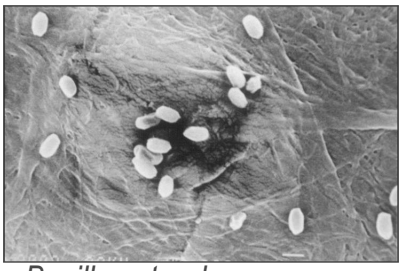
Biological Indicators

- **Select BIs that contain spores of *Bacillus atrophaeus***
  - Rationale: BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process



Bacillus atrophaeus

Biological Monitors

Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Steam - *Geobacillus stearothermophilus*
- Dry heat - *B. atrophaeus (formerly B. subtilis)*
- ETO - *B. atrophaeus*
- New low temperature sterilization technologies
  - HP gas plasma - *G. stearothermophilus*
  - HP/Ozone -*G. stearothermophilus*
  - VHP- *G. stearothermophilus*

Rapid Readout BIs for Steam Now Require a 1-3h Readout Compared to 24-48h

Rutala, Jones, Weber ICHE 1996. 17:423

Vol. 17 No. 7 INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY 423

COMPARISON OF A RAPID READOUT BIOLOGICAL INDICATOR FOR STEAM STERILIZATION WITH FOUR CONVENTIONAL BIOLOGICAL INDICATORS AND FIVE CHEMICAL INDICATORS

William A. Rutala, PhD, MPH; Suzanne M. Jones, MPH; David J. Weber, MD, MPH

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Super Rapid Readout Biological Indicators

Commercially available

1491 BI (blue cap)

- Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
- 24-minute result

1492V BI (brown cap)

- Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum, SFPP-steam flush pressure pulse) steam sterilization cycles
- 24-minute result

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Rapid (or Super Rapid) Readout Biological Indicator for Steam (20m-24m), ETO (4hr) and HP Sterilizers (15m-2h)

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Vaporized Hydrogen Peroxide (VHP) Biological Indicator Options (*all G. stearothermophilus*)

Refer to BI manufacturer's IFU for cycles the BI is cleared for

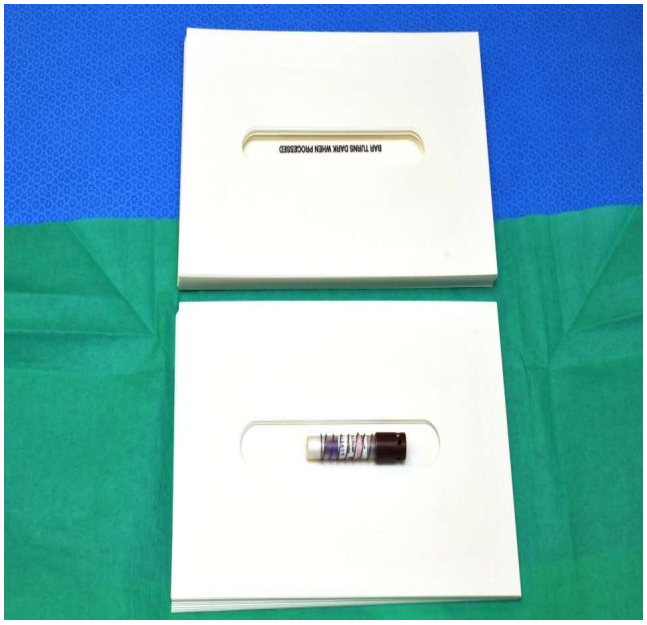
VHP read out time	Number of cleared biological indicators
2 hours	1
30 minutes	2
24 minutes	1
20 minutes	1
15 minutes	1

84

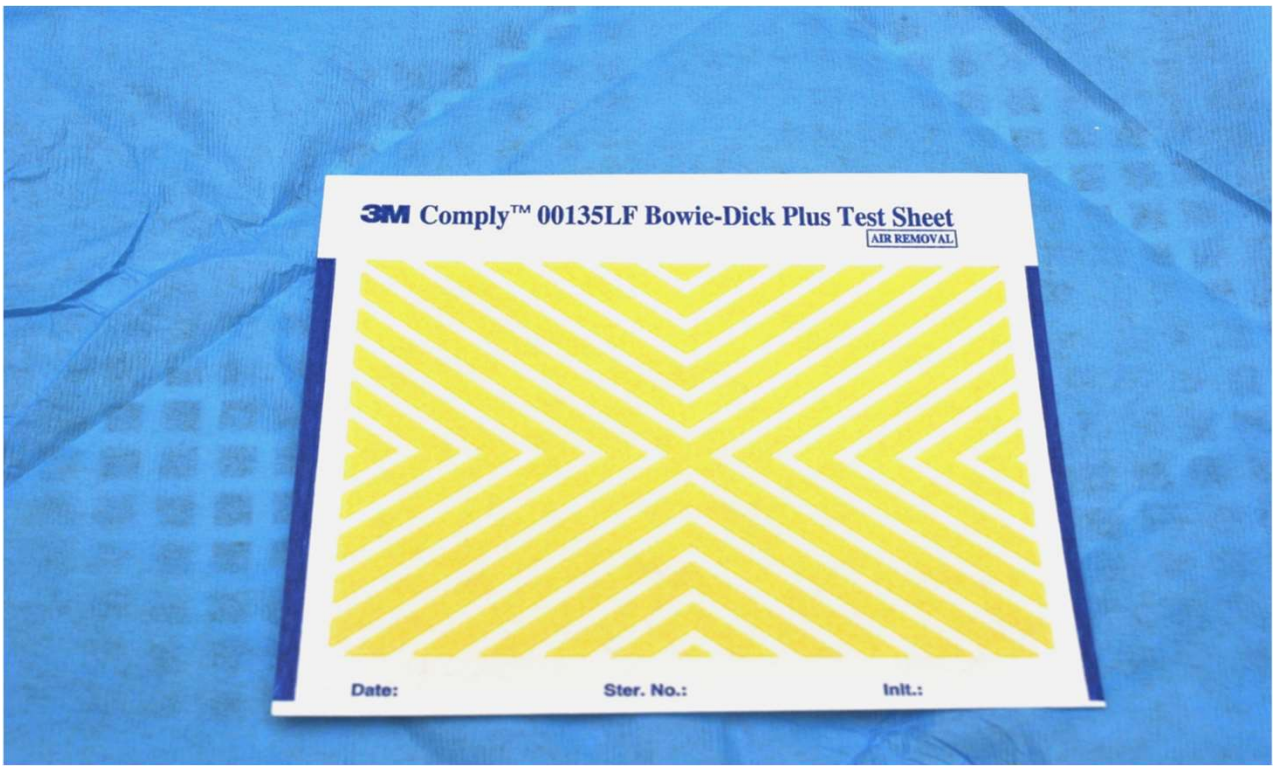
85

Process challenge device simulates an equal or greater challenge than the most difficult instrument/item routinely processed in a sterilization cycle

86



87


3M Comply™ 00135LF Bowie-Dick Plus Test Sheet
AIR REMOVAL
Date:
Ster. No.:
Init.:

88

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Recommendations
Monitoring of Sterilizers
Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Monitor each load with physical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items

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Recommendations
Monitoring of Sterilizers

Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Following a single positive biological indicator used with a method other than steam, treat as non-sterile all items that have been processed in that sterilizer, dating back to last negative biological indicator.
- Following a positive biological indicator with steam sterilization, objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or procedure is defective or inappropriate cycle settings. If additional spore tests remain positive, consider the items nonsterile and recall and reprocess the items from the suspect load.

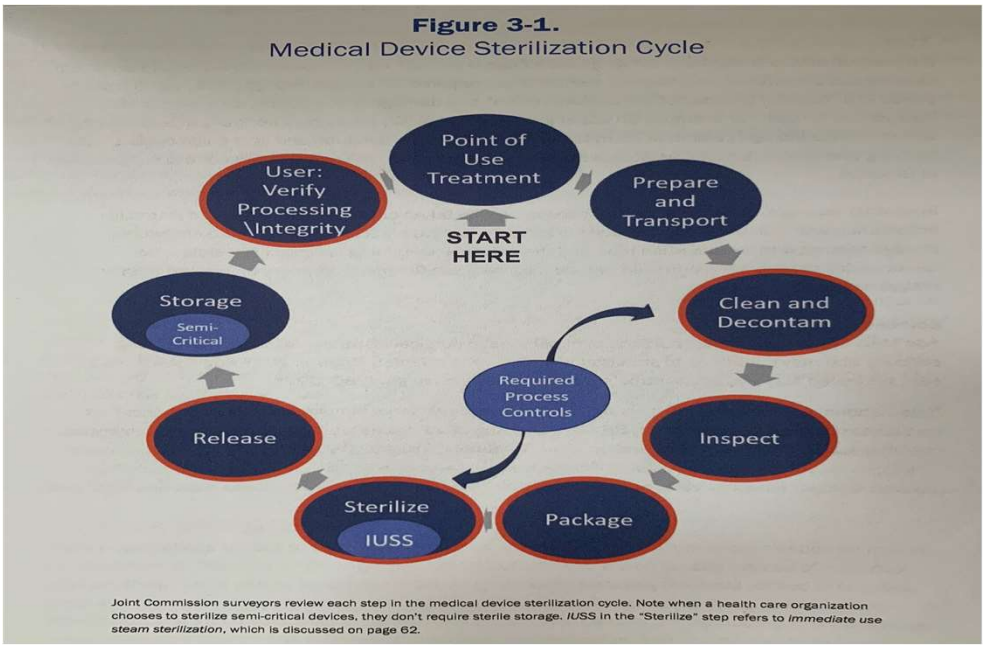
Recommendations
Methods of Sterilization

Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)

Medical Decice Reprocessing Cycle

Garcia-Houchins, Olmsted. TJC Guide. 2023



93

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orth Carolina Hospitals
hunt Basket
euro
LOAD NUMBER
JUL 1 02 189 2
STERILIZED S1
INDEFINITE SHELF LIFE UNLESS DAMAGED OR OPENED

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Storage

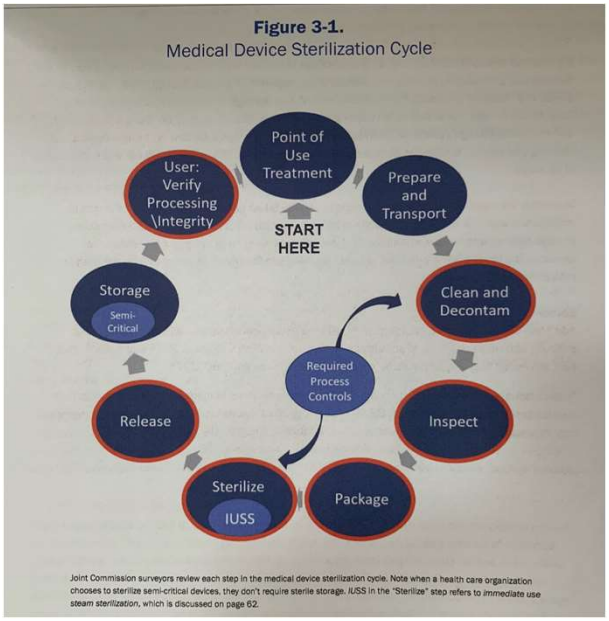
- Time-related shelf life-safe storage times for sterile packs vary with the porosity of the wrapper and storage conditions (e.g., 1 year, plastic wrapped pack)
- Event-related shelf life-product remains sterile until some event causes the item to become contaminated (e.g., tear in packaging, packaging become wet)
- Closed or covered cabinets are ideal but open shelving may be used for storage

Storage of Sterile Items

- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g., tear, wetness). Packages should be evaluated before use for lose of integrity.
- Time-related shelf life (less common) considers items remain sterile for varying periods depending on the type of material used to wrap the item/tray. Once the expiration date is exceeded the pack should be reprocessed.

Medical Decice Reprocessing Cycle

Garcia-Houchins, Olmsted. TJC Guide. 2023



Storage of Sterile Items

- Sterile storage area should be well-ventilated area that provides protection against dust, moisture, and temperature and humidity extremes.
- Sterile items should be stored so that packaging is not compromised
- Sterilized items should be labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and the expiration date (if applicable)

100

Detection of Surgical Wrap Defects in the OR

Kelly et al. Orthopedics. doi: 10.3928/01477447-20211001-15

Figure 2: Photograph of a demonstration of the screening process for wrap perforations as performed by operating room staff.

Defects in wraps missed at very high rate, which could lead to contamination.

Table 2

Detection of Surgical Wrap Defects Based on Years of Experience of Operating Room Staff

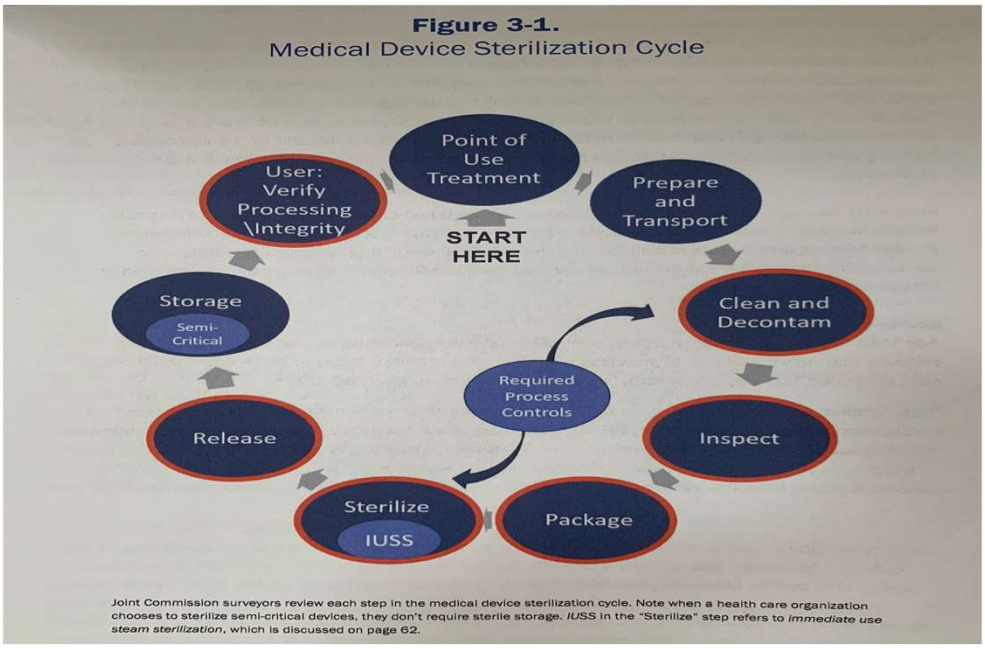
Detection rate	Operating room staff >1 y experience	Operating room staff <1 y experience	*P*
Overall score correct	67%	60.5%	.025
Detection rate for all holes	56%	48%	.039
Detection rate for small holes (1.2 mm)	2%	4%	.355
Detection rate for medium holes (3.7 mm)	81%	65%	.045
Detection rate for large holes (6.8 mm)	85%	75%	.074
Detection rate for wraps without defects	100%	98%	.168

Quality Control

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency, staff should:
  - hands-on training
  - all work supervised until competency is documented
  - competency testing should be conducted at commencement of employment and regularly
  - review written reprocessing instructions to ensure compliance

Medical Decice Reprocessing Cycle

Garcia-Houchins, Olmsted. TJC Guide. 2023



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Conclusions

- All sterilization processes effective in killing spores
- Cleaning removes salts and proteins and must precede sterilization
- Delivery of sterile products for use in patient care depends not only on the effectiveness of the sterilization process but also on cleaning, disassembling and packaging of the device, loading the sterilizer, and monitoring

THANK YOU!

www.disinfectionandsterilization.org

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- Rutala WA, Gergen MF, Weber DJ. Efficacy of a washer-disinfector in eliminating healthcare-associated pathogens from surgical instruments. Infect Control Hosp Epidemiol. 2014;35:883-885.

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- Rutala, Weber, HIPAC. Disinfection and sterilization in health care facilities.
- https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.htm