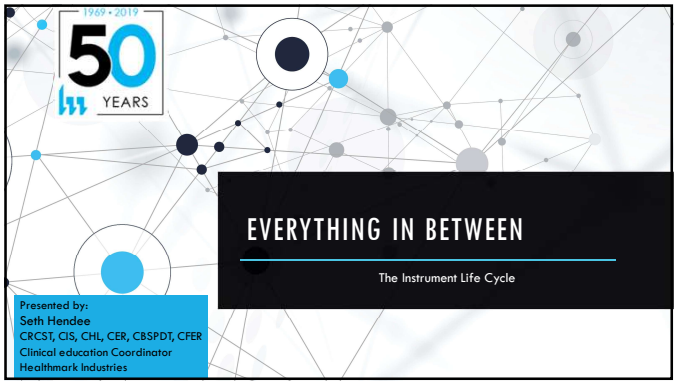


1

Healthmark's policy
is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost effective manner. This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.

Healthmark's philosophy
it is more than just buying a product or running a test. It is about having clinically relevant, evidence-based, products. Along with support for healthmark products both clinically and educationally with the understanding that an educated customer is our best customer.

Disclosure

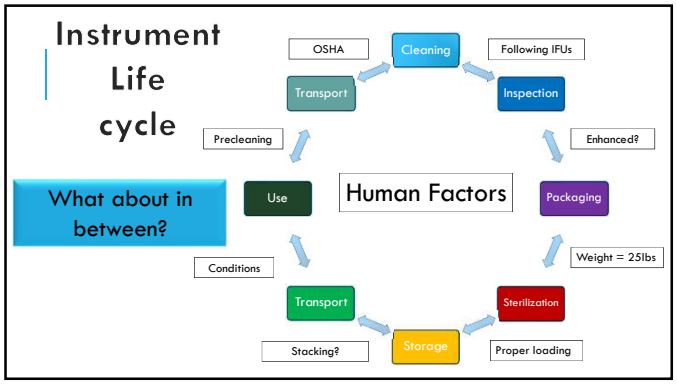
- I am an employee of Healthmark Industries Fraser, Michigan USA
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals
- All opinions are those of the presenter
- This presentation reflects the techniques, approaches and opinions of the individual presenter. This sponsored presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contradictions, warnings and precautions, and steps for the use of the device(s).

2

OBJECTIVES:

- ❑Discuss the life cycle of an instrument, purchase to disposal
- ❑Explain key processing factors from point of use treatment through the decontamination stages of the cycle
- ❑Explain key processing factors from inspection through packaging stages of the cycle
- ❑Explain key processing factors from sterilization through storage and delivery stages of the cycle.

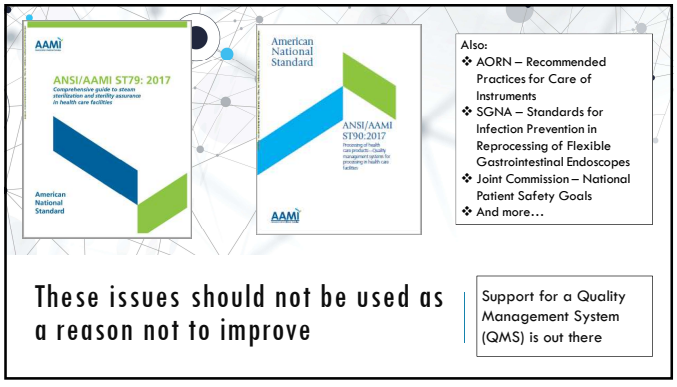
3


Instrument Life cycle
What about in between?
Human Factors
Cleaning
Following IFUs
Inspection
Enhanced?
Packaging
Weight = 25lbs
Sterilization
Proper loading
Storage
Stacking?
Transport
Conditions
Use
Precleaning
Transport
OSHA

4


Best practice is everyone's target. So why aren't we all perfect?
Lack of training & competency
Conflicting IFU between instruments & equipment
Budgetary restraints
Lack of space
Turnover pressure
Lack of inventory

5


AAMI
ANSI/AAMI ST79: 2017
American National Standard
American National Standard
ANSI/AAMI ST90:2017
AAMI
Also:
AORN – Recommended Practices for Care of Instruments
SGNA – Standards for Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes
Joint Commission – National Patient Safety Goals
And more…
These issues should not be used as a reason not to improve
Support for a Quality Management System (QMS) is out there

6

LET'S START AT THE BEGINNING

- Precleaning after use
  - This something IFUs call for
  - This is something surveyors are auditing for
- Cleaning after purchase, before first use
  - The manufacturing process can leave debris and oils on an instrument
  - The shipping process can leave lint, foam and cardboard on an instrument
- Cleaning after use
  - The first and most important step in rendering an instrument safe for the next patient
  - If an instrument is not clean, it cannot be disinfected or sterilized properly

7

PRE-TREATMENT AT POINT OF USE

TJC – FAQ
Instrument Reprocessing :
Point-of-Use and Pre-Cleaning Expectations

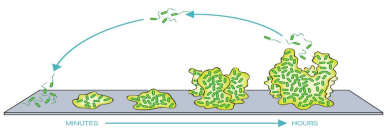
- *"**Pre-cleaning:** the means of removal of visible gross blood, body fluids, and/or bio-burden in order to prevent hardening of debris or the development of biofilm due to processing delays."*

https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=1479

8

BIOFILM FORMATION

- Particularly problematic in devices with lumens
- Once formed direct friction and/or oxidizing chemicals are needed to remove it
- Prompt cleaning reduces or eliminates the population of biofilm forming microorganisms



ANSI/AAMI ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.

9

What are they focusing on?

- Visible bioburden and dried blood found on instruments
- Enzymatic solution was not applied to maintain moisture on instruments
- Instruments were not transported from the point of use in a leak-proof puncture-resistant container with the biohazard symbol or color red
- Instruments in the closed position
- Facility is not following manufacturer IFU for drying
- Facility is not following manufacturer IFU for frequency of reprocessing

10

Preparation for decontamination

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Guideline for Disinfection and Sterilization in Healthcare Facilites,

2. Cleaning of Patient-Care Devices

ii. Clean medical devices as soon as practical after use (e.g., **at the POU**)...

- ✓ Dried or baked materials make the removal process **more difficult**, and
- ✓ the disinfection or sterilization process **less effective** or ineffective.

AORN

Guideline for Cleaning and Care of Surgical Instruments

III.a. Preparation for decontamination of instruments should **begin at the POU**.

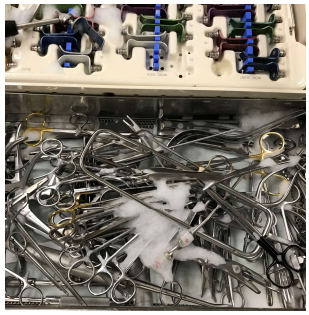
- Moistening and removing gross soil at the POU….
  - ✓ **More difficult to remove** when allowed to dry
  - ✓ Can **improve the efficacy** and effectiveness of cleaning and decontamination.

11

AAMI ST79 loading mechanical washing and disinfection equipment

If using a spray you must rinse off once received in the decontamination area.

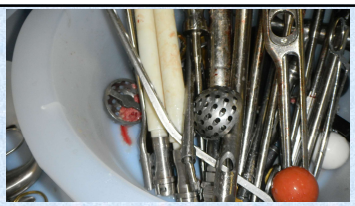
Remove all presoak chemicals either manually or mechanically before loading into the washer…. open hinged instruments…use hold down screens…. silicone and rubber mats should be removed from the set to permit full impingement action…

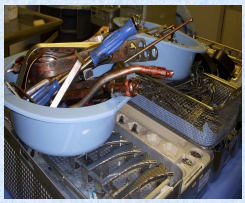


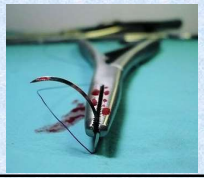
AAMI ST79 Section 7.6.4.3.2

12

UNACCEPTABLE







13

SOILED TRANSPORT – OSHA REQUIREMENTS

OSHA Occupational Safety and Health Administration www.osha.gov

OSHA's Bloodborne Pathogens Standard (**29 CFR 1910.1030**) as amended pursuant to the 2000 Needlestick Safety and Prevention Act, is a **regulation** that prescribes safeguards to protect workers **against health hazards** related to bloodborne pathogens.

All containers, devices, or carts used for containing contaminated items be marked with a **biohazard label**, a **red bag**, or other means of identifying contaminated contents; and be puncture-resistant, leak-proof on the sides and bottom, closable, and labeled containers **MUST** be used for devices with **edges or points** capable of penetrating container or skin.

ST79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79:2017 - 6.4 Containment

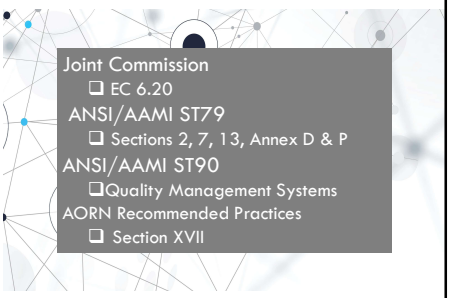
14

What about damage

15

HOW DO I KNOW MY INSTRUMENTS ARE CLEAN?

Many organizations recommend & support equipment and instrument cleaning verification



Joint Commission
- ❑ EC 6.20

ANSI/AAMI ST79
- ❑ Sections 2, 7, 13, Annex D & P

ANSI/AAMI ST90
- ❑Quality Management Systems

AORN Recommended Practices
- ❑ Section XVII

16

What equipment should be tested?

Section 7.6.4.3.3 list of cleaning equipment
- Ultrasonic Cleaning Equipment
- Irrigator Cleaners
- Ultrasonic Irrigators
- Ultrasonic Irrigator Washers
- Ultrasonic Irrigator Washer – Disinfectors
- Floor-Mounted Cart Washer – Disinfectors
- Single-Chamber Washer – Disinfectors
- Multi-Chamber Washer – Disinfectors
- Medical Washers

17

EQUIPMENT "VERIFICATION"

ST 79 – User verification: Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met.

installation qualification (IQ): Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

operational qualification (OQ): Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

performance qualification (PQ): Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

18

Equipment verification builds quality

ANSI/AAMI ST90: "Quality Management Systems for Processing in Health Care Facilities" Section 7.5.1 2017	AORN: "Recommended Practices for Care of Instruments" Section XVII 2019
The health care organization shall plan and carry out processing and servicing under controlled conditions. Controlled conditions shall include a) availability of information describing the characteristics of the product; b) availability of documented procedures, documented requirements, processing instructions (the manufacturer's written IFU), reference materials (national standards, recommended practices, and guidelines), and reference measurement procedures, as necessary; c) **use of suitable equipment for cleaning, decontamination, disinfection, and sterilization;** d) **availability and use of monitoring and measuring devices** (e.g., sterilizer temperature and pressure recording devices); e) **implementation of monitoring and measurement** (e.g., use of chemical and biological indicators and physical monitors on sterilization equipment, **cleaning verification**); f) implementation of release, delivery, and post-delivery activities; and g) implementation of defined operations for labeling and packaging.	"**XVII.a. A quality management program should include monitoring of manual and mechanical cleaning**" *[2: Moderate Evidence]* "Cleaning is a critical component of instrument processing and can affect the efficacy of a subsequent sterilization processes. Items that have been sterilized after inadequate cleaning processes have caused patient injury." 21-23,153 XVII.a.1. "Mechanical cleaners (eg, washer disinfectors/decontaminators) should be tested for correct function on installation, at least weekly (preferably daily) during routine use, after major repairs, and after significant changes in cleaning parameters (eg, changing cleaning solutions)."10 *[3: Limited Evidence]* "Monitoring washer function **provides information about whether the equipment is functioning correctly**. Thorough cleaning is dependent on how the equipment is used, how instruments are placed in the machine, and whether the equipment is functioning correctly." "Commercial tests to monitor cleaning efficacy of mechanical washer disinfector/decontaminators are available."

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VERIFICATION THROUGH OBSERVATION

Section 7.6.4.3.6 Unloading mechanical cleaning and disinfection equipment

"If the cleaning equipment provides cycle verification, the cycle selection should be checked, before the devices are unloaded, to ensure that the correct cycle was used. The printout should be saved for the period of time specified by the facility or by state and/or local regulations. As devices are unloaded, they should be inspected for debris and wetness."




20

Observation can detect issues


21

INSTRUMENT CLEANING VERIFICATION

ST 79 Section 13.2 Monitoring of mechanical cleaning equipment

Health care personnel should perform verification testing on all mechanical cleaning equipment as part of the overall quality assurance program. Methods of verification include

a) directly testing individual instruments for residual soils (e.g., adenosine triphosphate [ATP], protein, hemoglobin);

b) employing a test device that is a consistent and repeatable challenge to the cleaning effectiveness of the equipment; and

c) monitoring critical parameters to evaluate the performance of the mechanical cleaning equipment."

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ST 79 ON INSTRUMENT CLEANING VERIFICATION

Section 7.6.4.5 "Verification of the cleaning process"

"Visual inspection alone might not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure or detect organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures (see Annex D for available methods). Appropriate testing is based on the type of equipment. See Annex D for guidance on testing ultrasonic cleaners."

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CV: what to test for and how

ST 79 Annex D.2	ST 79 Annex D.3
"Published studies that have evaluated the **specific markers that can be used to determine cleaning efficacy** have indicated that the following markers are useful for benchmarking purposes": •protein •carbohydrate •hemoglobin (blood) •endotoxin •lipid •sodium ion •Bioburden •Adenosine triphosphate (ATP	**"Cleaning verification tests for users"** "There are a number of commercially available validated test methods for rapid detection of organic residues on surgical instruments. Ideally, cleaning tests for in-use verification of medical device reprocessing should be a) rapid, b) easy to perform, c) sensitive (i.e., meet realistic benchmarks),"

24

ANSI/AAMI ST 79 Annex P

"…Many types of soil could be present on reusable medical devices. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a challenge to cleaning…"

THE IMPORTANCE OF REMOVING BLOOD

25

ST91 on Cleaning Verification

WE CAN'T FORGET ENDOSCOPES

Cleaning verification is performed following cleaning to verify the effectiveness of a cleaning process PRIOR TO DISINFECTION

Residual organic soil and microbial contamination may be present on an accessible surface even though the device looks clean.

The use of methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be considered and included in facility policies and procedures on device cleaning

Lists commonly used cleaning verification products:

Protein, Carbohydrate, Hemoglobin, ATP

26

SGNA ON CLEANING VERIFICATION

To confirm the adequacy of manual cleaning, a rapid cleaning monitor (or rapid audit tool) for residual organic soil can be used prior to high-level disinfection.

If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection.

Rapid cleaning monitors are available and can provide documentation on cleaning efficacy but do not reflect microbial activity.

Real-time testing of endoscope lumens/elevator channel should be done immediately after manual cleaning so that any improperly cleaned devices are re-cleaned prior to HLD. Facilities should consider the use of monitors to verify ongoing cleaning adequacy.

27

INSPECTION & PACKAGING

- Visual inspection is the minimum
- Are you performing any enhanced visual inspection
- Specific tools are needed to inspect for proper function
- Aseptic presentation, does your staff know their packaging makes or breaks that process

28

IS INSPECTION WITH THE NAKED EYE ENOUGH

AAMI	AORN
In preparation for sterilization, devices should be: a) cleaned; b) dried; c) inspected for cleanliness, flaws, and damage; d) assembled; and e) packaged according to the manufacturer's written IFU. Individual instruments should be packaged in an acceptable packaging material that ensures adequate sterilant contact with all surfaces.	Visually inspect with lighted magnification for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization. Inspection helps to identify residual organic material and defective items and remove from service soiled/defective items that might put patients at risk for infection or injury. An endoscope that appears clean may harbor debris that cannot be seen without magnification. Lighted magnification may increase the ability to identify residual soil or damage. Internal channels of endoscopes may be inspected using a borescope. Borescopes penetrate the lumen and allow for improved visual inspection

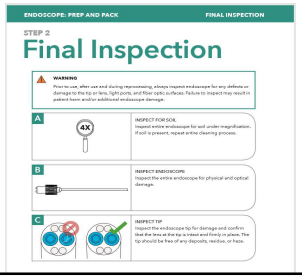
29

NOT IF YOU HAVE CERTAIN INSTRUMENTS

- Some IFUs call for enhanced visual inspection – beyond the unaided eye
- Complex devices have areas that are hard, if not impossible to see with the naked eye
- Regulatory and voluntary organizations are recommending enhanced inspection as best practice
- Some instruments have specific functions that cannot be assessed with your eyes

30

IFU ASKING FOR 4X MAGNIFICATION



Most tabletop magnifiers are only 2X

31

Stryker Corporation, Shaver Handpiece User guide

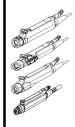
INSPECTION X 3 IN THIS IFU:

In decontam
- Visually inspect the handpiece, including all internal surfaces, for remaining soil. Use an endoscopic camera and endoscope if necessary, to see the inner surface of the lumen.
- If soil remains, repeat the manual cleaning procedure, focusing on those areas.

In Pack and Prep
- Visually inspect the handpiece, including all internal surfaces, for remaining soil. Use an endoscopic camera and endoscope if necessary, to see the inner surface of the lumen.
- If soil remains, repeat the manual cleaning procedure, focusing on those areas.

stryker

Shaver Handpieces



Prior to Surgery
- Federal law (United States of America) restricts these devices to use by, or on order of, a physician.
- To avoid potential serious injury to the user and patient and/or damage to these devices, read this user guide and the user guides for other components, namely the console, the footswitch, and the cutting blade thoroughly and be familiar with its contents prior to using this equipment.
- Before using the handpieces in a surgical procedure, inspect it for any damage. Ensure that there are no loose or missing components and that all parts move freely. Do not use the equipment if damage is apparent.
- Set up the entire system and verify each function before introducing a handpiece to the surgical site.
- Clean and sterilize the handpiece prior to the first use and every use thereafter.

32

AND THIS IS WHY

The FDA encourages facilities that use any of these types of devices to evaluate the adequacy of their cleaning procedures. Hospitals should consider taking the following steps to minimize any potential risk to patients:

- Be sure that all personnel responsible for device cleaning and sterilization at your facility are aware of and comply with all steps in the manufacturer's instructions for thoroughly cleaning these devices prior to sterilization. Please refer to the specific instructions provided in the labeling or user manual for each brand and/or model of shaver your facility uses.
- Consider inspecting the inside of the devices following cleaning to ensure that they have been cleared of any tissue or fluids. There may be multiple ways to accomplish this. As one example, the facility that brought this situation to our attention uses a 3mm video scope to inspect the channels of the shaver handpiece.

33

ENDOSCOPE ARE EXTREMELY COMPLEX DEVICES

AAMI - ST 79 and ST 91

AORN

SGNA

✓All support the practice of using some type of enhanced visual inspection

=

more than the unaided eye

34

Can this recess be seen with the naked eye

Duodenoscope IFU: Olympus 180 duodenoscope:

- "Inspect whether there is debris on the forceps elevator and in the forceps elevator recess while raising and lowering the forceps elevator, and repeat brushing and/or flushing the forceps elevator and the forceps elevator recess until no debris is observed upon the inspection."
- Inspect all items for residual debris. **Should any debris remain, repeat the entire cleaning procedure until all debris is removed.**

35

BEST PRACTICE IN INSPECTION

SGNA	AORN
Treat as a safety stop or "time out" to ensure the endoscope is visually clean before proceeding to the next step of HLD.	Visually inspect with lighted magnification for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization.
Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion, discoloration, retained debris).	Inspection helps to identify residual organic material and defective items and remove from service soiled / defective items that might put patients at risk for infection or injury.
Repeat manual cleaning step(s) if not clean.	
Minimum standard for cleaning assessment of scopes.	
Need adequate lighting	

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CDC – VISUAL INSPECTION

Ensure that the elevator mechanism is thoroughly cleaned and free of all visible debris.

- Visual inspection is to be done with the elevator in the "open/raised" position and "closed/lowered" position to ensure there is no visible debris above or below the elevator mechanism.

Consideration should be given to use of a magnifying glass (e.g., 10x) to improve detection of residual debris around the elevator mechanism

Centers for Disease Control and Prevention
National Center for Health Statistics

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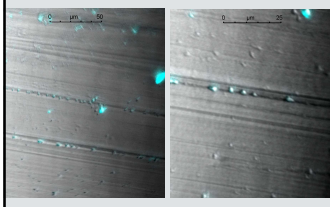
WHAT WE SEE INSIDE WHEN WE LOOK



Channel under magnification w/ bacteria stained

(SOURCE: US FDA OSEL)

38

WHAT ABOUT FUNCTIONALITY

STORZ KARL STORZ – ENDOSKOPE

"All moving p… stopcocks, handles, etcetera, should be ea… tubes. All instruments should be ch… king parts. Please refe… ach type of instrume…

Inspection

Inspection of KAR… ns of damage must be performed… surgical procedure. All instruments must be ex… function prior to use.

"WARNING: Do not use insulated instruments if any signs of damage are present."

39

NOT FOR JUST LAP INSTRUMENTS BUT ANY INSULATED INSTRUMENT

(Spectrum Laparoscopic Instrumentation) under Inspection and Assembly ***"Important Note: At this point in the process, Spectrum recommends testing the insulation for cracks, gaps where the shaft meets the tip assembly, and pinholes"***

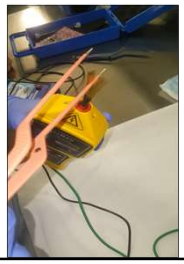
NOTE: This IFU does not come out and state every use, but how the IFU reads is after the decontam process, which is every instrument being used.

(ASSI Bipolar Scissor) under Inspection of instruments ***"Recommends establishing a procedural review, by which the instrumentation are inspected frequently (before and after each use) for damage such as: Bullet three, For insulated instruments: cracks, nicks, lacerations, or abrasions in insulation."***

(Vmueller Bipolar Jewelers Insulted Forceps)***"Prior to use, inspect devices to ensure proper function and condition. Do not use devices if they do not satisfactorily perform their intended function or if they have physical damage."***

40

HOW OFTEN ARE YOU TESTING YOUR INSULATION



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SUPPORT FOR INSULATION TESTING

ANSI/AAMI ST90

- Performance Qualification(PQ): demonstrating that the process is constantly producing acceptable quality; the user usually performs this - verifies
  - Visual inspect for defects
  - Check for leakage - Insulation testing
    - Verify integrity of all insulation with tester

AST

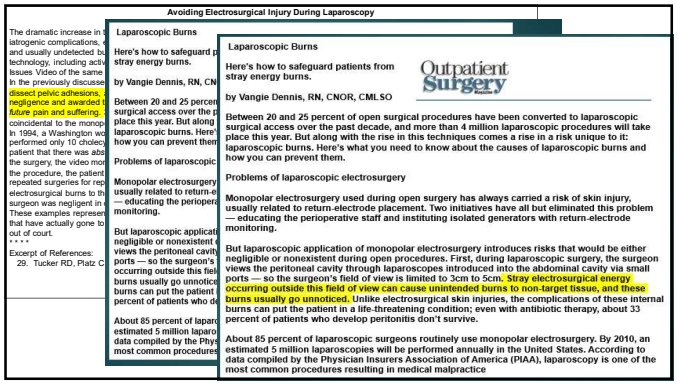
a) *"Visually inspect the insulation prior to completing the cleaning process. Instruments and electrodes with cracks or holes in the insulation should be removed from service and sent for re-insulation repair.*

b) *Instrument or electrode should be cleaned with a soft brush and nonabrasive cleaning agent, and rinsed.*

c) *A microscope should be used to visualize the integrity of the insulation of each item."*

https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard%20Electrosurgery.pdf

42



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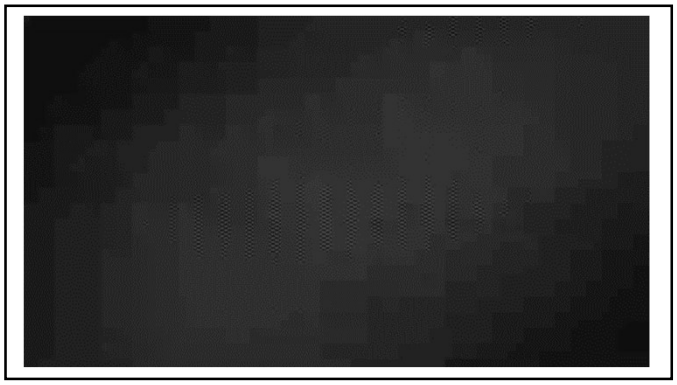

44

Not just any tray will work

For some devices, there might be special instructions regarding placement in an instrument set. Only devices and accessories designed and intended for medical device sterilization should be used. The device manufacturer's written IFU for placement should be followed, in addition to the following recommendations:

a) The assembler should verify that the items to be sterilized and any containers or organizing accessories being used are compatible with the intended sterilization cycle.
b) Instruments should be positioned to allow the sterilant to come into contact with all surfaces.
c) Lumened ports should be opened.
d) Ratcheted instruments should be unlatched. Racks, pins, stringers, or other specifically designed devices can be used to hold the instruments in the unlatched position.
e) Instruments comprising more than one part or with sliding pieces or removable parts should be disassembled if it is so specified in the manufacturer's written IFU.
f) Sharp items should be protected from damage. Tip protectors, if used, should be steam-permeable, fit loosely, and be used according to the manufacturer's written IFU.
g) Instruments should not be held together with rubber bands.
h) Items with concave surfaces and/or broad, flat surfaces that will retain water should be placed on edge.
i) Heavy instruments should be placed in such a way that they will not damage more delicate items. Lighter instruments should be positioned to protect tips and to prevent damage from changes in position.
j) Instrument sets, including the sterile barrier system, should weigh no more than 11 kg (25 lb) (ANSI/AAMI ST77).
k) Organizing containers and other organizing accessories may be placed in the set if they are designed and intended for sterilization. Paper–plastic sterilization pouches should not be used as organizing accessories (see 9.5.4).
l) Tray liners designed and intended for sterilization may be used to protect instruments from damage and/or absorb moisture.
m) When rigid sterilization container systems are used, all items should be contained in the basket or tray within the container system.
n) The instrument tray should be large enough to permit equal distribution of the contents in terms of weight and metal mass.
o) If a mat is used within an instrument containment device or tray, the container, mat, and device manufacturers' written IFU should all be followed.

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JUST NOT RIGHT

All of these examples can cause failures in sterilization, storage or opening on the field

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ST 79 SECTION 9.2 SELECTION OF BARRIER SYSTEMS

When selecting a sterile barrier system, personnel should obtain the current written IFU and have it readily accessible.

A sterile barrier system should

a) allow air removal to permit sterilant penetration of the package contents;
b) provide a barrier to microorganisms during sterilization processing, handling, distribution, transport, and storage;
c) resist tearing or puncture;
d) allow a method of sealing that results in a complete seal that is tamper-evident and provides seal integrity;
e) maintain protection for the sterile contents during storage and transportation to the point of use;
f) allow for aseptic presentation;
g) be free of toxic components and non-fast dyes;
h) be non-linting; and
i) be compatible with the intended methods of sterilization, sterilization parameters, and the devices to be sterilized.

Packaging policies and procedures and packaging techniques should be based on the sterile barrier system manufacturer's written IFU.

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ALL ARE ACCEPTABLE IF USED PROPERLY

Wrap	Peel pouch	Containers
Woven and nonwoven wraps should be: a) FDA cleared as medical sterilization packaging systems for use in health care facilities; b) stored and maintained according to the manufacturer's written IFU; c) examined prior to use for defects and debris; and d) selected according to the size, shape, and weight of the medical device to be processed. Items should be wrapped securely to prevent gaps in the wrap material. Items should not be wrapped too tightly because tears and punctures could occur.	Paper–plastic pouches are generally used for small, lightweight, low-profile items. The paper–plastic pouch should: a) be used, filled, and opened according to the pouch manufacturer's written IFU; b) be of a size and strength to accommodate the item being packaged; and c) be closed so that all pouch seals are smooth (i.e., without folds, bubbles, or wrinkles).	A rigid sterilization container system should be inspected before use to ensure that: a) the latching mechanism or closure will remain secure during the sterilization process; b) the sealing or mating surfaces or edges of the container system and lid are not dented or chipped; c) filter retention mechanisms and fasteners such as screws and rivets are secure and are not distorted or burred, the securing mechanism functions properly, and the filter medium is not damaged; d) the gaskets are pliable, securely fastened, and without breaks or cuts; and e) the valves work freely and are not broken, cut, chipped, or dented. Only filters recommended by the rigid sterilization container manufacturer should be used.

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WOULD YOU USE THESE

- Poorly maintained
  - Sticker residue
  - Flaking stickers
- Warped filter plate
- Dented lid




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ST 79 SECTION 10: STERILIZATION

The following should be considered when loading a sterilizer for processing:

a) The facility should establish written policies and procedures for loading sterilizers.

b) The sterilizer manufacturer's written IFU can be referenced for proper use of the sterilizer accessories (e.g., carts and carriages) and sterilizer control operation.

c) Items requiring the same cycle parameters should be processed in the same load.

d) Load configurations should ensure adequate air removal, penetration of steam into each package, and steam evacuation.

e) Cart shelf liners that have been validated for this purpose may be used and should be made of a non-linting, absorbent material that will dry in the drying time selected for the rest of the load. Follow the liner manufacturer's written IFU for use and replacement instructions.

f) Heavier items should be placed on the bottom of the sterilizer racks and the weight distributed evenly. (See Figure 7 for examples of proper loading.)

g) Stacking of items should be avoided unless the packaging manufacturer's written IFU supports such practice.

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IS THIS GOOD OR NOT?

Maybe – Maybe not

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STERILIZATION CYCLES

ST 79 Section 10.2.2

The sterilizer manufacturer's written IFU should be followed for operation of the sterilizer and indications for use.

a) Differences between the programmed cycle and the cycle parameters recommended by the device manufacturer should be investigated and, if possible, reconciled before the items are sterilized. If differing instructions cannot be resolved, the device manufacturer's IFU should be followed.

b) If a rigid sterilization container system or a sealed containment device designed for IUSS is used as packaging, the container system manufacturer's written IFU regarding exposure time should be consulted and reconciled with that of the sterilizer manufacturer.

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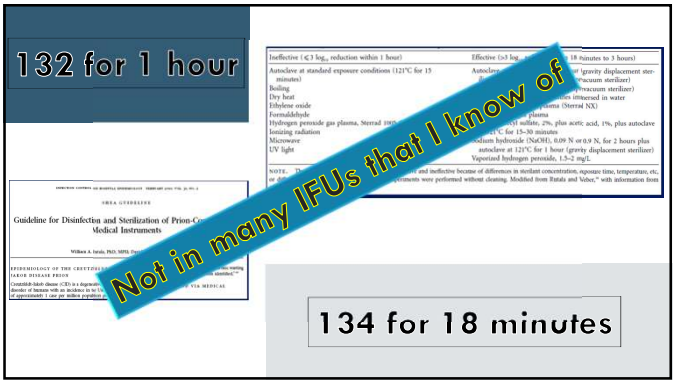
132 for 1 hour



Not in many IFUs that I know of

134 for 18 minutes

54

Sterile items should be stored under environmentally controlled conditions in a manner that reduces the potential for contamination.

Sterile storage areas should be kept clean and dry.

Sterile items should be

1) stored far enough away from the floor, the ceiling, and outside walls to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes;
2) stored at least 8 to 10 inches above the floor, at least 18 inches below the ceiling or the level of the sprinkler heads, and at least 2 inches from outside walls;
3) stored in such a way that wrapped packages are not stored beneath rigid sterilization containers on the same shelf; and
4) positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.

ST 79 section 11.1.1 Storage facilities

MAINTAINING STERILITY

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THIS ISN'T HOW ITS DONE

- Uncovered bottom shelf
- Stacked wrapped trays
- Compressed wrapped trays
- Inevitable sliding of trays when they are removed

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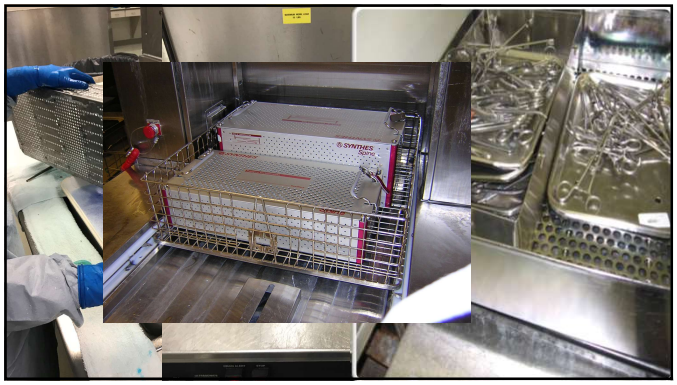
HUMAN FACTORS

One of the hardest things to control

57



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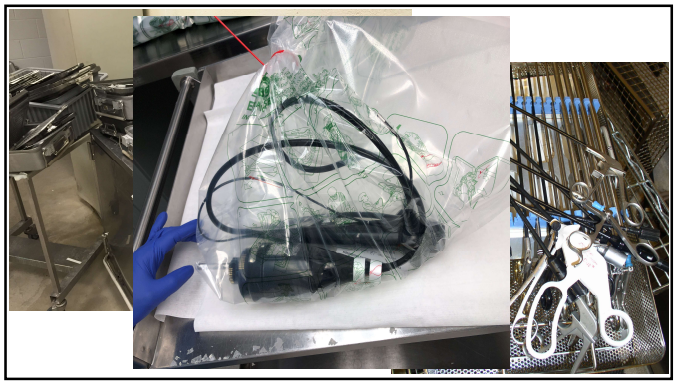

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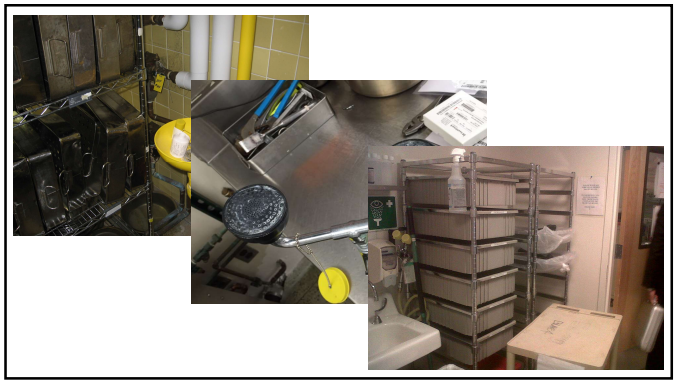

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IN CONCLUSION:

- ❑ CS departments play a crucial role in nearly all aspects of the instrument life cycle
- ❑ Building quality into each and every part of the cycle will create better outcomes
- ❑ Standards and guidelines for each step in the cycle should be consulted and followed

Seth definition of human factors: People are crazy ☺

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THANK YOU!

Question?

For a copy of this program please visit:

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