The WHY Behind Instrument Reprocessing

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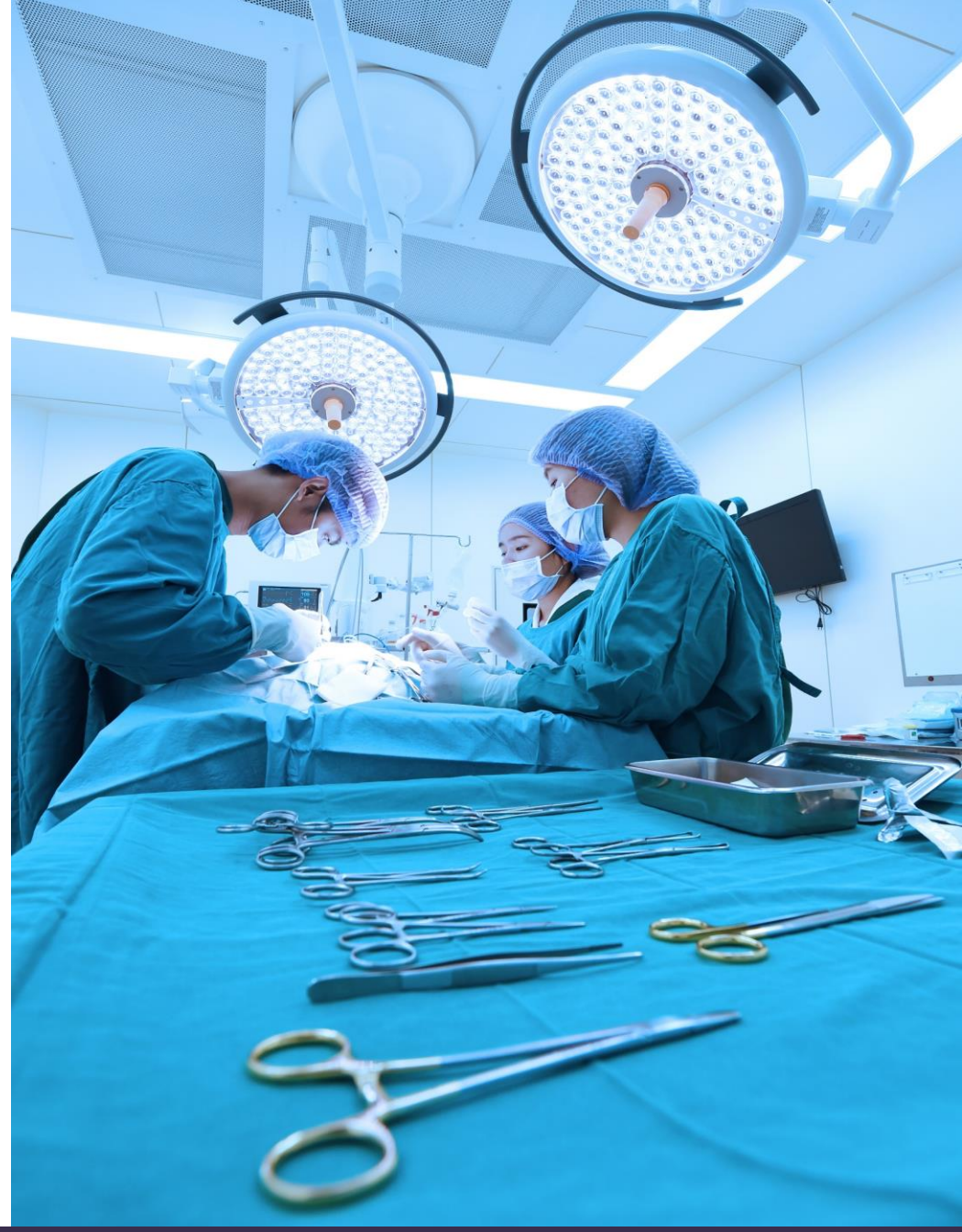
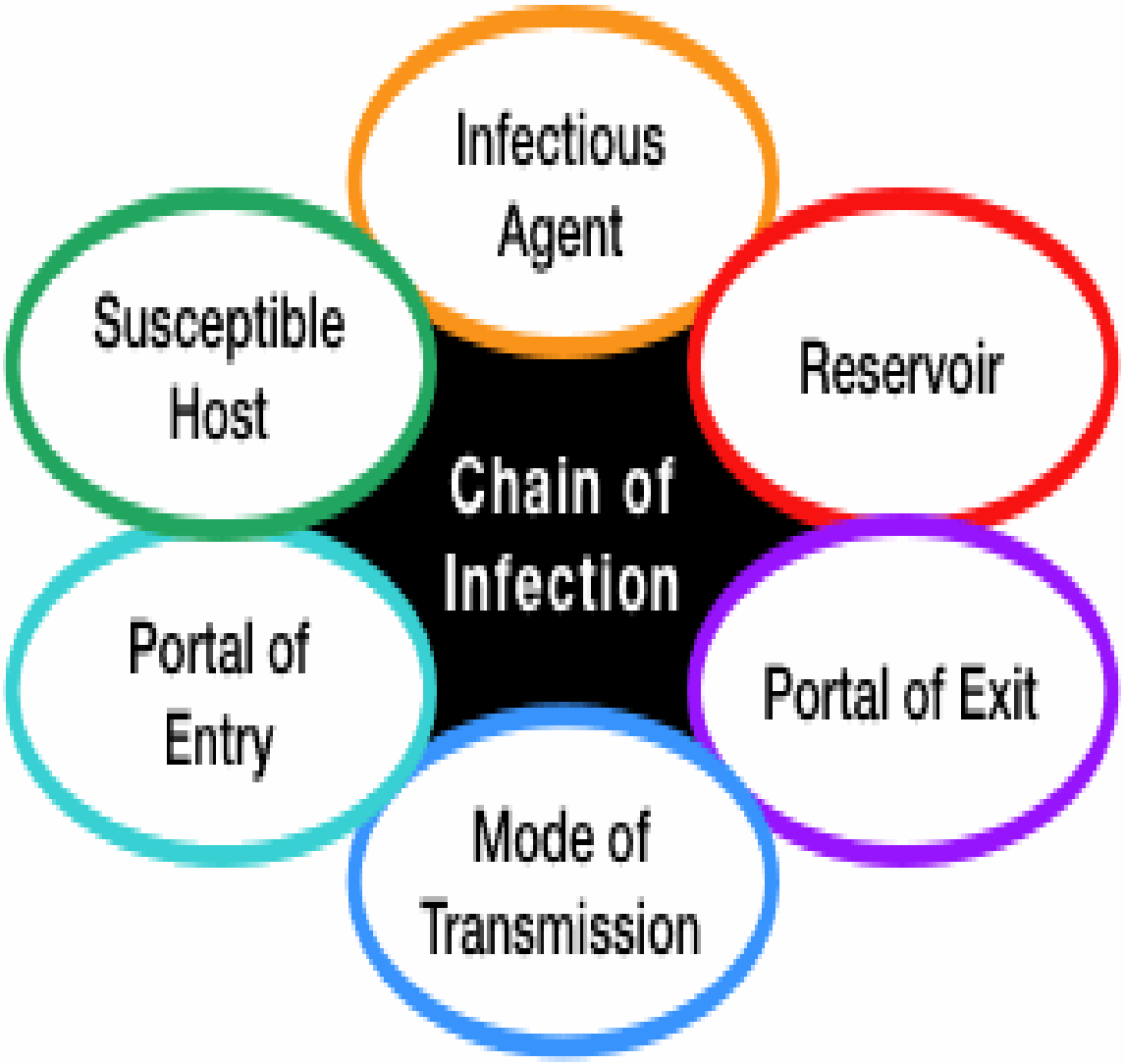
Objectives

- Describe the different steps in instrument reprocessing and why they are important for patient safety
- Understand the advantages of terminal sterilization versus high level disinfection.
- Discuss how AAMI and AORN standards/guidelines influence best practice for instrument reprocessing



The Chain of Infection



Surgical Site Infections (SSI)

- Occur within 30 days of surgery or 1year when an implant is involved.
- SSI constitute the majority of nosocomial infections.
- SSI account for 20% of all HAI.
- 157,000 SSI cases reported in the US in 2018…8,025 resulted in death.
- The US economic burden of SSIs is $3.3 billion.

The Steps in Reprocessing Medical Instruments

1. Point of use treatment

2. Preparing dirty instruments for transport

3. Transport

4. Cleaning and disinfection

5. Inspection

6. Packaging ***if not*** high-level disinfecting

7. Sterilization

Point of Use Treatment

- Begin preparation for instrument decontamination at the point of use.
  - Moisten and remove gross soil.
  - Use sterile water for removal of gross soil during the procedure.

  Before transport:
  - Dispose of sharps.
  - Protect delicate instruments.
  - Keep instruments moist by using enzymatic pre-treatment product or a water moistened towel over instruments.
  - Dispose of liquids before transport.

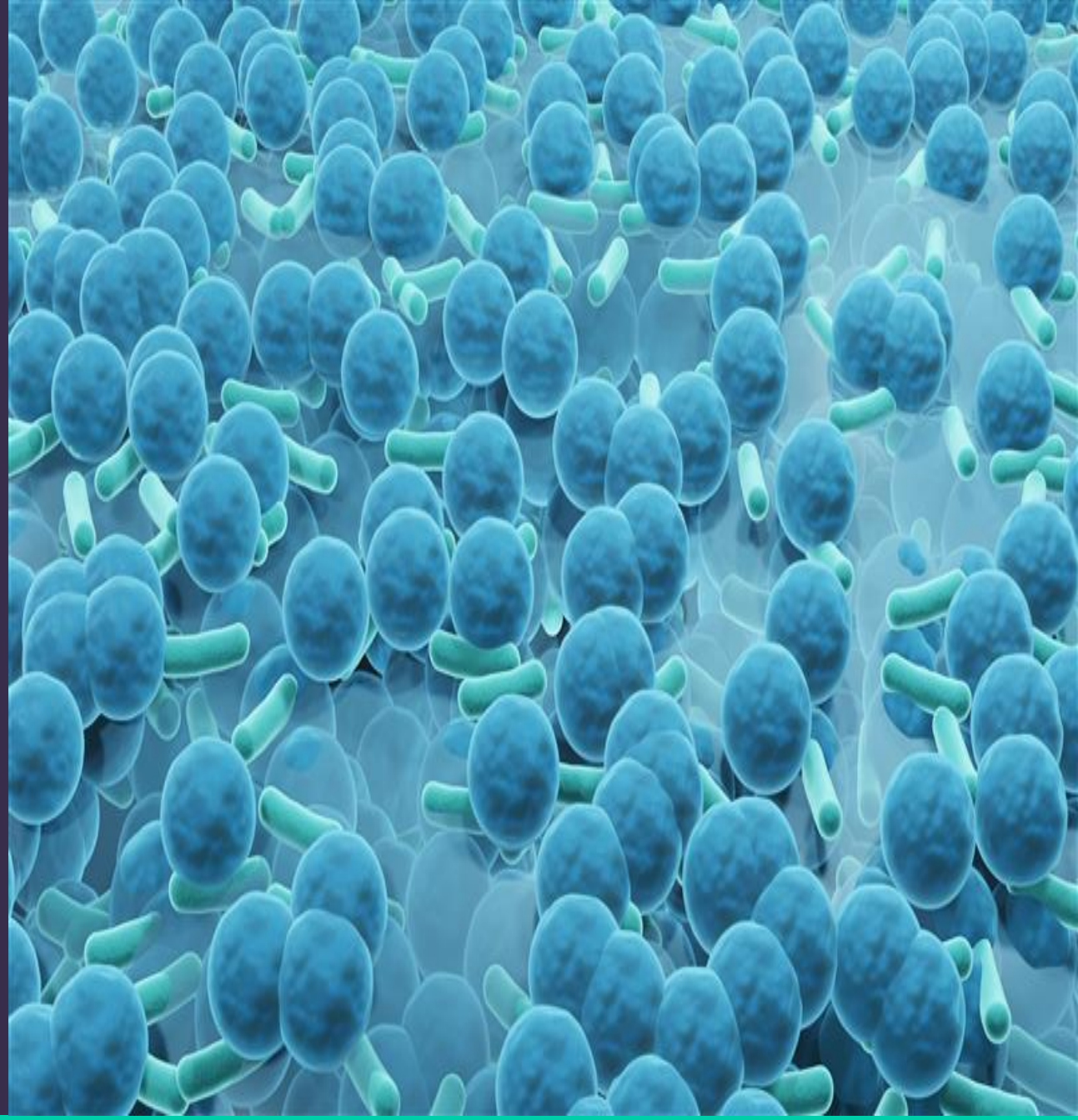
WHY?

- Once dried organic material is difficult to remove.
- Soil that is left on an instrument can affect the efficacy of subsequent disinfection and sterilization.
- Soil that dries promotes biofilm formation.

What is Biofilm?

According to the Centers for Disease Control (CDC)

"A biofilm is a community of living microorganisms embedded in a slimy matrix that provides protection against external aggressors, like desiccation, antibiotics, or disinfectants, as well as the host's immune system" (www.cdc.com).



Transport

ASAP

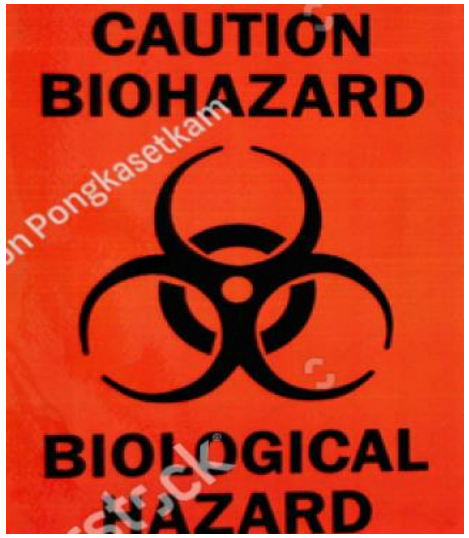
Transport in a **closed container** to decrease exposure to contaminated fluids.

- Leak Proof
- Puncture Resistant
- Biohazard label
- Size appropriate to contain items

WHY?

Protection of instruments

Containment of contaminated devices



Prior to Cleaning ……

What is Personal Protective Equipment (PPE)?

Personnel working in decontamination area handling contaminated instruments wear PPE

Fluid-resistant gown with sleeves

Gloves that extend beyond the cuff of the gown

Mask and eye protection or a full-face shield

Shoe covers or boots

Cleaning and Decontamination

Decontamination is a process or treatment that renders a device, instrument, or work surface safe to handle.

Policies and procedures:

Based on manufactures IFUs Instructions for Use contain the process for the decontamination of reusable devices

Policies set standards and expectations as to how the cleaning process will be accomplished

Manufacturers Instructions for Use (IFUs) should be current and accessible

Cleaning: Manual vs. Automation

Manual: Hand wash, brush, flush, rinse and dry.

Automated: Flushing systems, washer-disinfectors, ultrasonic cleaners.

Automated Cleaning

- Automated cleaning remove microbial load better than manual cleaning
- *In evaluating cleaning methods for minimally invasive surgical procedures, a study focused on assessing the effectiveness of ported and non-ported accessory devices employed in minimally invasive surgery. The results showed that automatic cleaning was more effective than manual cleaning. It achieved greater than 99% reduction of soil parameters in both non-ported and ported laparoscopic devices (sterileprocessingtech.org)*

Cleaning Verification Tests

“Different cleaning verification methods have benchmarks that have been established by the manufacturer or through third party studies” (AAMI p. 127).

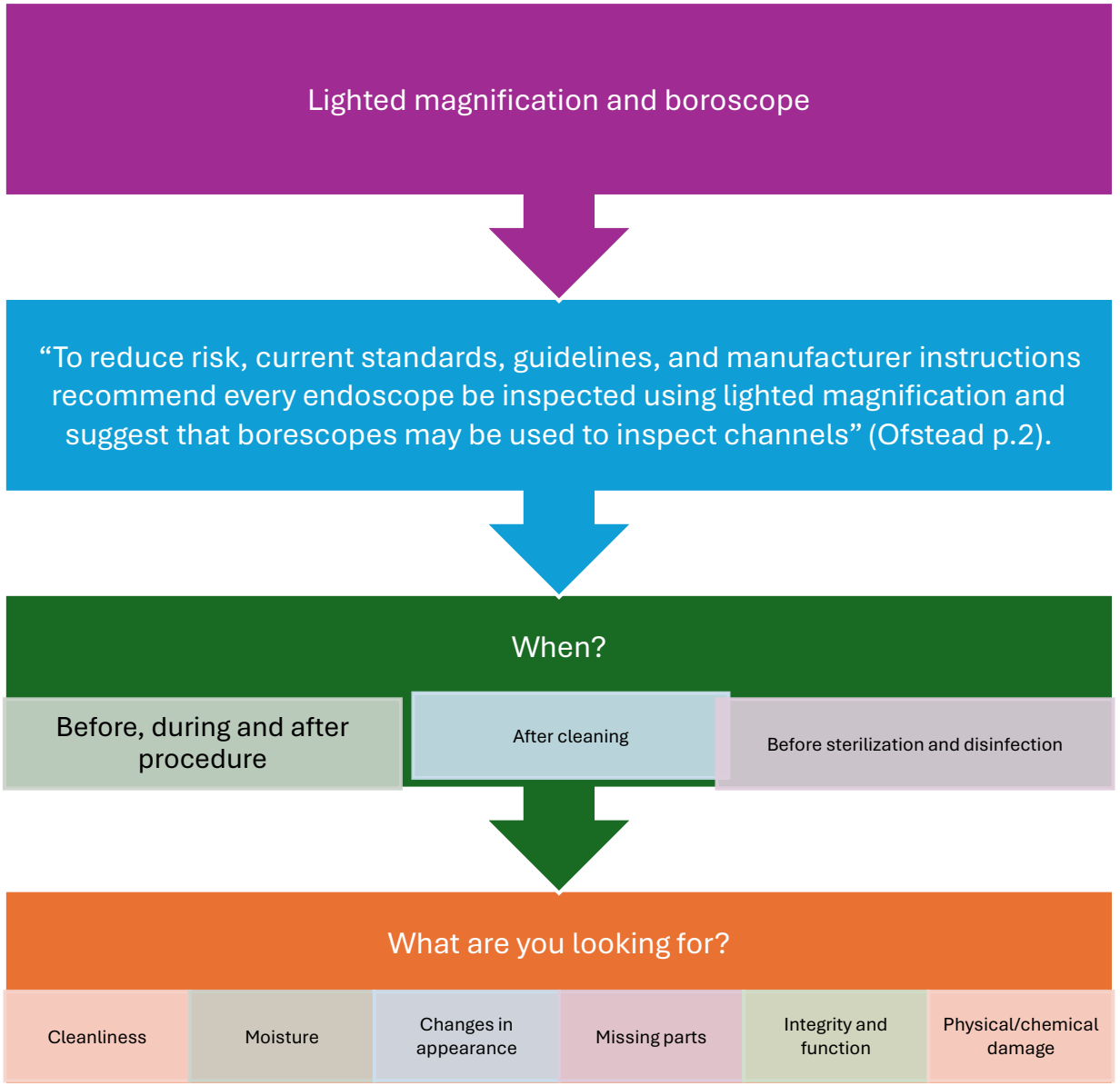
Read and understand the MIFU!

What about flexible endoscopes?

Cleaning Verification for Flexible Endoscopes

- Test after cleaning and before disinfection or sterilization
- Detects residual organic soil and microbial contamination
- Testing frequency determined by facility
- High Risks scopes test after each use
- Duodenoscopes (ERCP)
- Linear ultrasound (EUS)
- Bronchoscopes
- Endobronchial Ultrasound (EBUS)
- Ureteroscopes & Cystoscopes

Inspection


Lighted magnification and boroscope
“To reduce risk, current standards, guidelines, and manufacturer instructions recommend every endoscope be inspected using lighted magnification and suggest that borescopes may be used to inspect channels” (Ofstead p.2).
When?
Before, during and after procedure
After cleaning
Before sterilization and disinfection
What are you looking for?
Cleanliness
Moisture
Changes in appearance
Missing parts
Integrity and function
Physical/chemical damage

Inspection

WHAT?

Inspect for flaws, damage debris, detergent residue and completeness when dried (AAMI p. 43)

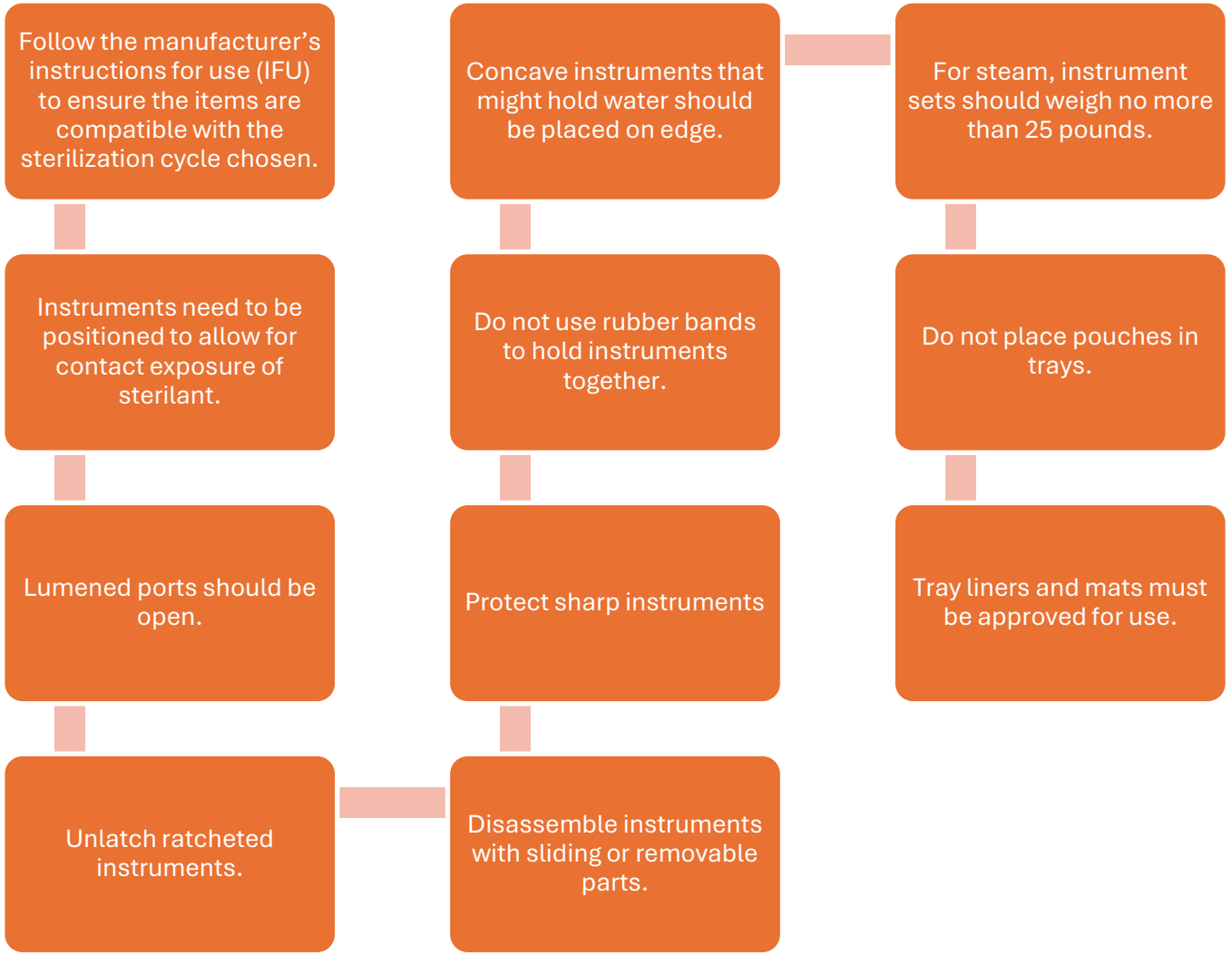
HOW?

Visual, including magnification
Cleaning verification. Different cleaning verification methods have benchmarks that have been established by the manufacturer or through individual studies (AAMI p. 127).

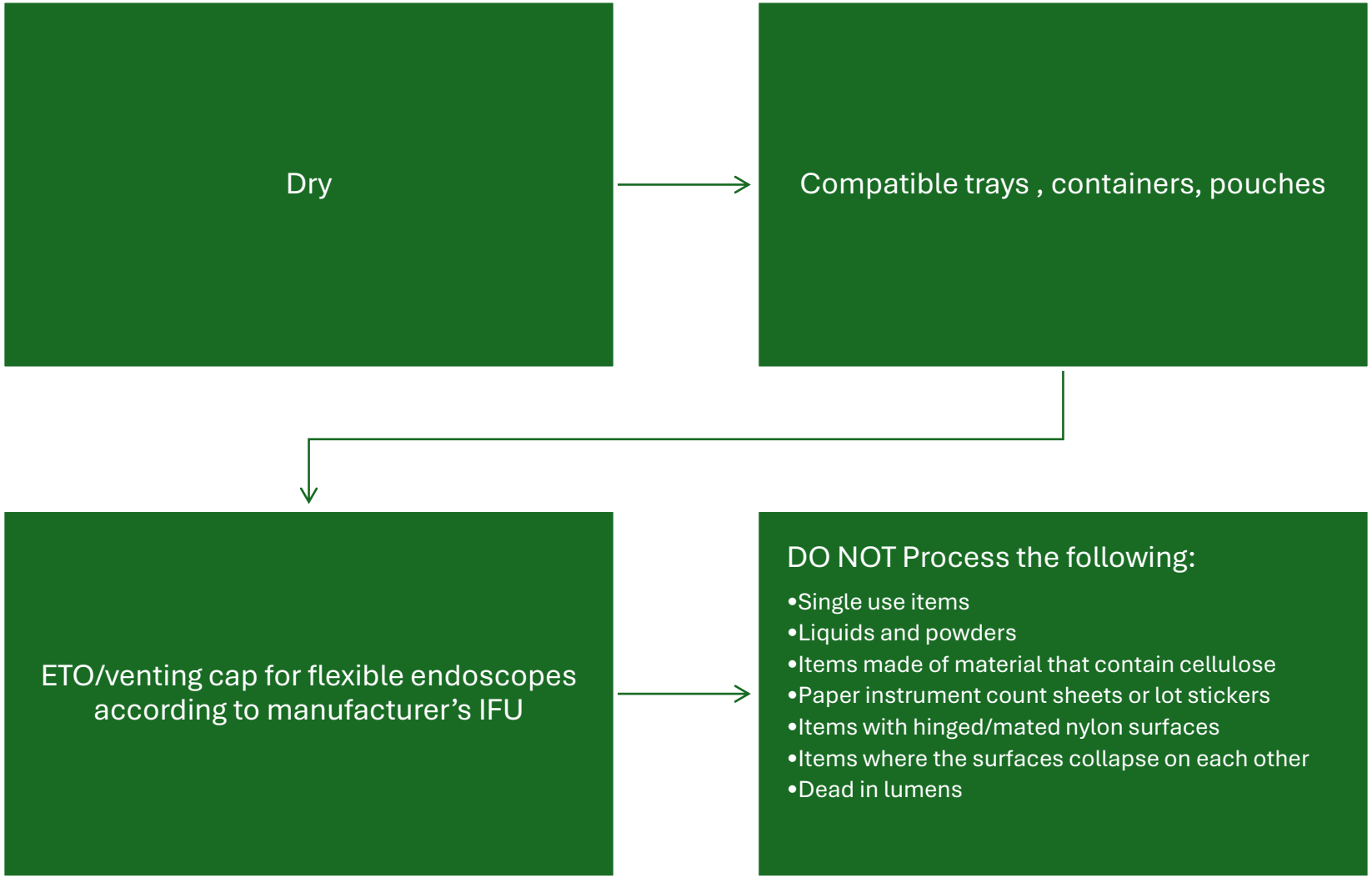
WHY?

Minimizing the contamination of a device through proper cleaning, inspection and assembly is important for effective sterilization AAMI p. 40).

Assembly - Steam



Assembly- Low Temperature Gas Plasma



Packaging

STEAM

- Paper-plastic pouches
- Polypropylene wrapped trays
- Rigid containers (approved)
- Indicators and integrators

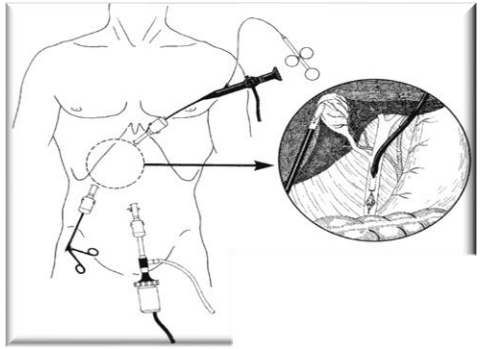
Low Temperature Gas Plasma (LTGP)

- Tyvek-mylar pouches
- Polypropylene wrapped trays
- Rigid containers (approved)
- Indicators and integrators

Determine Whether a Device Can Be Reprocessed

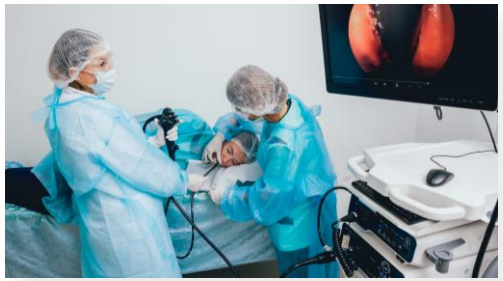
Manufacturer's Instructions for Use

Spaulding's Classification



→ **CRITICAL**

SEMI-CRITICAL ←



→ **NON-CRITICAL**

High Level Disinfection vs. Terminal Sterilization

High Level Disinfection:

“A process that kills all microbial organisms but not necessarily large numbers of bacterial spores” (AAMI p.6).

Sterilization:

“Validated process used to render a product free from viable organisms.”

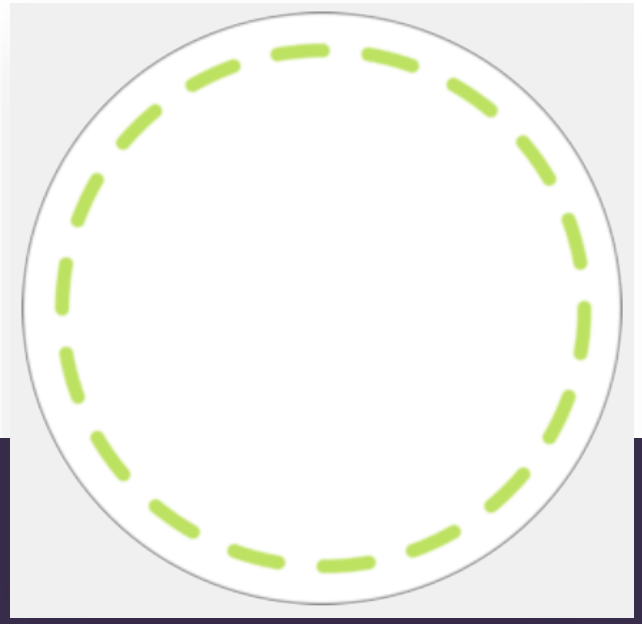
Terminal Sterilization:

“Process by which the product is sterilized within a sterilie barrier system that permits storage for use at a later time” (AAMI p.10).

Disinfection and Sterilization

WHAT'S THE DIFFERENCE?

Illustration of microbial life post-reprocessing



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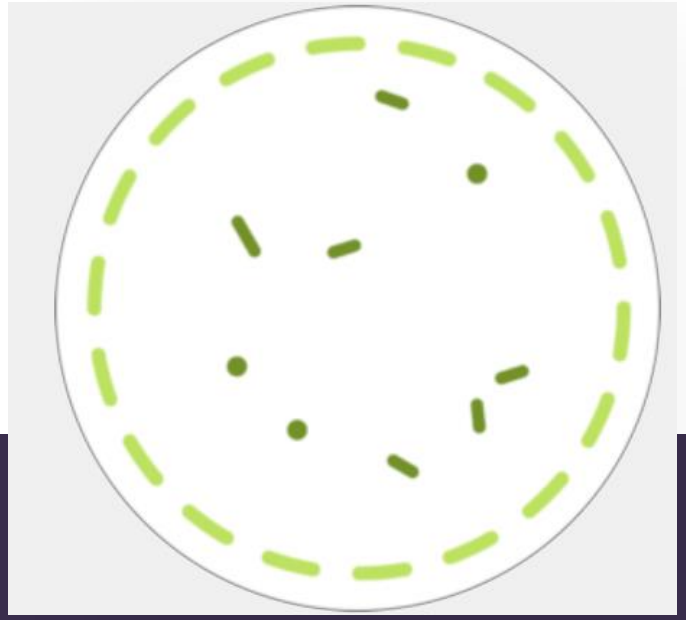
Sterilization



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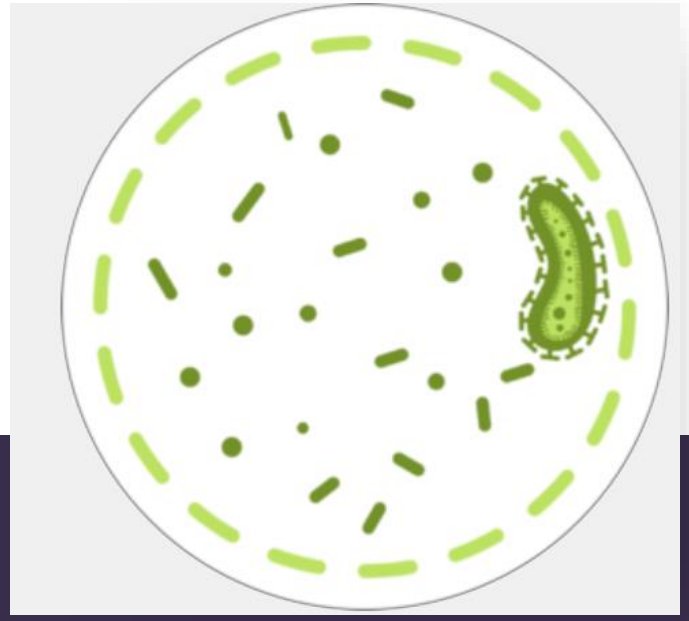
High-level Disinfection



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Low-level Disinfection

General Consideration for Loading Steam/LTGP

Steam

- Follow the sterilizer's IFU
- Load configurations need to allow for air removal, steam penetration and removal
- Place heavier items on the bottom of sterilizer racks
- Avoid stacking, Trays/containers should be placed horizontally
- Paper-plastic pouches-stand on edge in same direction (paper to plastic)

LTGP

Follow the sterilizer's IFU
Do not stack
Do not place items in contact with RF electrode
Only use Tyvek –Mylar pouches and place on edge in the same direction or lay flat

Choosing the Cycle

Follow the manufacturer's IFU

1.3 Effective use of vaporized hydrogen peroxide sterilizers

"To ensure efficacy when using a vaporized hydrogen peroxide sterilizer, the user should observe the following guidelines:

a) The medical device and/or sterilizer manufacturers' written IFU should be consulted to determine the compatibility of the device with vaporized hydrogen peroxide sterilization" (AAMI ST 58 p.147).

Immediate Use Steam Sterilization (IUSS)

Sterilization method that involves the shortest amount of time between processing and transfer to the sterile field

"Immediately" implies that a sterilized item is used during the procedure for which it was sterilized

A sterilized item for IUSS is not stored for future use nor held from one surgery to another

IUSS (cont)

Avoiding the need → **Receive loaner instruments on time**

→ **Ensure adequate inventory**

→ **Allow for sufficient turnover time when scheduling surgeries**

If a rigid container system or a sealed containment device designed for IUSS is used as packaging, follow the manufacturer's instructions for use for exposure time/reconcile with sterilizer manufacturer

Monitoring Terminal Sterilization vs. HLD

Steam/LTGP

- Chemical
- Physical/mechanical
- Biological

HLD

Manual

- Temperature
- Time
- Efficacy using test strips

Automated Endoscope Reprocessor (AER/ECR)

- Follow MIFU
- Time/proper cycle
- Efficacy of disinfectant using test strips or automated process

Chemical Indicators

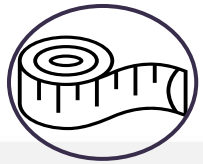
"Chemical Indicators provide visual confirmation that the sterilization process has reached the required conditions for effective sterilization"

ANSI/AAMI ST 79 2017

- Helps to detect sterilization failures
- Used following manufacturer's written IFU
- Used as part of quality assurance program
- Used with physical monitors and BI

Types of Indicators

There are 6 Types



Type 1

Process Indicator
Example: Tape

Type 2

Indicators used for Specific Tests
Example: Bowie Dick

3

Type 3

Single critical process variable indicators
Example: Internal indicator

4

Type 4

Multicritical process variable indicators
Example: Internal indicator

Type 5

Integrating indicators
Example: Internal integrator used for implants

Type 6

Emulating indicators
Example: Used for special cycles

Is One Type Better Than the Other?

Type 2 CI Testing: Bowie Dick, Why is it Done?

Bowie Dick tests are used for dynamic air removal sterilizers, not gravity sterilizers

To check for air leaks or inadequate air removal

To check for inadequate steam penetration

To check for non-condensible gases

Processing a Bowie Dick:

- Place horizontally on the cart of shelf, over the drain
- Select the cycle per the steam sterilizer manufacturer
- Interpret the results

What is the difference between type 5 and 6?

Type 5: Integrating Indicators

- ✓ Reacts to all critical variables (time, temperature, pressure of saturated steam)
- ✓ Correlates with biological indicators (Bis)
- ✓ Used in conjunction with Bis for release of loads containing implants

Type 6: Emulating Indicators

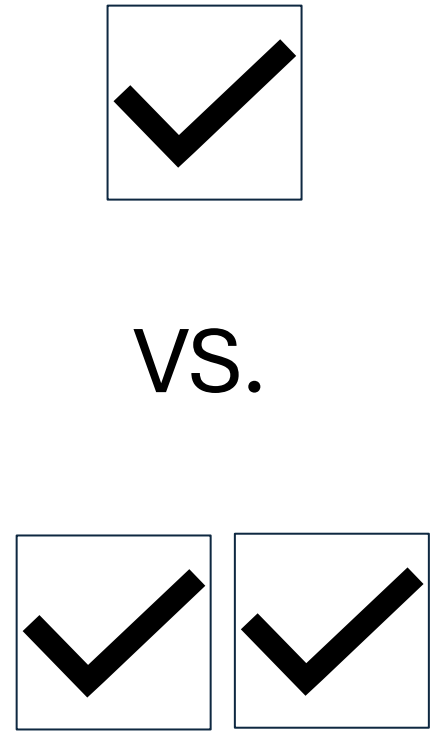
- ✓ Reacts to all critical variables of specified sterilization cycles
- ✓ May be used for release of non implant loads

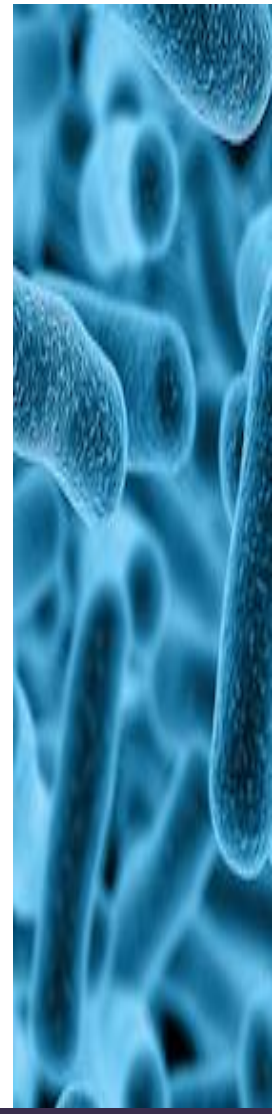
What about LTGP?

- “Chemical indicators cleared by the FDA for use in the specific vaporized hydrogen peroxide sterilizer should be used to monitor the process.
- A CI should be used on the outside of each package unless the internal indicator is visible.
- An internal pack CI should be used inside each package, tray, containment device (rigid sterilization container system, medical device case, cassette, or organizing tray) to be sterilized.
- The use of a multivariable chemical indicator as cleared by the FDA monitors two or more parameters of the chemical vapor sterilization process and provides more information about the process as compared to sterilization process indicators as cleared by the FDA and can provide additional quality assurance for the individual monitoring of such items as complex devices, surgical trays, and rigid sterilization container systems” (AAMI ST58 p. 148).

Biological Indicator vs Process Challenge Device (PCD)

BI	PCD
• Accompanies products during sterilization process • Monitors adequacy of sterilization • Contains a known number of microorganisms (Ex: *Geobacillus Stearothermophilus*)	• Is an item designed to constitute a defined resistance to a sterilization process • Used to assess performance of the process • Contains an Integrator and BI





What do the Standards and Guidelines say?

ANSI/AAMI ST 79 2017

13.5.1

"A Type 5 integrating CI within a PCD (that also contains a BI) should be used to monitor each load containing implants and may be used as a basis for early load release in documented emergency situations only; however, loads containing implants should always be biologically monitored. Implants should be quarantined until the BI results (early readout or spore growth) are available.

In an emergency situation, implants may be released before the BI results are available (see 13.6.3); however, the BI should continue to be incubated" p.78.

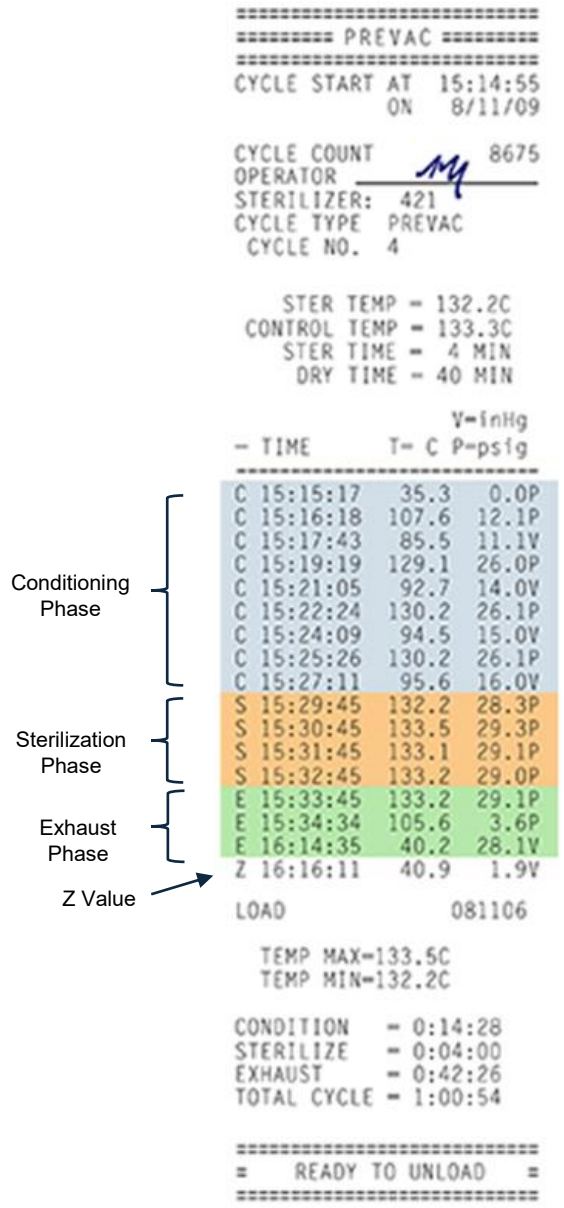
ANSI/AAMI ST 79 2017

13.5.3.2 Using biological indicators

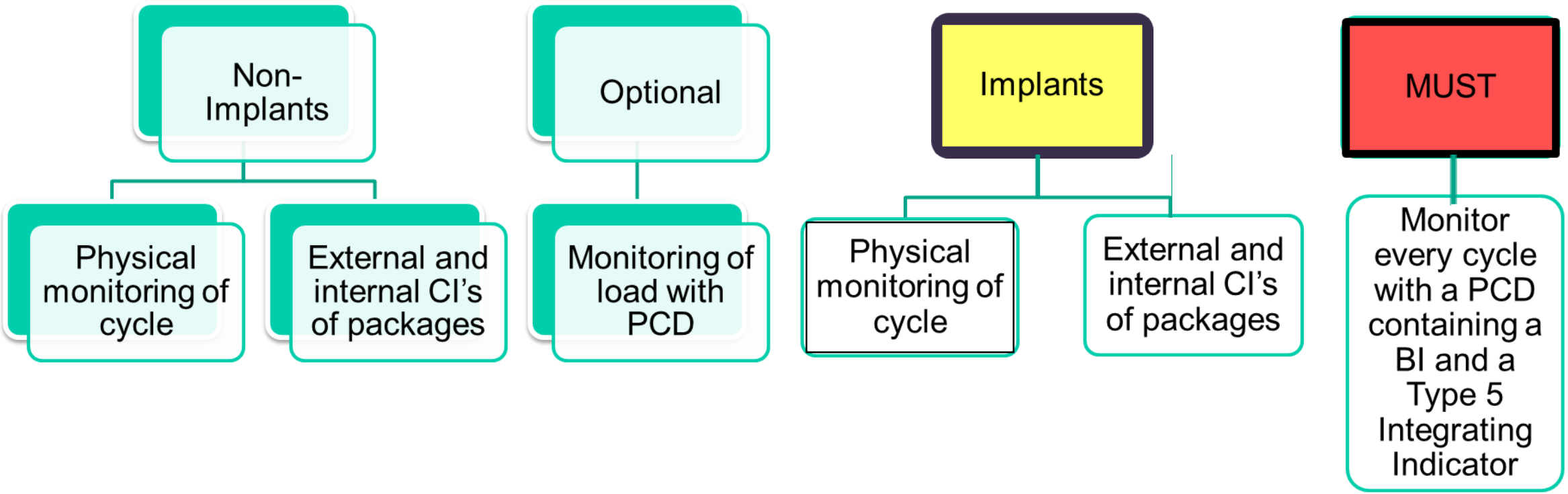
"Biological indicators should be used within PCDs (see 13.5.4, 13.7.2.1, 13.7.3.1, and 13.7.4.1) for routine sterilizer efficacy monitoring at least weekly, but preferably every day that the sterilizer is in use (see 13.7)" p. 80.

Physical Monitoring/Documentation

- Used to monitor sterilizer performance
  - Time
  - Temperature
  - Pressure monitors
  - Manual or digital documentation
- Confirms that cycle parameters were met
- Operator signs the chart, printout or electronically



Routine Steam Sterilization Load Release



What is a Standard and Why is it Important?

What

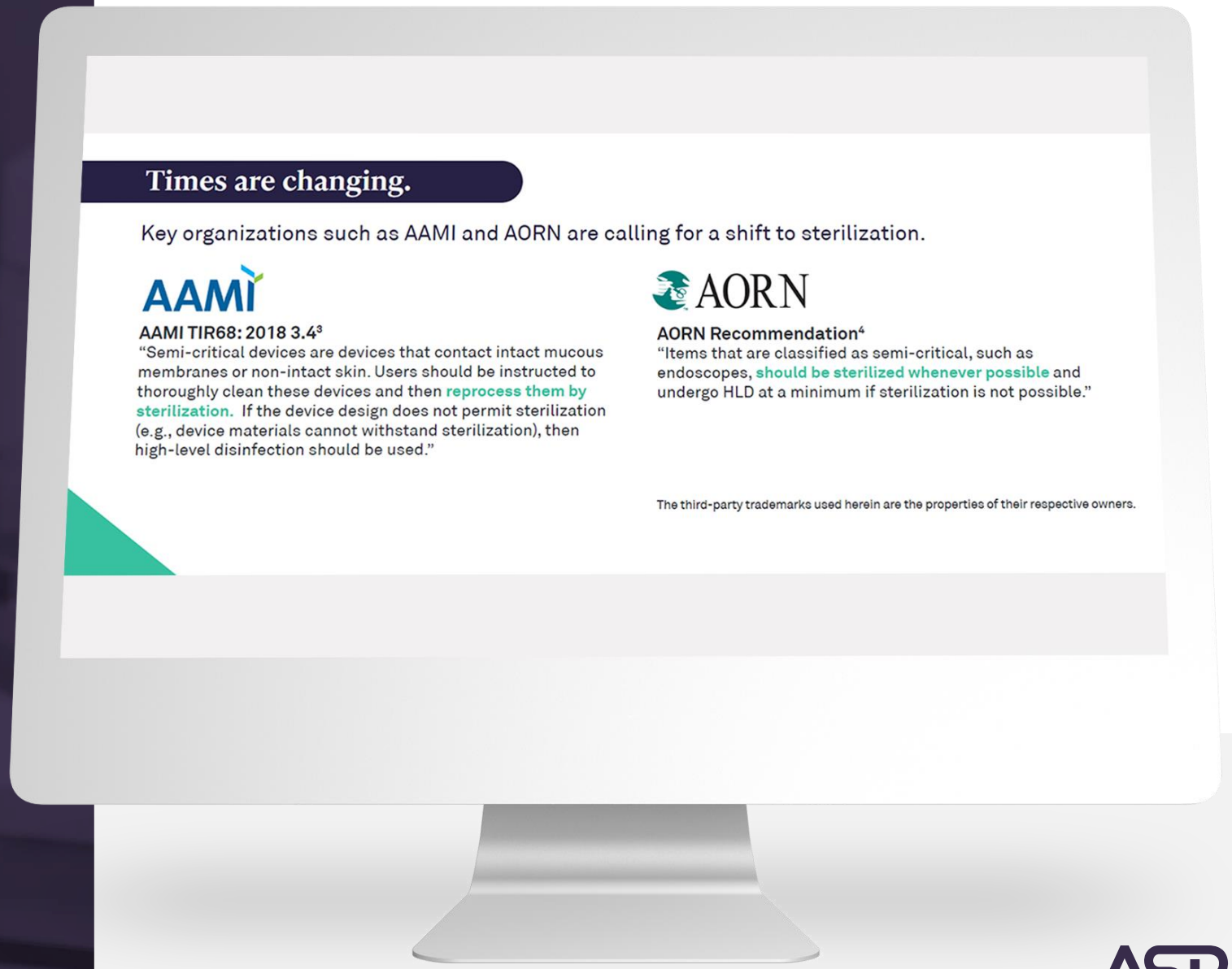
- A standard is a blueprint for ensuring the highest patient care and safety standards (Frieders).
- A standard is a set of agreed-upon guidelines or specifications for developing a product, performing a task, or designing a process (Array/AAMI,org)

Why

- Standards are used to ensure the quality, safety, and reliability of products and services (Array/AAMI.org).
- Standards are used to assist in writing policies and procedures that relate to best practice.

Why Sterilization for Semi-Critical Devices?

IF YOU CAN STERILIZE, YOU SHOULD



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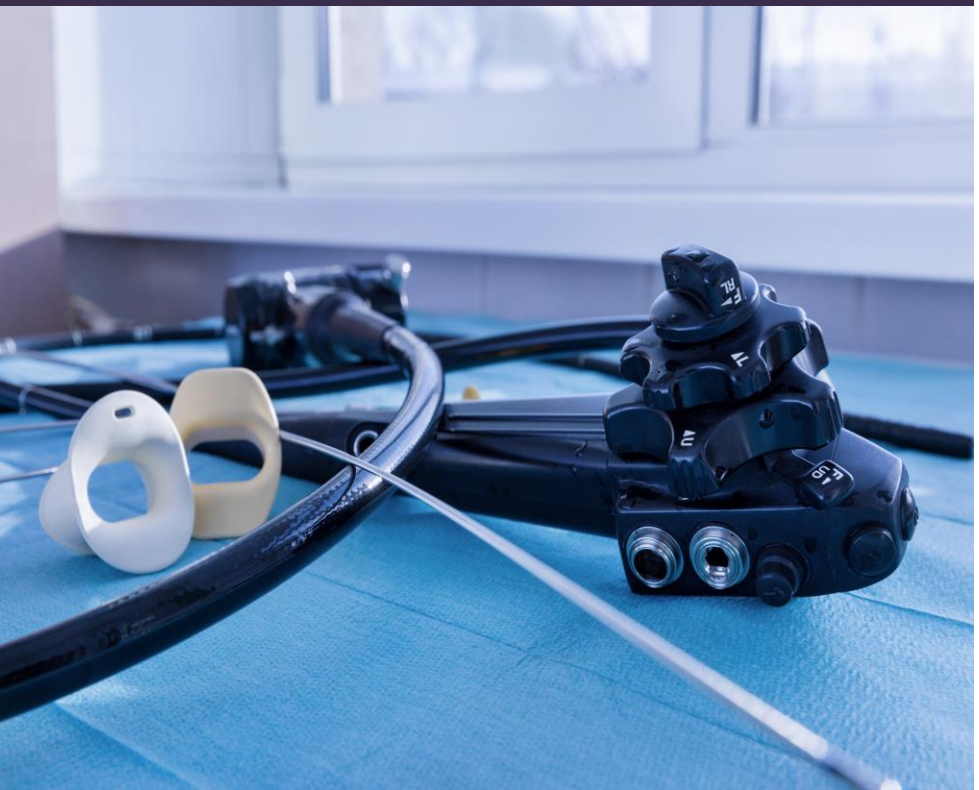

Sterilization vs. HLD Flexible scopes

Evidence supports sterilization provides a higher level of assurance.

Facilities should make steps towards sterilization when possible.

ST91 Recommends against manual high-level disinfection

WHY?

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