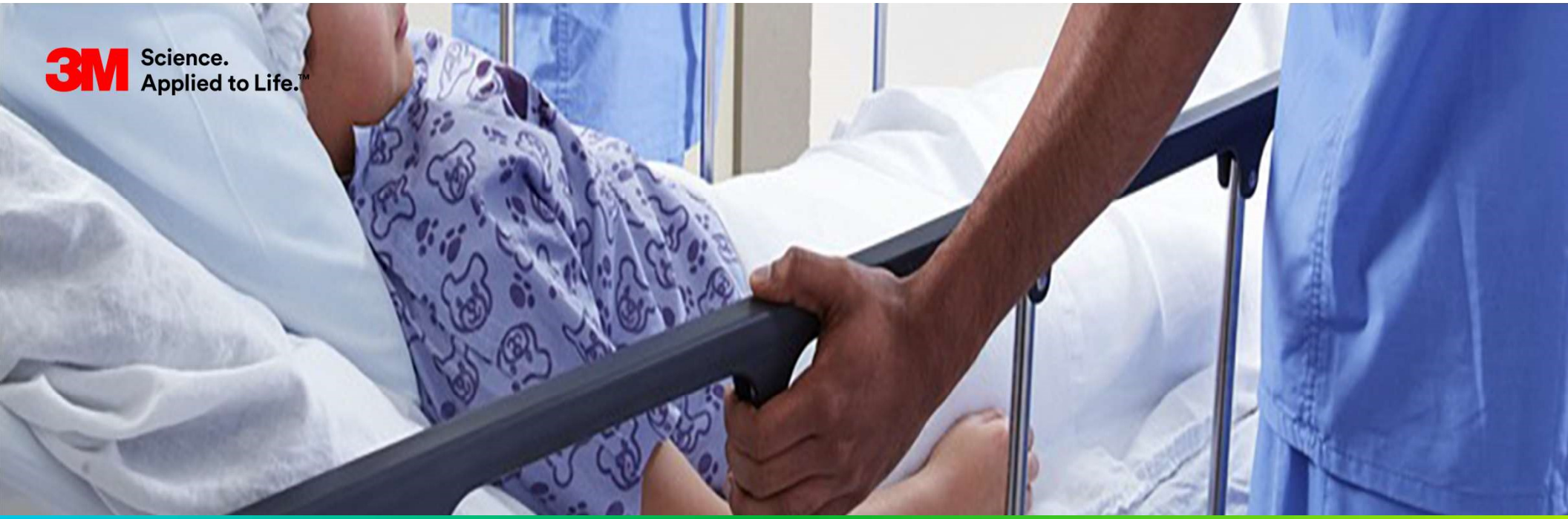

3M℠ Health Care Academy

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Quality Indicators:
Know your Role

Patient Safety

- The number one goal of every healthcare facility
- **Safe sterilization** practices play a major role in keeping patients safe

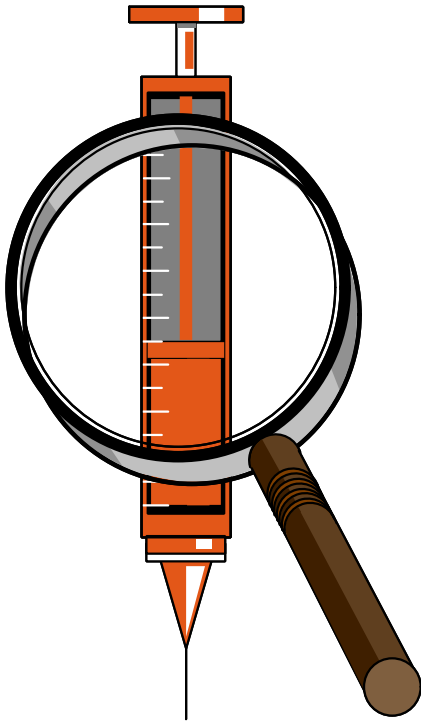
The truth is….

*You can have the **BEST** surgeon in the world, with the **most experienced** medical team, using the **best products**…*

*BUT if their instruments are contaminated that patient **will** develop an infection….*

Why monitor the Sterilization Process??

Is it Sterile ???



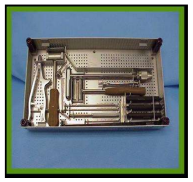
Can’t see sterility !

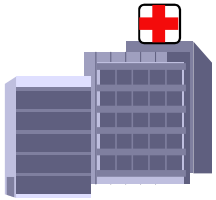
Sterilization Monitoring

Rationale

- Ensure probability of absence of all living organisms on medical devices being processed, i.e., **sterility**
- Detect failures ASAP
- Verify corrected failures ASAP
- Remove medical devices involved in failures ***before*** patient use
- Improve patient outcomes and safety
- Control costs

Sources of Sterile Medical Devices

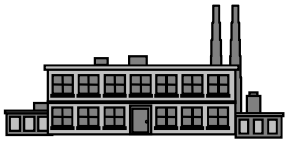




Hospital Sterile Processing Dept.
"Health Care"

Patient

Medical Device Manufacturers -
"Industry"



“Industry” & “Health Care” are consistent regarding:

- **Sterility of medical items used in patient care is an integral component of an infection prevention strategy.**

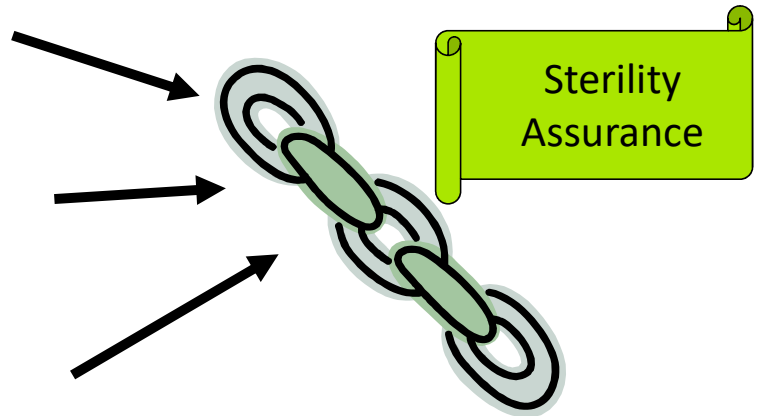
- **Sterilization is a ‘special’ process in that the result can not be tested on the end product.**

- **A non-destructive, direct check of sterility is impossible.**

and Finally…

The 3 fundamental tools for monitoring the sterilization process:

- **Physical monitors**
- **Chemical monitors**
- **Biological monitors**



Sterilization Process Monitoring

Physical Monitoring

Biological Monitoring

emical Monitor

Physical Monitors

Verify that parameters of sterilization cycle are met

- Recording charts
- Gauges
- Printouts
- Digital displays

Provide real time information

BUT Only monitor one point in the chamber

Chemical Monitors

3 Basic Types indicators:

1) Process Indicators (External)

2) In-Pack indicators (Internal)

3) Load control indicators (PCD)

Chemical Monitors

ISO 11140-1 Standard

Classifies indicators according to performance criteria/intended use

- Type 1 Process indicators → Outside Packs
- Type 2 Equipment Control
- Type 3 Single parameter
- Type 4 Multi-variable indicators
- Type 5 Integrating indicators
- Type 6 Emulating indicators

Inside Packs

Type 1 - Exposure Control

Type 1: Process Indicators

- Use with individual units to indicate that the unit has been directly exposed to the sterilization process.
  - Exposure Control (e.g. indicator tapes)
  - Distinguish between processed and unprocessed units
- Designed to react to one or more of the critical process variables

Type 2 - Equipment Control (Pre-vacuum Sterilizer)

Bowie-Dick tests can detect:

- Air leaks
- Inadequate air removal
- Inadequate steam penetration
- Presence of non-condensable gases: air or gases from boiler additives

Pack Control - Internal Chemical Indicators

AAMI and AORN recommend practices

- Use inside each package
- Recall and reprocess packs if the chemical indicator shows a problem

Type 3, 4, 5 & 6 - Pack Control (Internal)

4 Basic Types

- Type 3
  - Single Variable Indicators
- Type 4
  - Multi-Variable Indicators
- Type 5
  - Integrating Indicators
- Type 6
  - Emulating Indicators

Type 4 - Multi-variable Indicators (Internal)

- Designed to react to two or more of the critical variables
- Indicates exposure to a sterilization cycle at stated values of the chosen variables

Type 5 - Integrating Indicator

Critical Variables:
Time, Temperature and Steam

Type 5 Integrating Indicators

- Measures ALL critical variables of the sterilization process (3 time - temperature relationships)
- Approximate response of biological indicators in a resistometer test vessel under ideal steam sterilization conditions
- Lets you know if conditions for sterilization have been met in each pack

Type 6 - Emulating Indicators

"Emulating indicators are cycle verification indicators which shall be designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilization process."

ANSI/AAMI/ISO 11140-1, 2005 (Mfrs. Standard)

Biological Indicators - ISO 11138:2006

- Test system containing viable microorganisms providing a defined resistance to a specified sterilization process

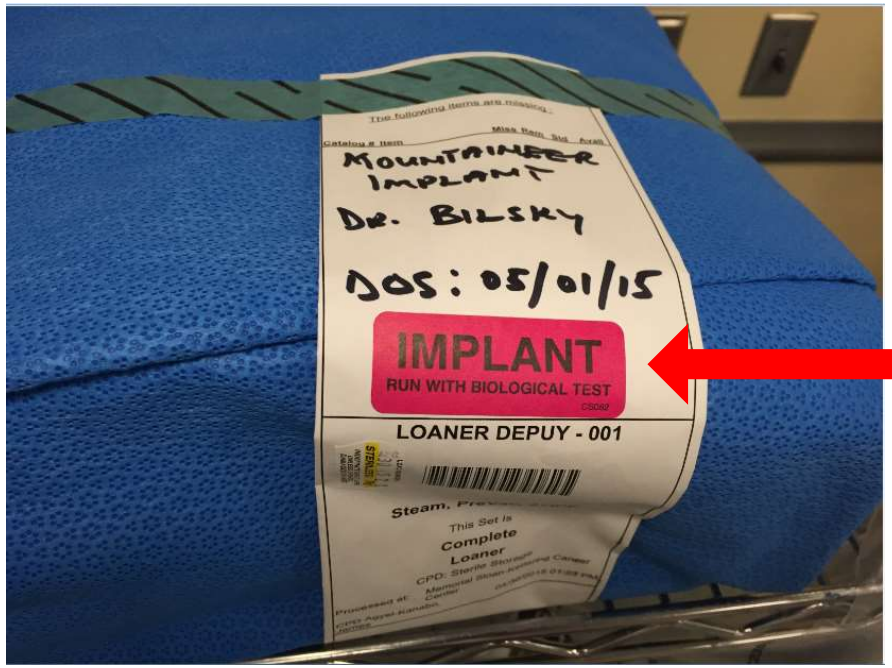
- *Self-contained*
- *Spore strip*
- *Ampoule*
- *Results directly applicable to bioburden of medical instrument*
- *Longer times needed for results*

CDC Guidelines

- "Biological indicators are recognized by most authorities as being closest to the ideal monitors of the sterilization process, because they measure the sterilization process directly by using the **most resistant organisms** (i.e. *Bacillus* spores) and not by merely testing the physical and chemical conditions necessary for sterilization."

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, Monitoring, p. 76

Load Control
Biological Indicator

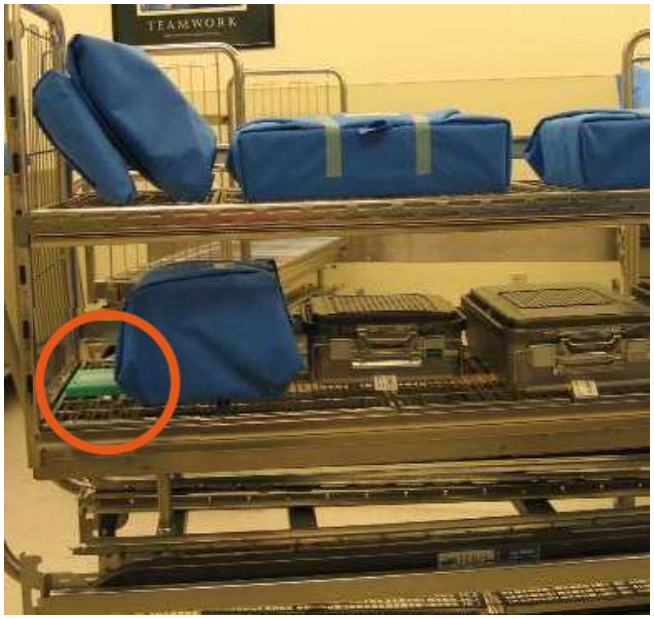


Steam Sterilization

Use a Biological Indicator:

- At a minimum, once a day
- With every load containing an implantable device
- Loads containing implantable devices should be quarantined until biological indicator results are available

BI Monitoring Frequency



Some facilities are moving to a higher standard of patient care by monitoring every sterilization load with a biological indicator.

BI Monitoring Frequency

Why monitor every load?

- Universal standard of patient care
- Cost and impact of a recall
- To be certain all implants, including those in loaners, are appropriately monitored
- Ensure every type of sterilization cycle used is monitored
- Ensure every type of packaging used in flash sterilization is monitored
- Reduce risk and cost of Healthcare Associated Infections (HAIs)

Record Keeping

Good record keeping is required for traceability purpose, especially in the event of sterilization failure, and recall is needed.

Setting up Sterilization Assurance Program

Step 1: Equipment Control

Step 2: Exposure Control

Step 3: Pack Control

Step 4: Load Control

Step 5: Record Keeping

What you can’t measure….you can’t manage.

Thank you