

# Preventing Surgical Site Infection:

## Role of the Central Sterile Department

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# Disclosures

- Speaker's Bureau
  - 3M
  - Sage

# Learning Objectives

- Review the role of the Joint Commission in the Central Sterile Department
- Understand the role of AAMI in the Central Sterile Department
- Describe the areas of Central Sterile Department that Impacts Prevention of Surgical Site Infection
- Discuss best practices for monitoring the sterilization process and why biological indicators are considered the most effective method for monitoring the sterilization process
- List the Issues of Concern in the Central Sterile Department



# The Joint Commission National Patient Safety Goals

- ***NPSG.07.05.01*** - Implement evidence-based practices for preventing surgical site infections.
- ***EP3:***
  - Implements policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Center for Disease Control and Prevention [CDC] and/or professional organization guidelines).





# The Joint Commission

- **LD.04.01.01, EP2**
  - The hospital provides care, treatment, and services in accordance with licensure requirements, laws and regulations
- **LD.04.03.07**
  - Patients with comparable needs receive the same standard of care, treatment, and services throughout the hospital
- **LD.04.04.07**
  - The hospital considers clinical practice guidelines when designing or improving processes.
- IC.02.02.01 - The organization reduces the risk of infections associated with medical equipment, devices and supplies.
  - The hospital implements infection prevention and control activities when doing the following:
    - **EP1-** Cleaning and performing low-level disinfection of medical equipment, devices, and supplies.
    - **EP2 -** The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.



# The Joint Commission Survey

- The Joint Commission will survey for:
  - Orientation, training and competency of the health care worker (HCW) who process medical equipment, devices and supplies
  - Levels of staffing and supervision of the HCW who process medical equipment, devices and supplies
  - Standardization of the process regardless of whether it is centralized or decentralized
  - Ongoing quality monitoring
  - Observation against the manufacturers guidelines and the organization procedures.



# Who is AAMI?

- Association for the Advancement of Medical Instrumentation
  - Nonprofit organization founded in 1967
  - “professional society,” not a “trade association”
  - Consensus-building forum
  - 7000+ professionals from healthcare institutions, industry, regulatory, and consultants that provide multidisciplinary leadership
  - Develops domestic and international standards or reports



# AAMI Standards Program

- Approved and published by AAMI or under the auspices:
  - American National Standards Institution (ANSI)
  - International Organization for Standardization (ISO)
  - International Electrotechnical Commission (IEC)
- All standards and recommended practices are voluntary



# AAMI Technical Documents

- **Device Standard** – Consensus document authored by Committee
  - primarily directed to the manufacturer
- **Recommended Practice (RP)** – Consensus document authored by Committee
  - provides guidelines for the use, care and/or processing of a medical device or system
  - oriented toward health care professionals
- **Technical Information Report (TIR)** –does not imply the same level of consensus as a standard or RP
  - addresses a particular aspect of medical technology
  - approved for distribution by a technical committee and the AAMI Standards Board
  - allows the inclusion of differing viewpoints on technical issues
- **Monograph** – Educational document, not subject to consensus process, but usually peer-reviewed



# Standards Development Process

- Committees Proposals
  - Sterilization Packaging Systems for Reusable Medical Devices
  - Low- and intermediate-level disinfection
  - Endoscopy
  - Human Factors
- Working draft developed
- Reviewed/revised by working group (W/G)
- Balloted by the W/G or drafting committee
- Resolution of objections
- Standards/RP - 60-day public review
- 30-day final committee/public review
- Submission to Standards Board for approval
- If approved, document published

# ANSI/AAMI ST79:2006 – Comprehensive guide to steam sterilization in healthcare facilities

## **ANSI/AAMI ST46**

Steam sterilization and sterility assurance in health care facilities

## **ANSI/AAMI ST42**

Steam sterilization and sterility assurance using table-top sterilizers in office & amb facilities

## **ANSI/AAMI ST37**

Flash sterilization: Steam sterilization of patient care items for immediate use

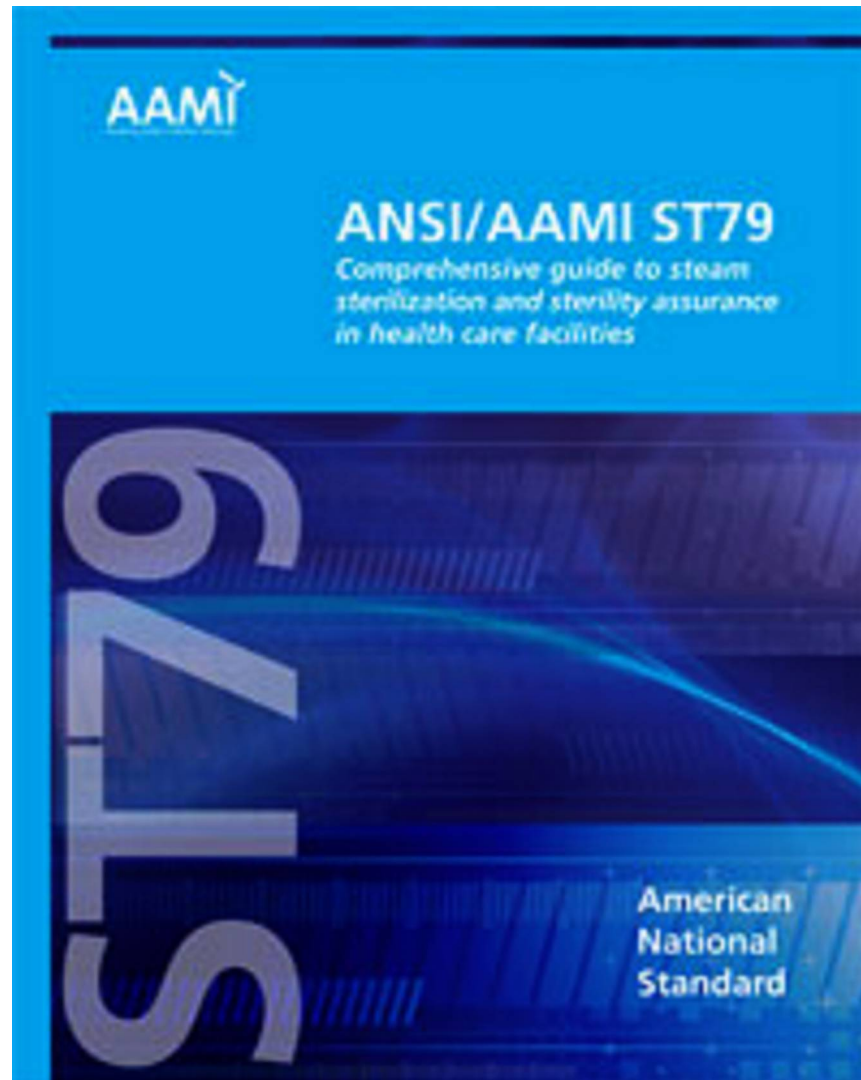
## **ANSI/AAMI ST35**

Safe handling and biological decontamination of devices in facilities & nonclinical settings

## **ANSI/AAMI ST33**

Guidelines for reusable rigid sterilization containers for EO and steam sterilization in facilities

# ANSI/AAMI ST79:2010 & A1:2010 & A2:2011





# Role of Central Sterile Department (CSD/SPD)

“The importance of this [CSD/SPD] role in the prevention of nosocomial [HAIs] is clear: *reusable medical devices improperly handled, disinfected, or sterilized provide a source of contamination and increase the risk of transmission of infection to both patients and the staff involved in reprocessing procedures.*”

# Role of the CSD/SPD

Direct healthcare providers (such as physicians, nurses,...) and ancillary personnel (such as housekeeping and *equipment-processing personnel*) *are responsible for ensuring the appropriate infection prevention and control practices are used at all times* (including hand hygiene; strict adherence to aseptic technique; cleaning and disinfection of equipment and the environment; *cleaning, disinfection, and sterilization of medical supplies and instruments and appropriate surgical prophylaxis protocols*).

# Health-Care Associated Infections – Adverse Outcomes

- **1961** – 3 cases of *Clostridium perfringens* SSI related to inadequate cleaning of instruments and sterilizer failure
- **1981** - 6 cases of *Pseudomonas aeruginosa* meningitis or intraabdominal abscess traced to sterilizer failure
  - Epidemiologic link to possible flash sterilization processing of implantable neurosurgical devices
- **1991**- Improperly sterilized surgical equipment linked to an outbreak of postsurgical nasal cellulitis with *Mycobacterium chelonae*
- **1992** - 281 infections transmitted by gastrointestinal endoscopy; 96 infections transmitted by bronchoscopy
- **2002** - Improper packaging of surgical linens/drapes prior to autoclaving associated with an outbreak of polymicrobial ventriculitis in a surgical ICU
- **2009** - 3-state VA outbreak of bloodborne pathogens due to improperly reprocessed endoscopes

# *Report: Dirty surgical tools in hospitals putting patients at risk*

*When 63-year-old John Harrison had surgery to repair his rotator cuff in 2009, he assumed the ordeal would be quick and relatively painless.*

*Instead, Harrison, who had the surgery performed at The Methodist Hospital in Houston, developed an infection that ate away at his shoulder bone and rotator cuff. The infection led to a lengthy recovery time, and he became dependent on nurses to help him dress and shower. Harrison was one of seven patients who developed an infection after having surgery at Methodist within a two-week timeframe. As a result, the hospital voluntarily closed its operating room and asked the U.S. Centers for Disease Control and Prevention (CDC) to investigate.*

*“Evidence from the investigation suggests the Methodist infection outbreak was most likely caused by retained tissue,” said Dr. Pritish Tosh, a former investigator at the CDC’s Epidemic Intelligence Service, in a 2011 issue of Control and Hospital Epidemiology. In Harrison’s case, the likely causes of infection were the two surgical tools – an arthroscopic shaver and an inflow/outflow cannula – which, when inspected using tiny video cameras, were found to have traces of human tissue and blood caked onto them.*

...

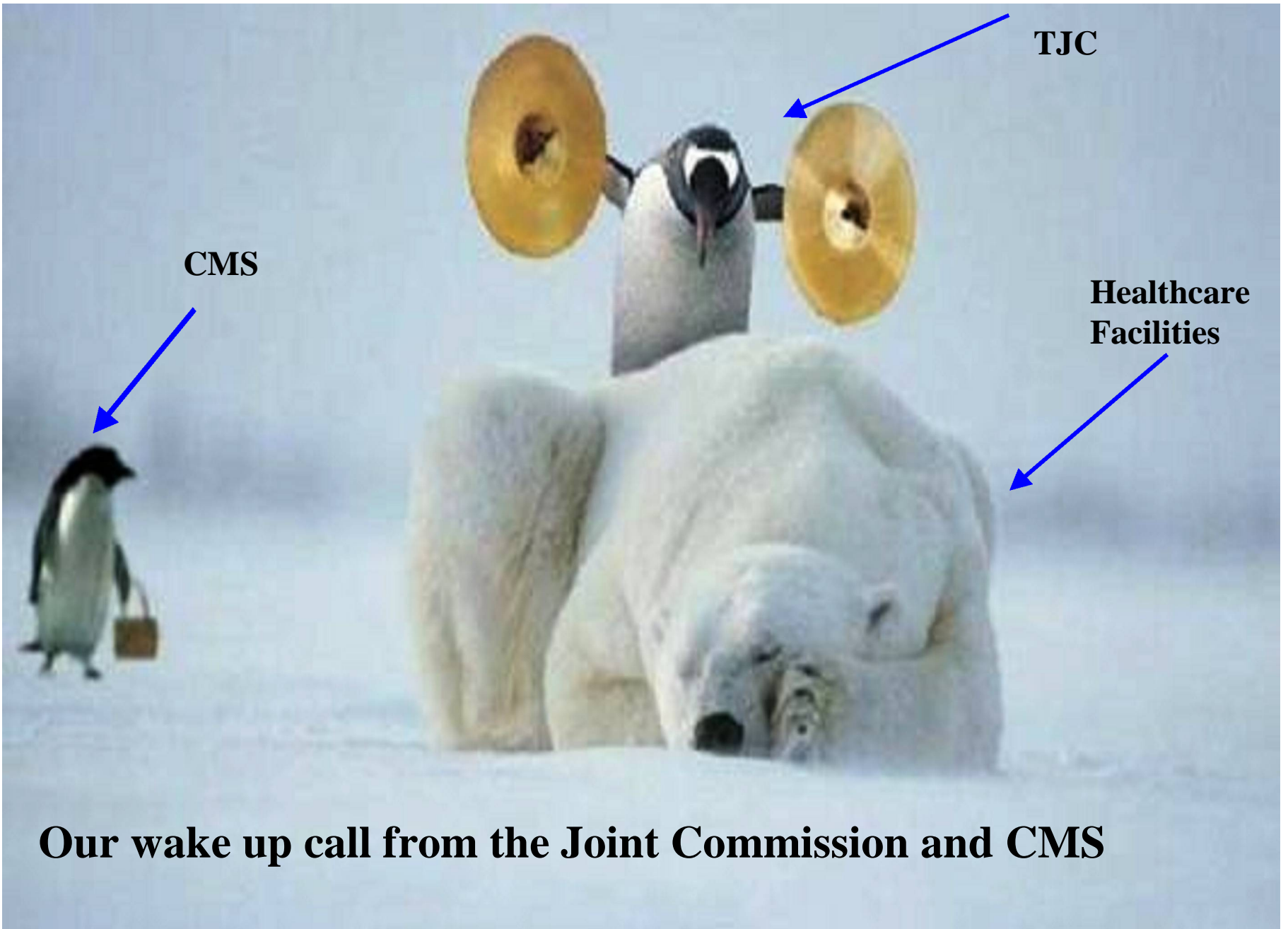
Source: NBC Today Show  
Fox News

## *Report: Dirty surgical tools in hospitals putting patients at risk*

*Methodist is not the only hospital where dirty surgical tools have led to health problems. Also in 2009, the Department of Veterans Affairs admitted more than 10,000 patients in Florida, Tennessee and Georgia had colonoscopies and endoscopies with contaminated tools between 2002 and 2009. Some of these patients have tested positive for HIV, hepatitis C and hepatitis B. Lawsuits ensued.*

*In 2008, an outpatient surgical center in Las Vegas found six patients had been sickened with hepatitis C after it reused biopsy forceps.*

Source: NBC Today Show  
Fox News



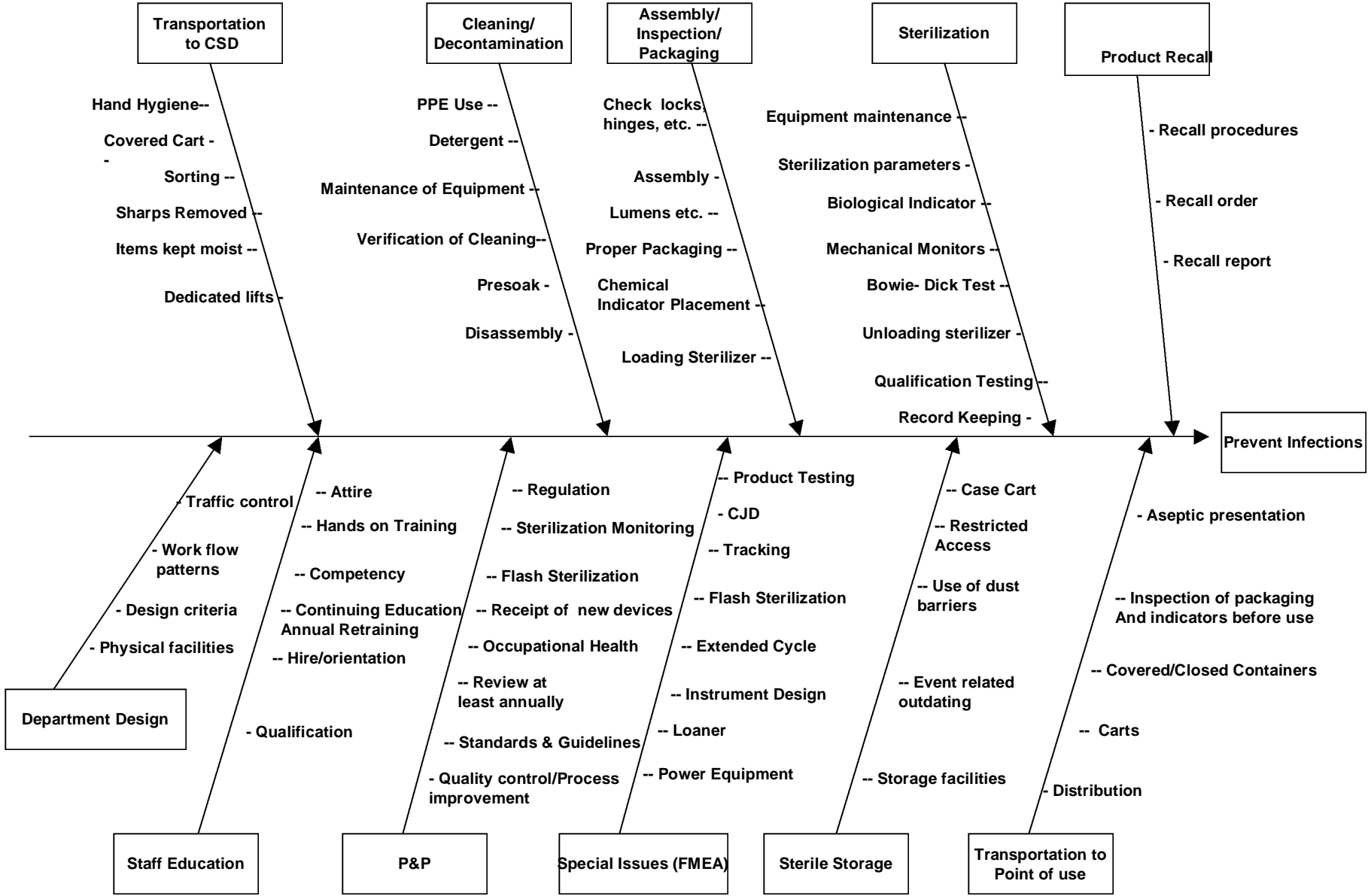
**TJC**

**CMS**

**Healthcare  
Facilities**

**Our wake up call from the Joint Commission and CMS**

# Central Sterile Process - Ishikawa (Fishbone) Diagram



# What are the parts of the process?

- Cleaning and Decontamination
- Preparation and Packaging
- Sterilization
- Sterile Storage and Distribution
- Record Keeping
- Recall Procedures



# Cleaning and other Decontamination Processes

Manual or Mechanical? If you can't  
clean it, you can't sterilize it!

*The purpose of decontamination is to prevent the spread of infection.*



Tim Peckham

# Proper Attire

Personal Protective Equipment

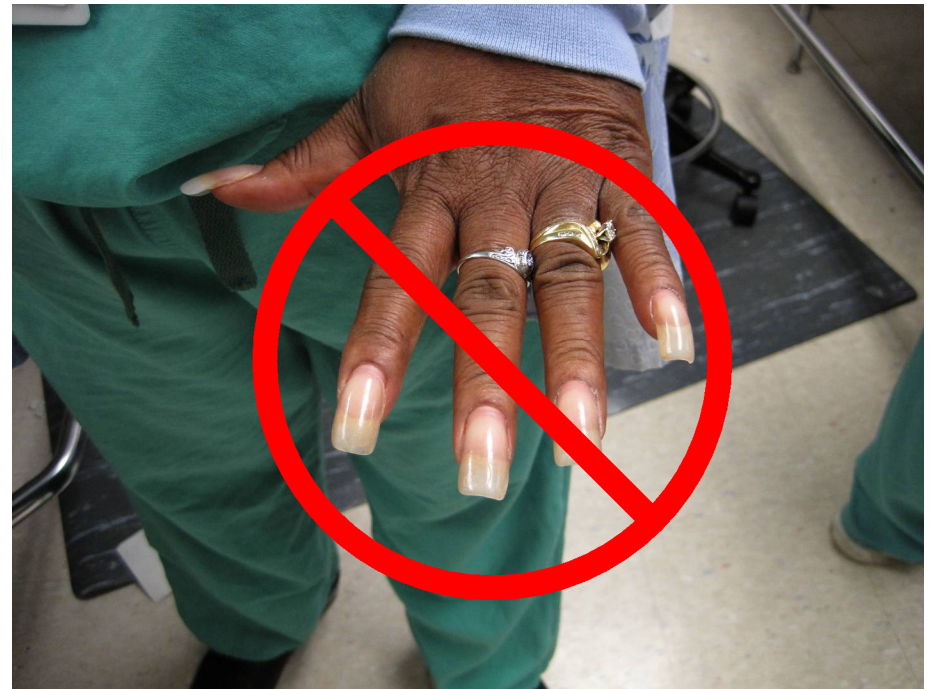
# Personal Protective Equipment (PPE) – Portal of Exit/Entry

- Liquid-resistant covering with sleeves
- Heavy-duty latex free or plastic gloves
- Surgical face mask (impervious to fluid and high filtration)
- Safety glasses that wrap around the eye or face shield
- Disposable hair covering
- Proper footwear



# Personal Protective Equipment (PPE) – Portal of Exit/Entry

- Fingernails and Artificial Nails
  - Natural nail tips should be kept to ¼ inch or less in length (CDC II; WHO II)
  - Artificial nails or extenders are not be worn when having direct contact with high-risk patients (e.g., ICU, OR) (CDC 1A; WHO 1A)
- Especially important in Assembly / Prep and Pack



# Cleaning and other Decontamination Processes

- “To be **rendered safe to handle**, some medical devices require only thorough cleaning; others, because of occupational exposure considerations, must be cleaned and subjected to a microbicidal process. Some devices can be prepared for patient reuse following the decontamination process, whereas others must be prepared and subjected to terminal sterilization (e.g., steam sterilization of surgical instruments).” (Clause 7.1)
- “The type of decontamination required for a particular contaminated device depends on the biohazard that the device presents.” (Clause 7.1)
- “The **written [instructions for use] IFU** of the device manufacturer should always be followed.” (Clause 7.2.2)
- “Surgical instruments and other items composed of more than one part or piece (e.g., metal tracheostomy tubes, procedure needles, dental handpieces, laparoscopic instrumentation, trumpet valves) should be disassembled to expose all surfaces to the cleaning process.” (Clause 7.4.1)



“For all reusable medical devices, the first and most important step in decontamination is thorough cleaning and rinsing.” (Clause 7.5.1)



**What are you doing to save time?**

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 Clause 7.5.1

# Manual Cleaning

- “Manual cleaning is often recommended for delicate or complex medical devices, such as microsurgical instruments, lensed instruments, and air-powered drills. Immersible devices should be cleaned under water to minimize aerosolization; devices that cannot be immersed should be cleaned in a manner that will not produce aerosols and should be rinsed and dried according to the device manufacturer’s written IFU.” (Clause 7.5.3.2)





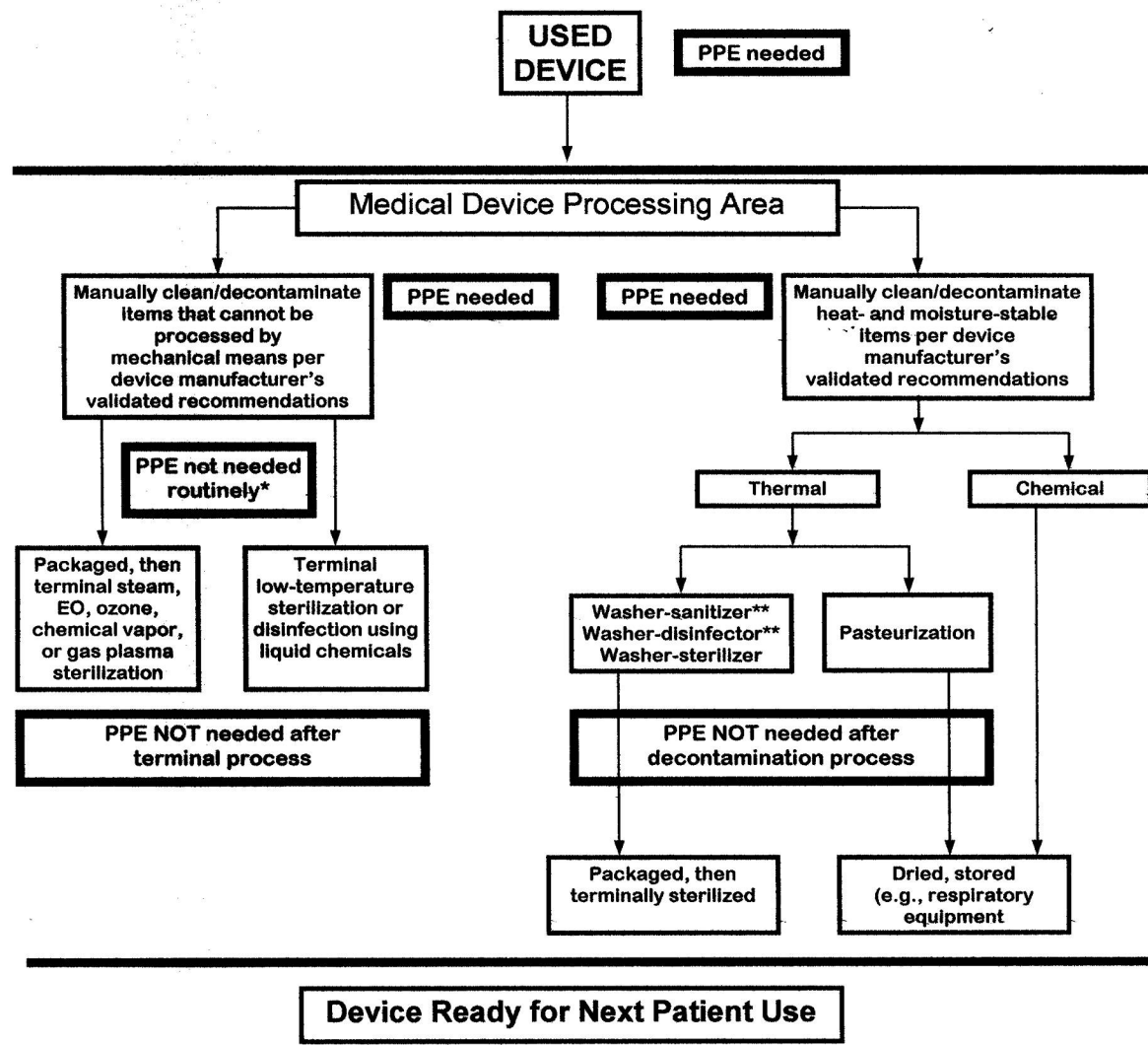
# Mechanical Cleaning

“Mechanical cleaning equipment removes soil and microorganisms through an automated cleaning and rinsing process. Some types of equipment incorporate thermal disinfection processes and/or chemical disinfectant rinses capable of destroying various numbers and types of microorganisms. Mechanical cleaning equipment includes utensil washers and cart washers, washer-sanitizers, pasteurization equipment, washer-disinfectors, washer-decontaminators, and washer-sterilizers.” (Clause 7.5.3.3)

- Ultrasonic cleaners used for fine cleaning



# Figure 3—Microbicidal processes and use of PPE



# Packaging

“The primary functions of a package containing a medical item are to allow the sterilization of the contents, to maintain the sterility of the contents until the package is opened, and to provide for the removal of the contents without contamination.”  
(Clause 8.2)

# Effective Packaging Materials

- Allow adequate **air removal** and steam penetration
- Adequate **barrier** to microorganisms or their vehicles
- Resist tearing or puncture
- Allow a method of **sealing** that results in a complete seal that is tamper-evident and provides seal integrity
- Allow for ease of **aseptic presentation**
- Be **free of toxic ingredients and nonfast dyes**
- Be **non-linting**
- Be shown by value analysis to be **cost-effective**

ANSI/AAMI ST79:2010 & A1:2010  
&A2:2011 Clause 8.2



- **Reusable woven textile**
- **Disposable nonwoven materials**
- **Peel pouches**
- **Reusable rigid sterilization containers**

# Packaging Concerns

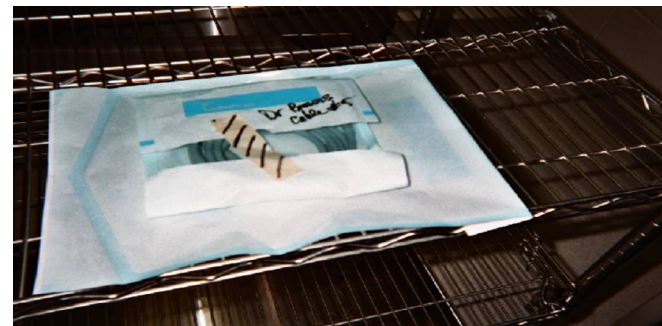
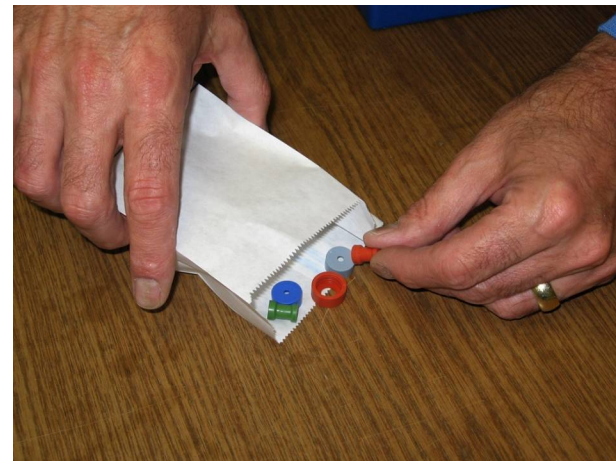
Paper-Plastic Pouches – “The **plastic laminate** used in paper–plastic pouches is **impervious to the sterilant** and, therefore, might prevent the sterilant from reaching the surface of anything with which the plastic side is in physical contact. Therefore, paper–plastic pouches **should not be used within wrapped sets or containment devices unless the practice has been validated by the packaging manufacturer and verified by product testing in the health care facility.**

- **ANSI/AAMI ST77:2006 Rigid Container Systems (Manufacturer Standard)**
- Ergonomic issue
  - “The combined weight of the containment device, the instruments, and any accessories or wrappers shall not exceed **25 pounds...**”
  - When containment devices, including their contents and any accessories or wrappers, are too heavy, **sterilization and/or drying could be compromised** in commonly available hospital sterilization cycles.



# Packaging Concerns

**100% medical grade paper bags**



ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 Clause 8.3.4 & 8.4.2 Rationale

# Packaging Concerns

- **Wet packs should not be released for use**
  - Repackage, replace chemical indicators (CIs)
    - Disposable products (e.g. gauze or cotton balls) should be discarded
  - Review the sterilizer cycle conditions
    - Drying cycle length and temperature
    - Set contents, weight, & density (especially metal mass)
    - Loading of the sterilizer and position of wet pack
  - Reprocess after detecting the error or probable cause of the wet pack
- Perform process audits to ensure adherence to packaging procedures

# Steam Sterilization

The first step in being able to monitor the steam sterilization process is to know the type of steam sterilizer that is used.



# Steam Sterilization

Approximately 85% of medical item sterilization in healthcare facilities is achieved with saturated steam under pressure



- Fast
- Highly effective
- Reliable
- Relatively low cost
- Easy to use
- Readily available
- Technology well understood
- No toxicity or hazardous residues

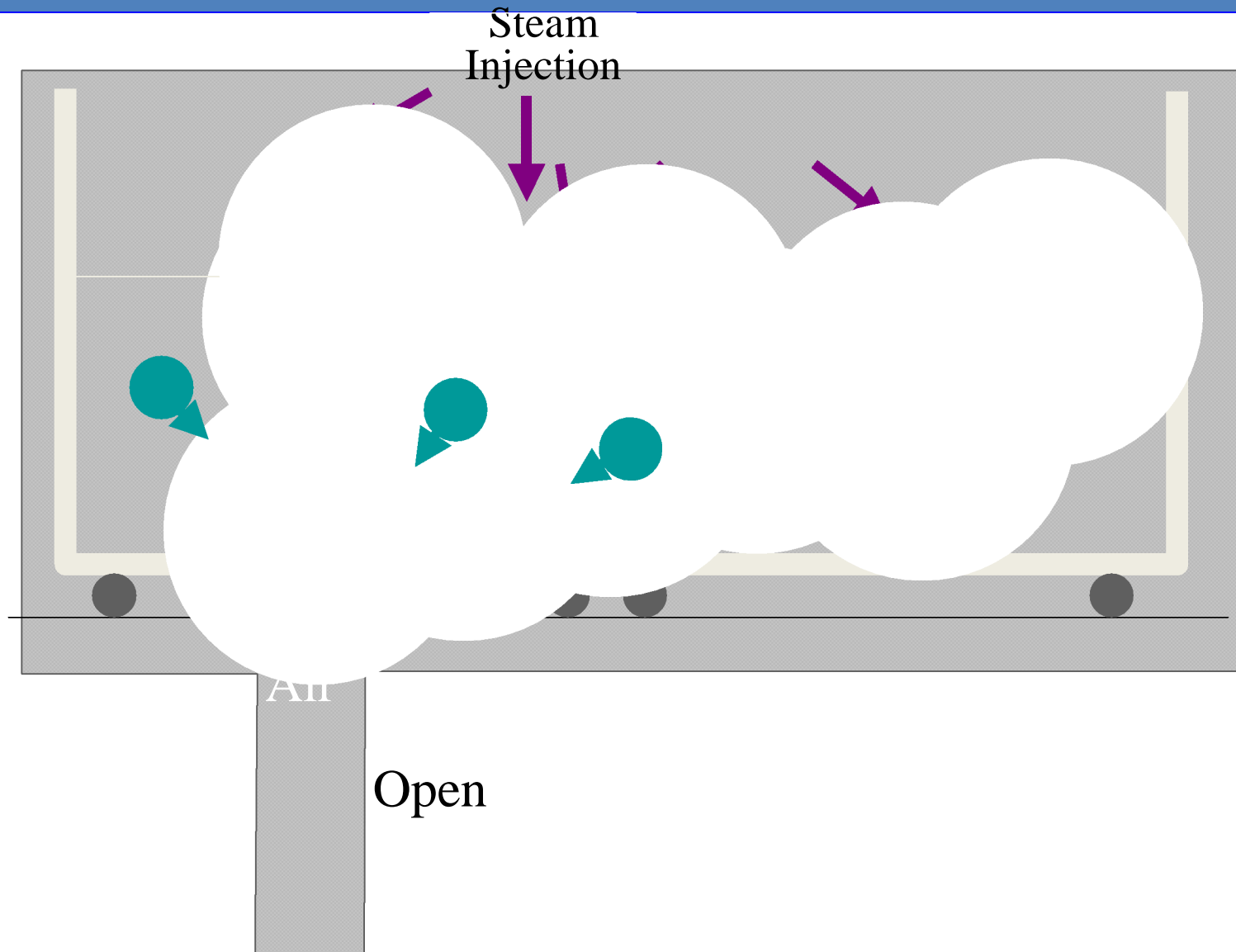
# Types of Steam Sterilization Processes



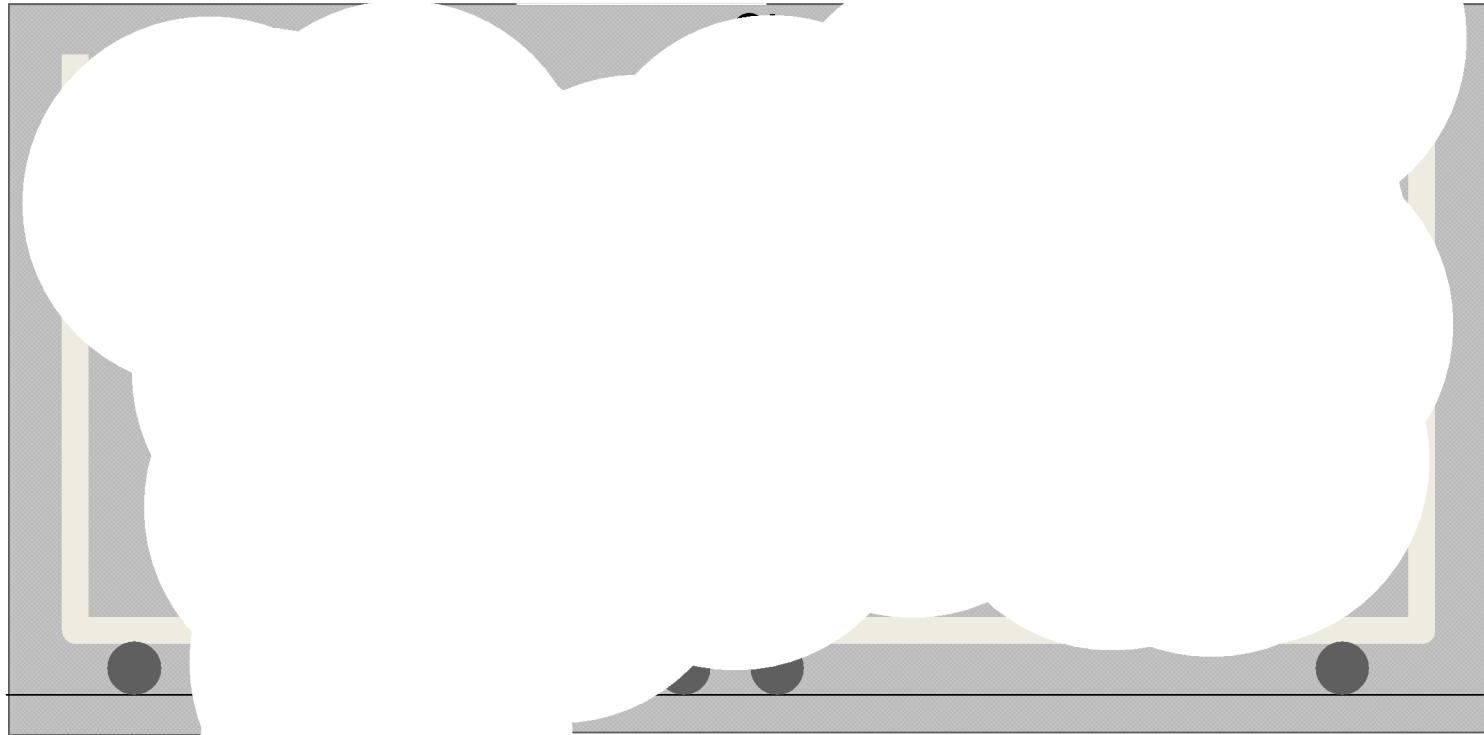
- ✓ Gravity Displacement
- ✓ Dynamic-Air-Removal  
Prevacuum
- ✓ Steam-flush pressure-  
pulse (SFPP)

# Gravity Displacement Cycle Come-up Phase

Incoming steam displaces air through drain

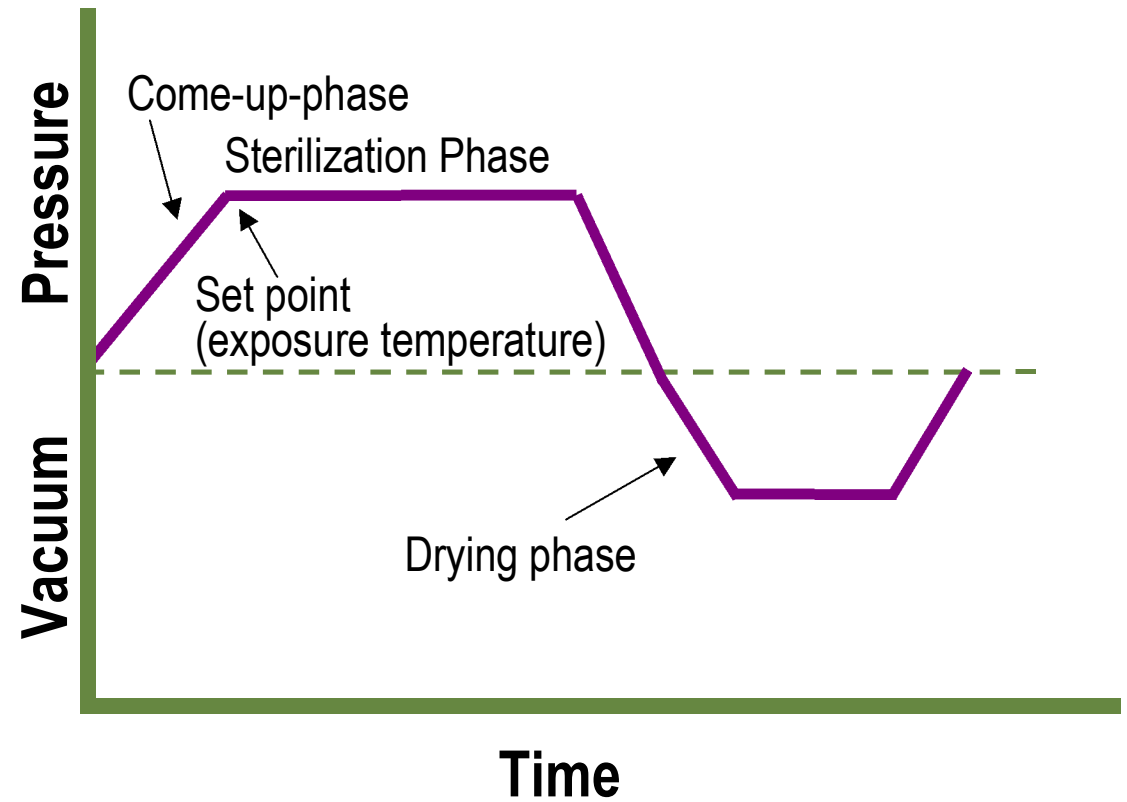


# Gravity Displacement Cycle Exposure Phase



closed

# Profile of a Gravity Displacement Cycle



# Cycle Time Examples

Minimum cycle times at 250°F/121°C for gravity displacement steam sterilization cycles for sterilizers >2 cubic feet

Load Contents	Time (Min)
Wrapped instruments	30
Textile packs	30
Wrapped utensils	30

# Dynamic-Air-Removal

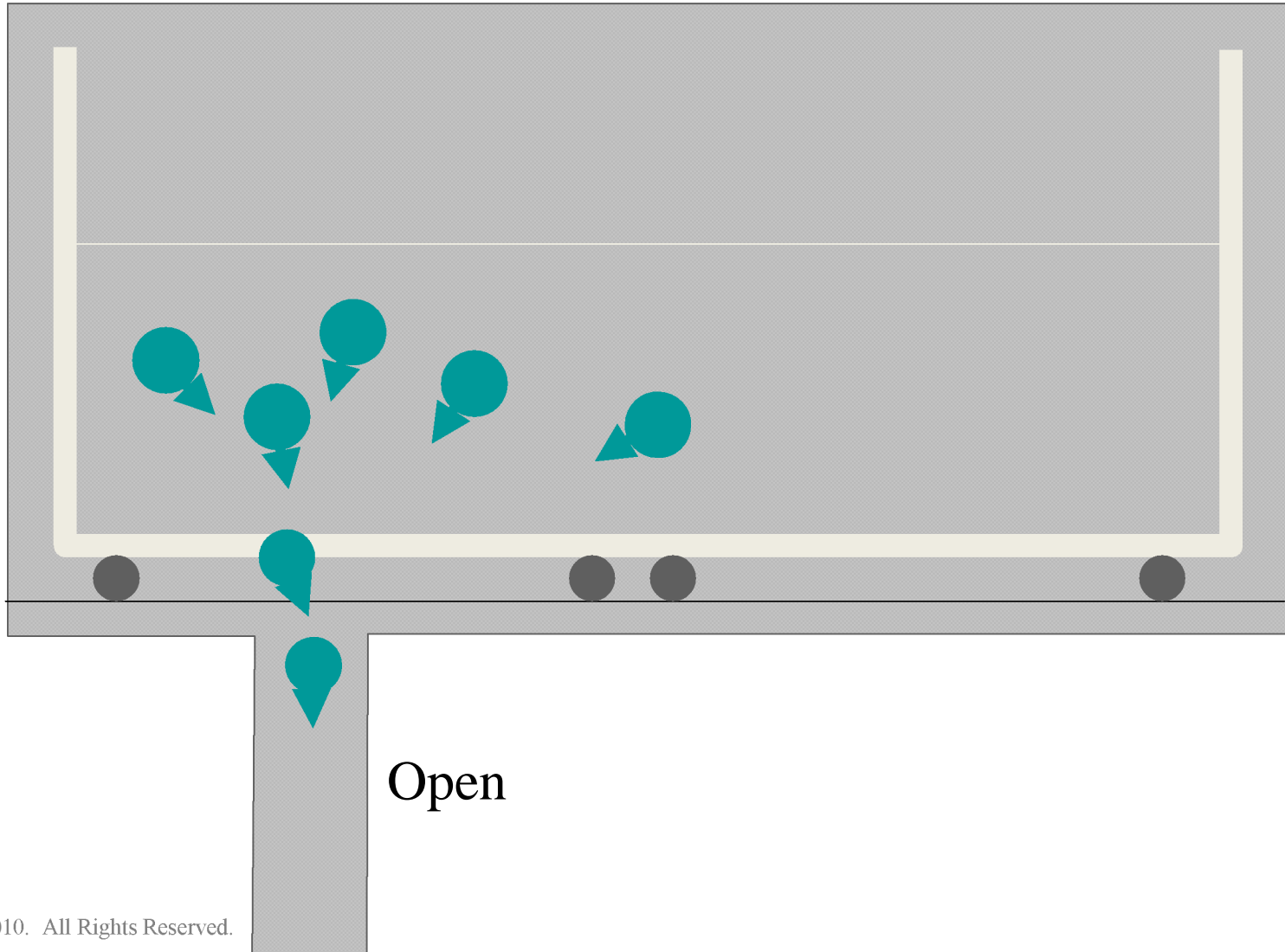


- Prevacuum
- Series of pressure and vacuum excursions
- Steam-flush pressure-pulse (SFPP)
- Series of steam flushes and pressure pulses above atmospheric pressure

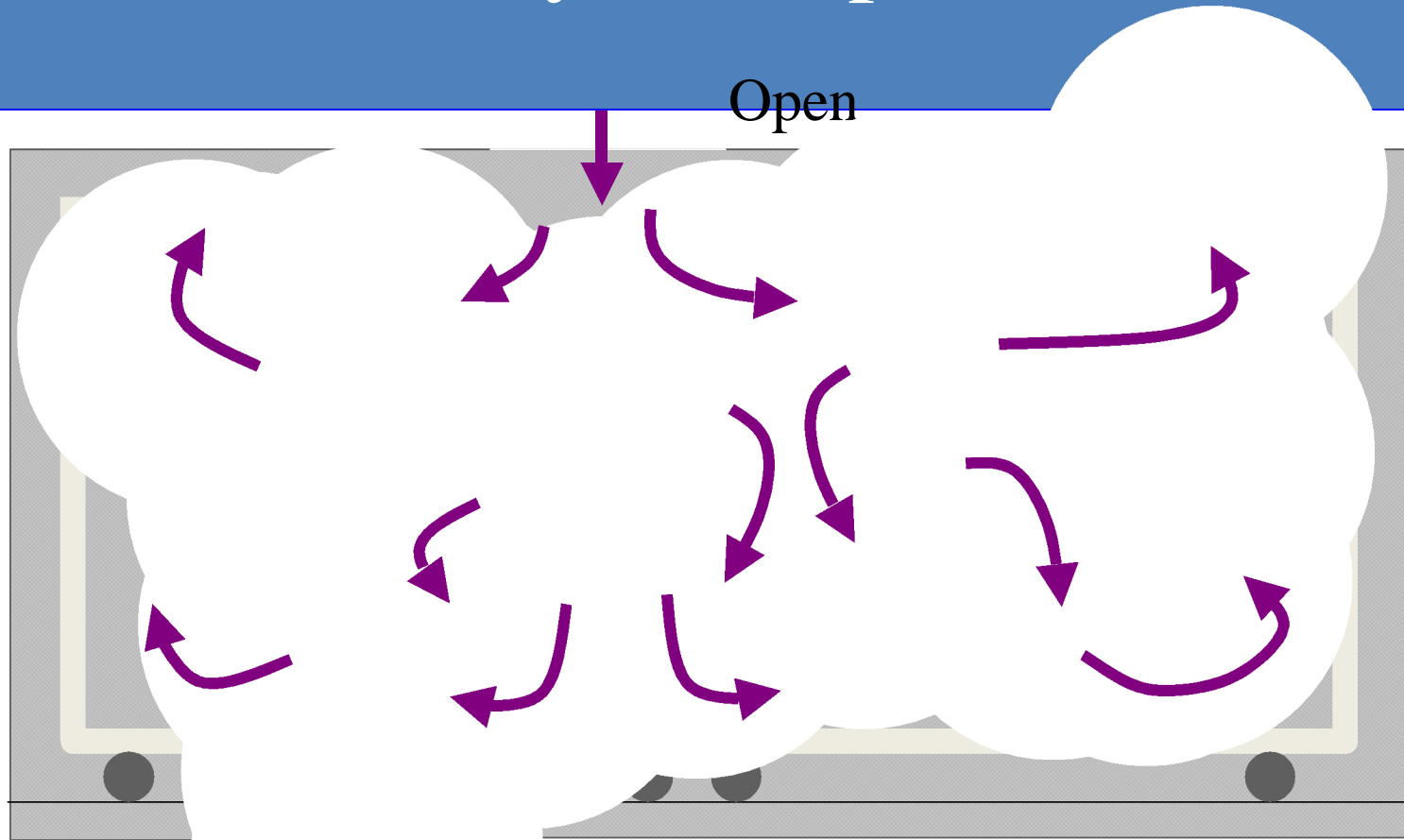


# Prevacuum Cycle Come-up Phase

Closed

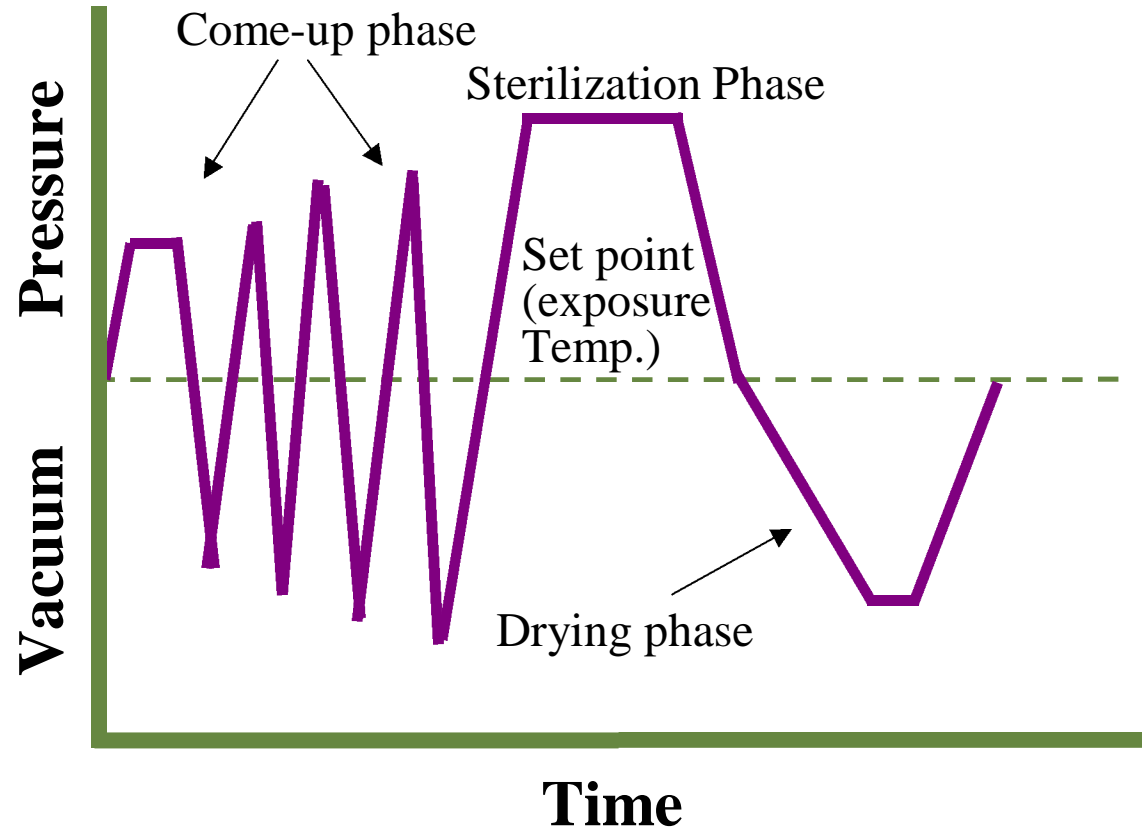


# Prevacuum Cycle Exposure Phase



closed

# Profile of a Prevacuum Cycle

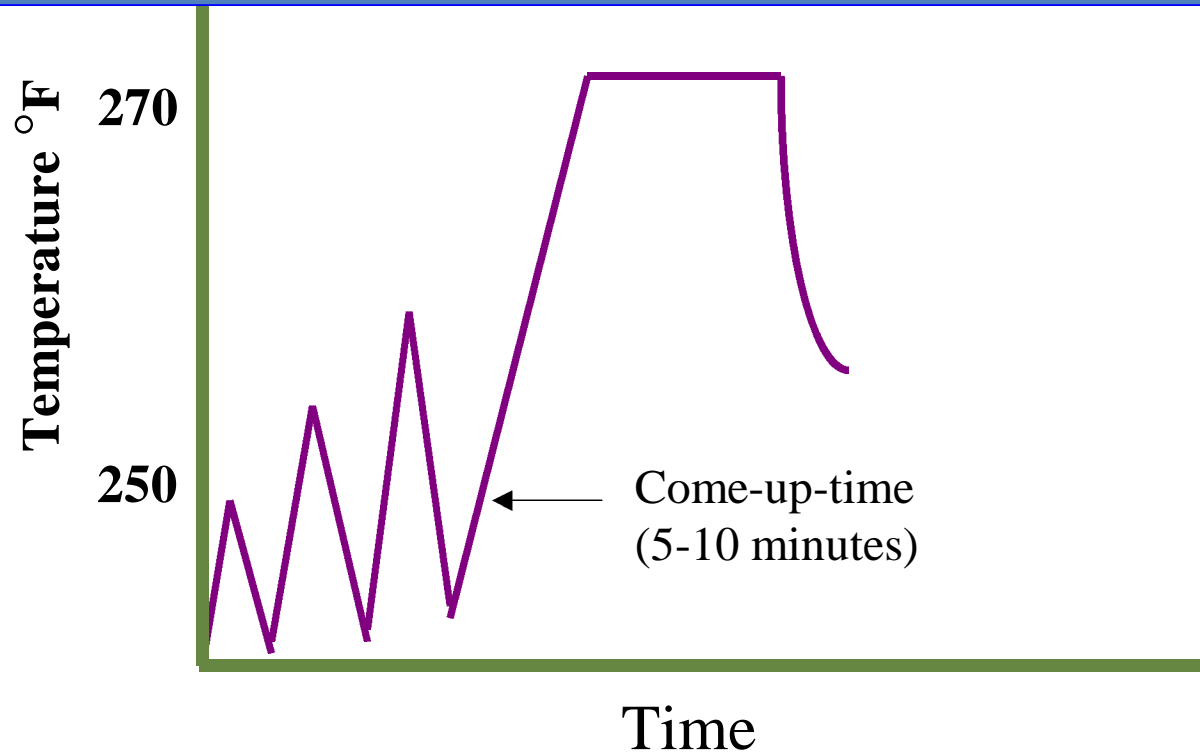


# Cycle Time Examples

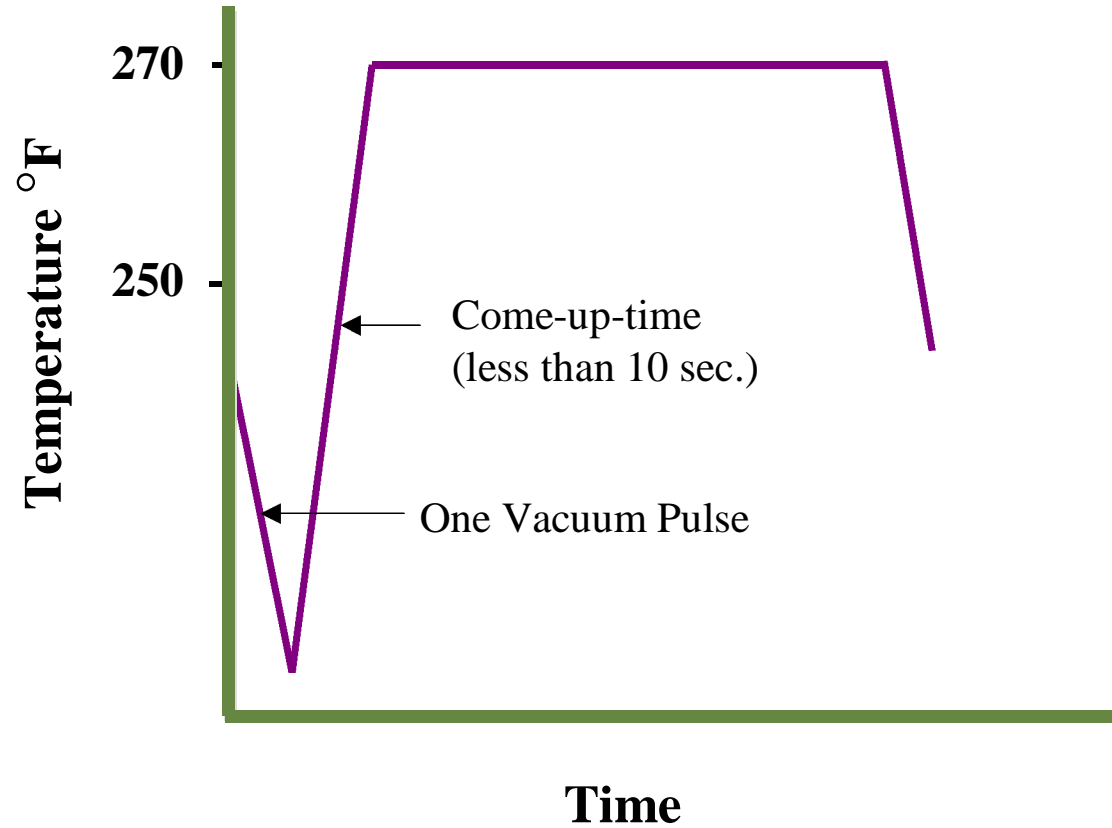
Minimum cycle times for dynamic-air-removal steam sterilization cycles >2 cubic feet

Load Contents	Temp	Time (Min)
Wrapped instruments	270°F/132°C	4
	275°F/135°C	3
Textile packs	270°F/132°C	4
	275°F/135°C	3
Wrapped utensils	270°F/132°C	4
	275°F/135°C	3

# Profile of Hospital Sterilizer (pulse prevacuum)



# Profile of Steam Resistometer Cycle (Test Vessel)



# Table Top Steam Sterilizers





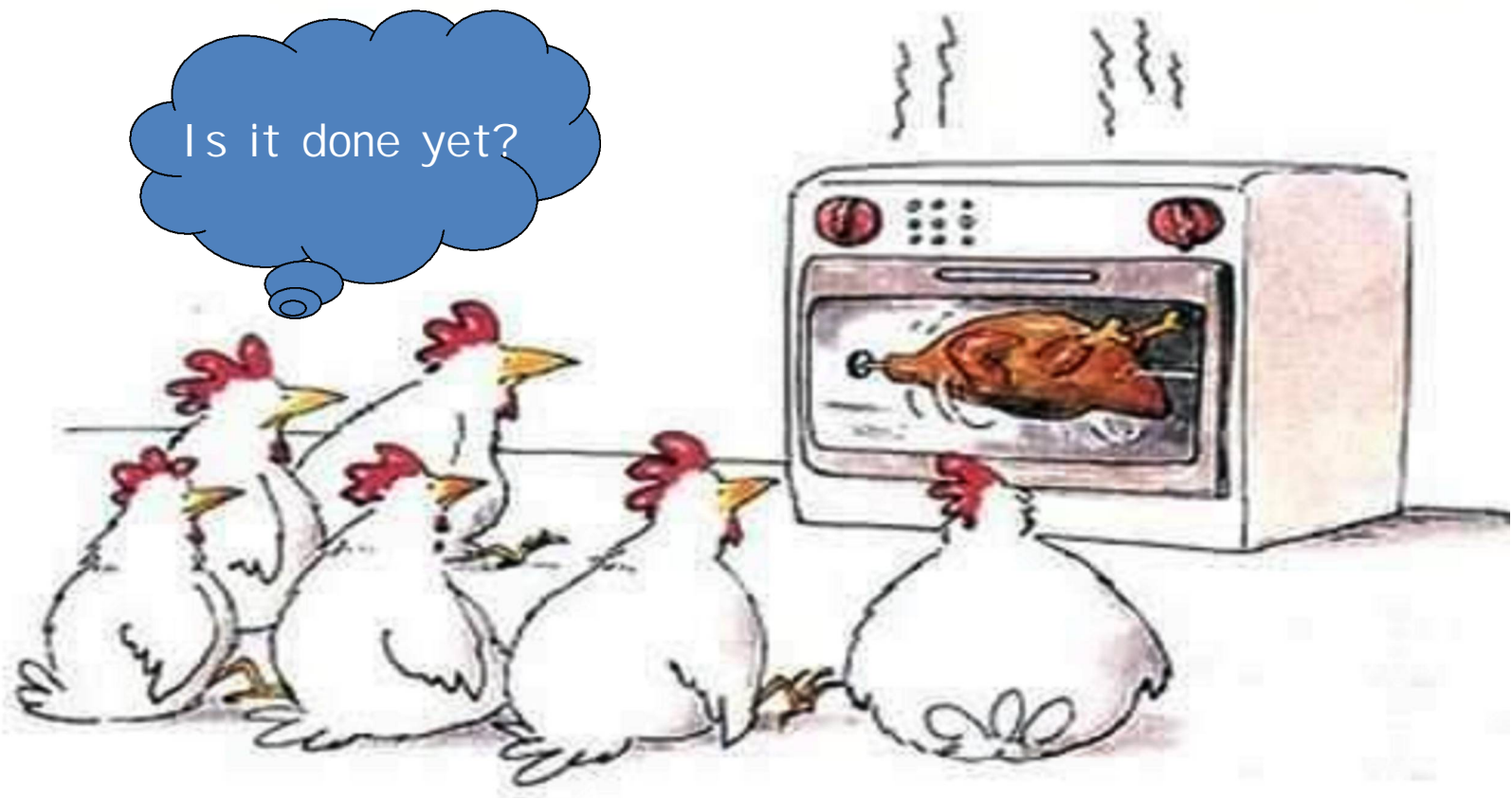
# Table Top Gravity Steam Sterilizers

<b>Load Contents</b>	<b>Temp</b>	<b>Time (Min)</b>
Unwrapped instruments on tray or glassware	270°F/132°C 275°F/135°C	3
Wrapped trays of instruments, instruments in peel pouches	270°F/132°C 275°F/135°C	5
Packs, wrapped	250°F/121°C	30

# Immediate Use Steam Sterilization (Flash Sterilization)



- Process designed for the steam sterilization of patient care items for immediate use
- High temperature (270-275°F/ 132-135°C)
- Gravity or dynamic-air-removal
- No dry time
- No storage



Sterilization Monitoring - not as simple as it looks!

# Continuous Quality Improvement (CQI)

- CQI programs are used to assess and improve all components of the sterilization process
  - Desired outcome of improving patient care by consistently delivering sterile product to the user  
No single “right way” to implement CQI
  - Team approach

# CQI Topics

- Risk Analysis
- Recalls
- BI Monitoring Frequency
- Managing Loaner Instrumentation
- Cleaning Verification
- TASS

# System Design – How is your system designed?

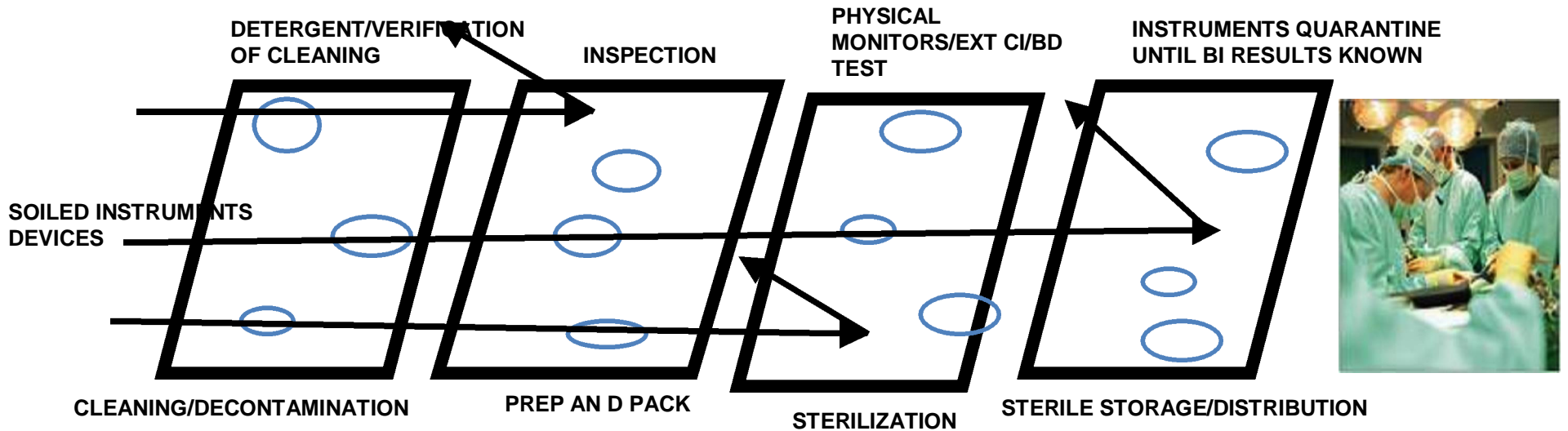
**Every system is perfectly designed to get results it consistently achieves.**

*Donald M. Berwick, MD, MPP, FRCP, President and CEO,  
Institute for Healthcare Improvement (IHI)*

**Is your system/process designed to consistently break the chain of infection? Prevent infections?**

# Is Your System/Process Designed for Infection Prevention?

**EVERY STEP IN THE PROCESS HAS POTENTIAL FOR FAILURE!**



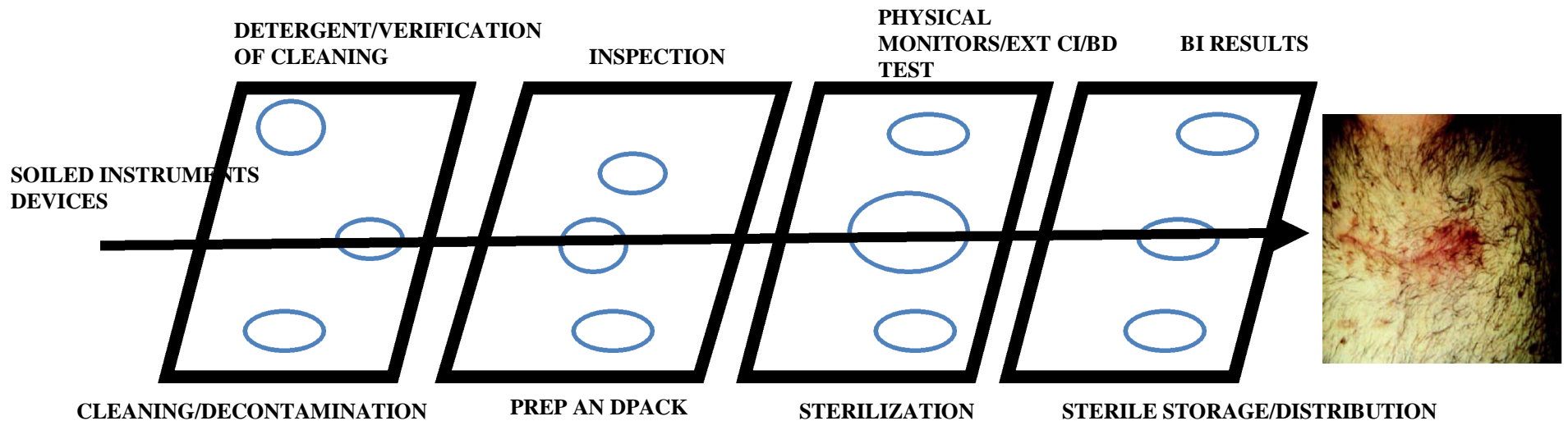
Based on James Reason's Swiss Cheese Model

<http://consumerist.com/368325/california-hospital-takes-botched-operations-seriously> from Google Images



# ... Or Is Your System/Process Designed for Infection Control?

EVERY STEP IN THE PROCESS HAS POTENTIAL FOR FAILURE!



**It is a flawed system that will allow a problem at the beginning to progress all the way through to adversely affect patient safety.**

Based on James Reason's Swiss Cheese Model

Image from Gordon, Steven New Surgical Techniques and Surgical Site Infections. EID 2001; 7 (2):217-219

# Sterilization Risk Analysis

**Risk analysis = risk assessment + risk management + risk communication**

“The sterilization risk analysis should be part of the overall infection prevention and control risk analysis in accordance with accreditation agency requirements.”

- Risk assessment (FMEA)
- Risk management (ANSI/AAMI ST79, Root cause analysis)
- Risk communication (Recall procedure)

“It should be performed annually and should be reevaluated whenever significant changes occur.”

# Sterilization Risk Analysis

- **Risk assessment**

- Identify sources of potential sterilization failures
- Estimate likelihood that each failure will occur
- Assess the consequences if that failure does occur

- **Risk management**

- Determine which of the potential sterilization failures identified require management
- Select and implement the plans or actions needed to ensure those failures are controlled
- AAMI ST79 describes the accepted means of managing these risks

## Design the sterilization process to prevent error? (SCARR)

- Standardize the process
- Checklists - outline all the steps
- Automate the process
- Reduce the number of steps and handoffs
- Redundancy (double checks)

# Quality Control

- Monitoring and verifying the cleaning process
- Sterilization process monitoring
  - monitoring of every package and sterilization load
  - routine monitoring of sterilizer efficacy
  - qualification testing of the sterilizer after installation, relocation, sterilizer malfunction, major repairs, and sterilization process failures
  - periodic product quality assurance testing

# Sterilization Process Monitoring Devices

- *Each monitoring tool “plays a distinct and specific role in sterilization process monitoring, and each is indispensable to sterility assurance.”*
- Physical monitors
  - time, temperature and pressure recorders, displays, digital printouts and gauges
- Chemical indicators (CIs)
  - external/internal CIs
  - Bowie-Dick (BD) type tests
- Biological indicators (BIs)

# Reasons for Testing the Sterilization Process

- ✓ Ensure probability of sterility of processed medical devices
- ✓ Detect sterilization failure  
ASAP: quarantine medical devices until final BI result known
- ✓ Verify a corrected failure  
ASAP... .. get sterilizer back into service
- ✓ Control costs
- ✓ Remove medical devices involved in failures before patient use
- ✓ Helps determine if events during sterilization process met parameters
- ✓ Provides verification of adherence to policies/procedures
- ✓ Promote patient safety and improve outcomes



# Physical Monitors

- Verify that parameters of sterilization cycle are met
  - Recording charts
  - Gauges
  - Tape
  - Printouts
  - Digital displays
- Limitations
  - Generally only monitor one location in the sterilizer
  - Conditions not revealed in the temperature recording, such as:
    - Improper packaging
    - Improper loading procedures

# Chemical Indicators AAMI

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 10.5.2.1

- **Class 1** Process Indicators
- **Class 2** Indicators for use in Specific Tests
- **Class 3** Single Variable Indicators
- **Class 4** Multi-variable Indicators
- **Class 5** Integrating Indicators
- **Class 6** Emulating Indicators

ANSI/AAMI/ISO 11140-1, 2005 Sterilization of health care products-Chemical indicators  
- Part 1: General requirements

# Class 1: Process Indicators (External Indicators)

- Tapes, labels, printed legends
- Designed to react to one or more of the critical process variables
- Placed on each hospital assembled package or rigid sterilization container system intended for sterilization
- Identifies processed from unprocessed packages
  - if not changed, do not use



# Class 2: Indicators for Specific Tests



- Equipment Control
- Testing sterilizer performance
  - Bowie-Dick Test monitors efficacy of air removal and steam penetration in 270-275°F dynamic-air removal sterilizers (i.e., vacuum assisted sterilizers)

## Class 2: Indicators for Specific Tests

- Bowie-Dick tests can detect:
  - Air leaks
  - Inadequate air removal
  - Inadequate steam penetration
  - Presence of non-condensable gases: air or gases from boiler additives

# Bowie-Dick Test

Follow the sterilizer and Bowie-Dick test pack instructions for use

Run warm up cycle

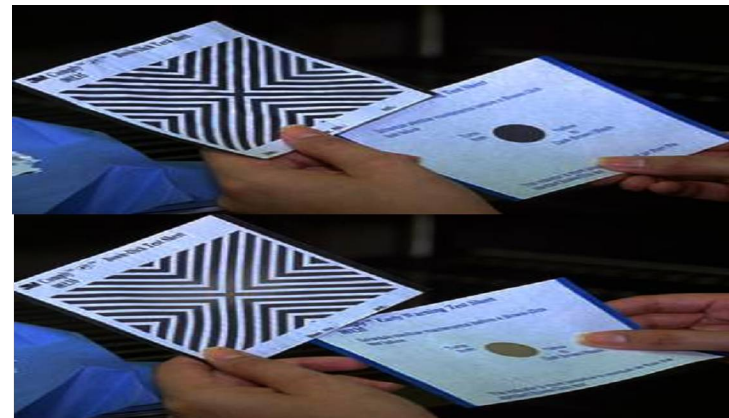
Place on bottom shelf of sterilizer rack, over drain

Run not more than 3.5 to 4 minutes, 270-275°F, remove immediately

One pack per load

# Class 2: Indicators for Specific Tests

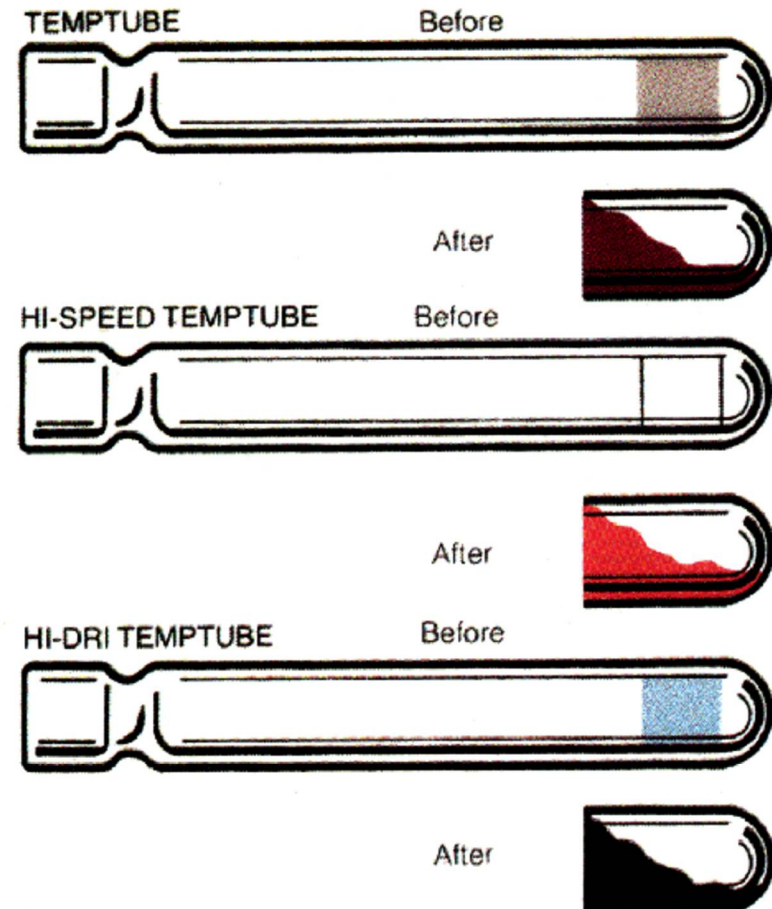
- Bowie-Dick Test
  - Uniform color change – Use
  - Not uniform color change – Retest
  - If not uniform, shut down and call repair person
  - Re-qualify if major repair





# Class 3: Single Variable Indicators

- Responds to one critical variable for sterilization
- Usually temperature
- Indicates exposure to a sterilization process at a stated value (SV) of the chosen variable





# Internal Chemical Indicators



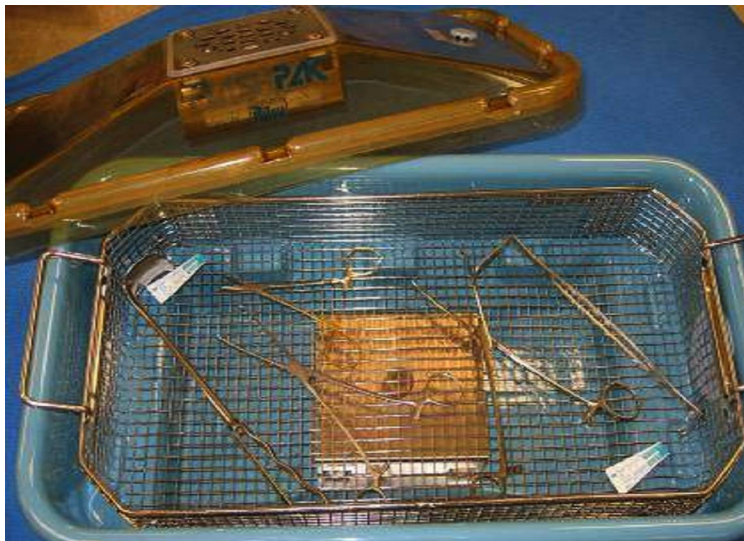
- Class 4 – Multi-variable
  - Measures 2 or more of the critical variables of the sterilization process
- Class 5 – Integrating indicator
  - Reacts to all critical variables
  - Internal chemical indicators
  - In a PCD to release non-implant loads
  - In a BI PCD to monitor implant loads
  - Correlates to the BI

# Chemical Indicator Placement



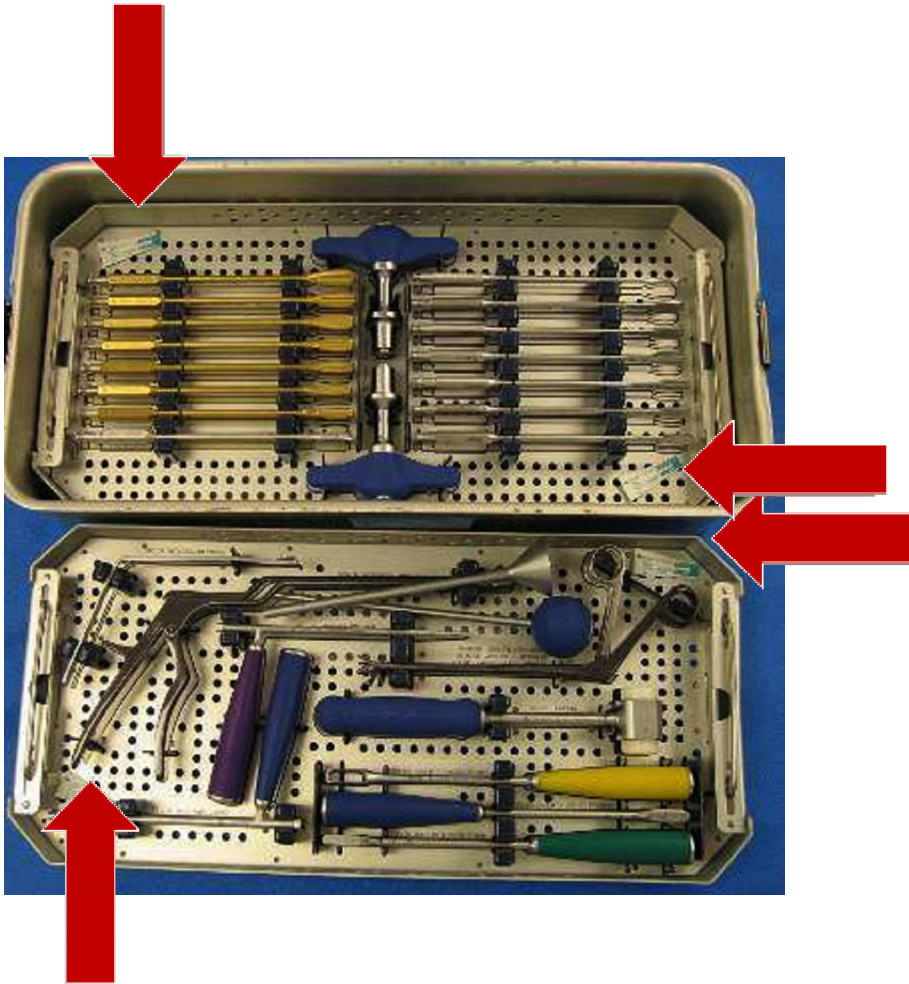
- **Rigid container**

- Place two CIs inside rigid containers
- Place one in each of two opposite corners



AORN Perioperative Standards and Recommended Practices. Recommended Practices for Selection and Use of Packaging Systems for Sterilization, Recommendation IX. 2012

# Chemical Indicator Placement



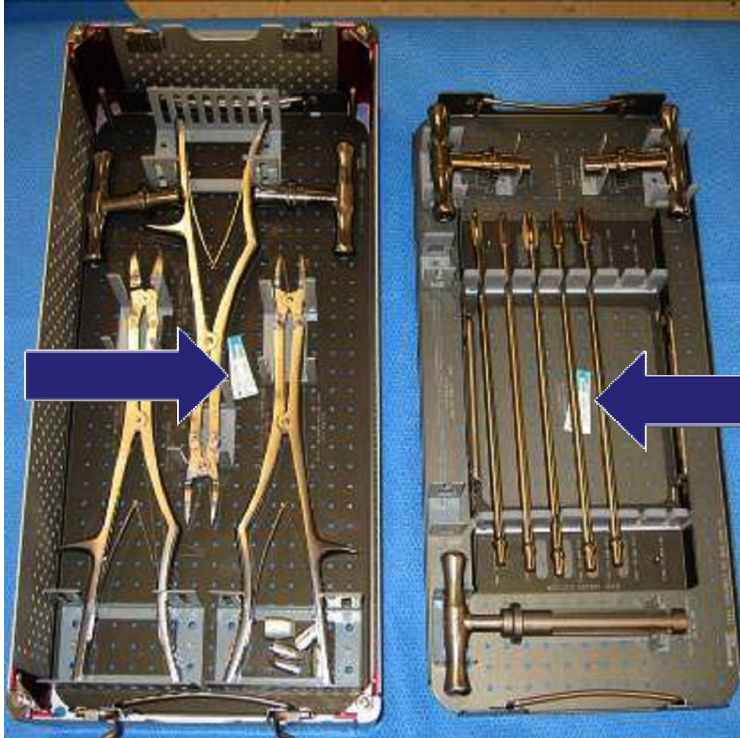
- **Multi-layer container**

- Place two CIs in each level of multi-level rigid container
- Place one in each of two opposite corners on each level

AORN Perioperative Standards and Recommended Practices. Recommended Practices for Selection and Use of Packaging Systems for Sterilization, Recommendation IX. 2012



# Chemical Indicator Placement



- Multi-level container

- Supplied by the manufacturer, holes in tray, has to be wrapped
- Place a CI in center on each level

AORN Perioperative Standards and Recommended Practices. Recommended Practices for Selection and Use of Packaging Systems for Sterilization, Recommendation IX. 2012

# Biological Indicator Monitoring

Biological indicators provide the only direct measure of the lethality of the sterilization process.

# Biological Indicator Monitoring

- 1** Routine load release    Testing of each non-implant and implant load
- 2** Routine sterilizer efficacy monitoring    Establishing a regular pattern of testing the efficacy of the sterilization process
- 3** Sterilizer qualification testing    Testing of the sterilizer after events occur which could affect the ability of the sterilizer to perform
- 4** Periodic product testing    Testing of routinely processed items to ensure the effectiveness of the sterilization process and to avoid wet packs

# CDC Guidelines

- Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
  - “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.”

# Biological Indicators/PCDs (Test Packs)

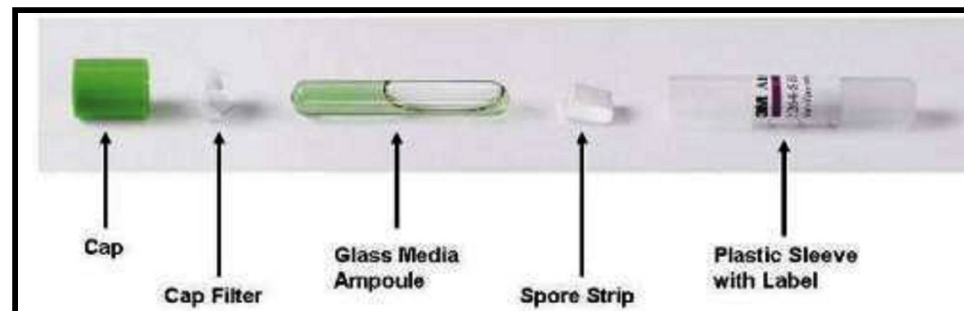




# Biological Indicators

- How they work . . .
  - Spores are exposed to the sterilization process
  - After processing, exposed spores immersed in optimized recovery media and incubated at optimal temperature
    - Spore strips are transferred to medium using aseptic technique
    - Self-contained designs allow immersion without transfer

*If spores viable –  
process failure*



# Biological Indicators Performance Specifications

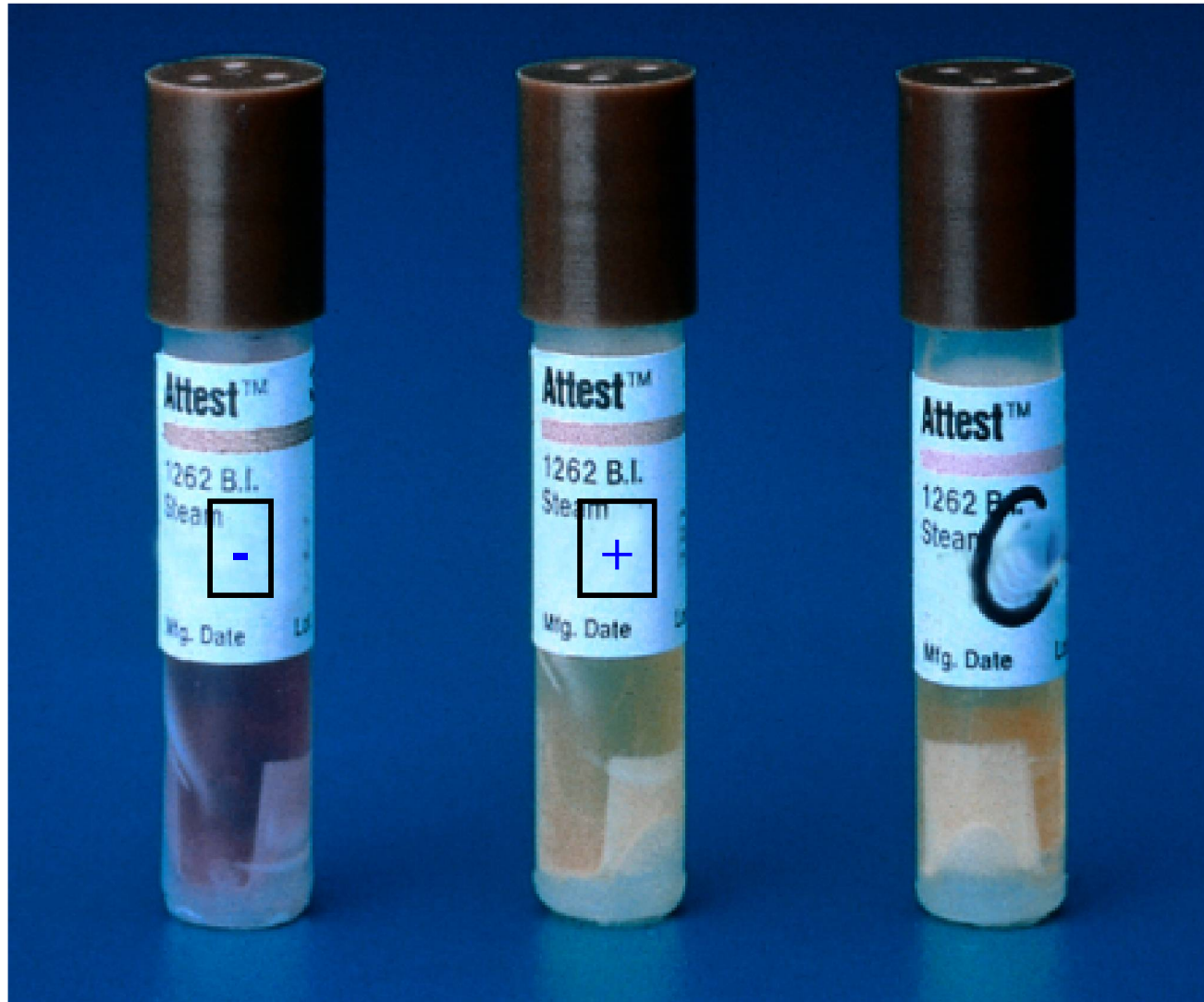
- ISO 11138-1, (2006) Sterilization of health care products- Biological Indicators - Part 1: General
- ISO 11138-2, (2006) Part 2: Biological indicators for ethylene oxide sterilization
- ISO 11138-3, (2006) Part 3: Biological indicators for moist heat sterilization

# Biological Indicators

## *(Geobacillus stearothermophilus)*

- With enzyme-based early-readout capability (AAMI) or rapid-action readout (AORN)
  - Fluorescence in 1 to 3 hours
  - Visual color change in 24 to 48 hours for steam
- “Conventional”
  - Visual color change in 24-96 hours
- Manufacturer’s incubation instructions should be followed
- AAMI ST79 – *“Periodic verification of the early-readout with spore growth should be performed in accordance with the manufacturer’s instructions and facility policy and procedures.”*
- Incubate a positive BI control each day a test vial is incubated in each incubator or auto-reader
- *From same lot number as the test BI*
- Purpose is to validate the test system is working and ensure
  - Correct incubation conditions
  - Viability of spores
  - Capability of medium to promote growth
  - Proper functioning of auto-reader and incubator
- Good Science

# “Conventional” Biological Indicators



# Sterilization Process Monitoring Devices

- Process challenge device (PCD)
  - designed to simulate the product to be sterilized
  - constitutes a defined resistance to a sterilization process and used to assess effective performance of the process
  - placed in the most challenging area in the sterilizer for sterilant penetration
- BI
- BI and a Class 5 integrating chemical indicator
- Class 5 integrating chemical indicator
- Class 6 Emulating Indicator

# Routine Sterilizer Efficacy Monitoring

- Routine load release
  - non-implant
  - implant load
- Routine sterilizer efficacy monitoring
  - Establishing a regular pattern of testing the efficacy of the sterilization process for both gravity and dynamic air-removal testing.
  - BI PCD
    - Every load
    - Daily plus every implant load
    - Weekly plus every implant load
  - BD PCD
    - Daily
- Immediate Use Steam Sterilizer (IUSS)
  - BI PCD representative of tray routinely processed
  - Each type of tray configuration in routine use should be tested separately
    - Perforated, mesh bottom, open surgical tray
    - Rigid sterilization container system
    - Protective organizing case
    - Single-wrapped surgical tray
    - Empty load on bottom shelf over drain
  - BD PCD if dynamic-air-removal
    - Daily

# Routine Sterilizer Efficacy Monitoring

- Table-top sterilizers
  - BI PCD representative of package or tray routinely processed and most difficult to sterilize
  - BI PCD should contain items normally present during routine sterilization
  - Full load in cold point (check with sterilizer manufacturer)

# Biological Indicator Monitoring Frequency

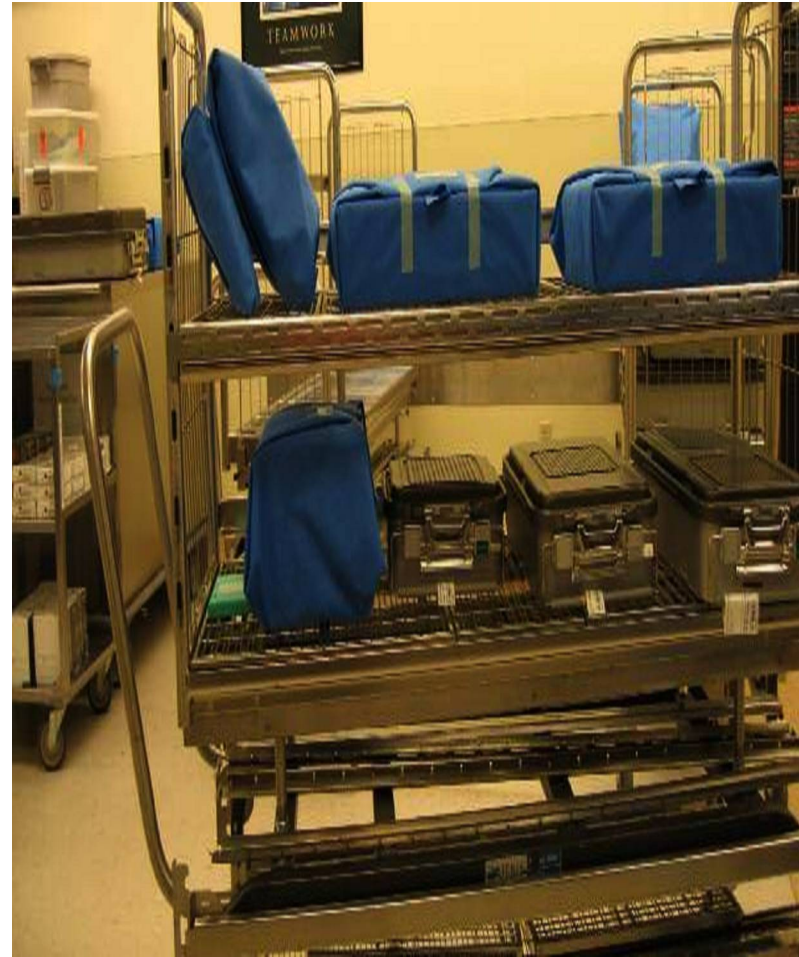
- Weekly, preferably daily
- Every load with an implant
- Some sterilization systems (e.g., Ethylene Oxide) require every load monitoring
- Why monitor every load?
  - Universal standard of patient care
  - Cost and impact of a recall
  - To be certain all implants, including those in loaners, are appropriately 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)





# Routine Load Release

## Nonimplant Loads



# Routine Load Release-Non-Implant Loads

- Physical monitors
- External process indicator (Class 1) on every package
- Internal CI (Class 3, 4 or 5, or enzyme-only) inside every package
- If desired, a PCD containing a
  - BI
  - Class 5 integrating
  - Evaluation of all data by an experienced, knowledgeable person
- Do not distribute load if any data suggests a sterilization process failure
- If desired, a PCD containing a
  - BI
- If a BI PCD is not used in each load
  - Do not know spores were killed
  - Need to do a recall when a positive BI is obtained
  - More frequent monitoring → less to recall and reduce chance of patient receiving a non-sterile medical device
- **Immediate Use Steam Sterilization Cycles (IUSS)**
- **Class 5 Integrating Indicator Challenge Pack for Releasing Flash Loads**
  - Representative of load
  - Open surgical tray
  - Rigid sterilization container
  - Protective organization case
- Use as internal CI and to release non-implant loads

# Routine Load Release-Implant Loads

## *What is an Implant?*

According to FDA, “device that is placed into a surgically or naturally formed cavity of the human body if it is **intended to remain there for a period of 30 days or more**. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also ‘implants.’ ” 21 CFR 812.3(d)

- **Only BI results can be used to release implants**

- **“BIs within a PCD should be used to monitor every load containing implants (see 10.6.1).”**

- **The PCD should include a Class 5 integrating CI**

- **“The load should be quarantined until the results of the BI testing are available (CDC, 2008).”**



# Implant Load Release (Emergency Situations)

- Releasing implants before the BI results are known is unacceptable
- Immediate use steam sterilization (IUSS) should not be used for implantable devices except in cases of emergency when no other option is available.
- Exception, not the rule
- Define emergency situations in written guidance developed in consultation with infection prevention and control, the surgeon, and risk management

*In an emergency, when flash sterilization of an implant is unavoidable, a rapid-action BI and a Class 5 chemical integrating indicator should be run with the load. The implant should be quarantined on the back table and should not be released until the rapid-action BI provides a negative result.”*

# Sample - Implant Exception Form

- Name of
  - Implant prematurely released
  - Patient
  - Surgeon
- Reason for premature release
- What could have prevented premature release

## Exception Form for Premature Release of Implantable Device/Tray

NOTE—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. Operating Room personnel should complete this form and return it to Central Service within 24 hours.

### PLEASE COMPLETE ALL INFORMATION:

DATE: \_\_\_\_\_ SHIFT: \_\_\_\_\_ TIME: \_\_\_\_\_ AM PM

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: \_\_\_\_\_

The following implantable devices/trays were prematurely released to the Operating Room:

\_\_\_\_\_  
\_\_\_\_\_

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:

\_\_\_\_\_

### OPERATING ROOM REPORT:

PATIENT NAME: \_\_\_\_\_

SURGEON NAME: \_\_\_\_\_

TIME OF PROCEDURE: \_\_\_\_\_ AM PM DATE: \_\_\_\_\_

REASON PREMATURE RELEASE WAS NEEDED: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE? TRAY? \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

NAME OF OR PERSON COMPLETING THIS REPORT: \_\_\_\_\_

DATE REPORT COMPLETED: \_\_\_\_\_ FORM RETURNED TO CENTRAL SERVICE ON: \_\_\_\_\_

\_\_\_\_\_

Figure L.2—Exception form for premature release of implantable device/tray

# Steam Sterilizer Qualification Testing

# Steam Sterilizer Qualification Testing

- This qualification testing should be conducted in the health care facility by health care personnel in cooperation with the manufacturer.
- Testing should be performed
  - at the time the steam sterilizer is installed, relocated, or repaired and the time it is released for use in the health care facility.
  - for both gravity-displacement and dynamic-air-removal sterilizers
  - three consecutive cycles should be run, one right after the other, with a PCD
- Negative results from all test BIs and appropriate readings from all physical monitors and CIs.
- Dynamic-air removal sterilizers
  - three consecutive cycles should be run, one right after the other, with the Bowie-Dick test pack
  - each test result demonstrating sufficient air removal
  - empty chamber should be used for the tests.
- Cool transfer cart between each cycle to ensure that superheating does not occur and to more closely duplicate normal processing procedures



# Sterilizer Qualification Testing

- Major repairs of steam sterilizer

- Repairs outside the scope of normal maintenance

- Examples:

- Weld repairs of pressure vessel
- Replacement of chamber door or piping assembly
- Rebuilds or upgrades of controls

- Major repairs of utilities

- Changes to the utilities connected to the sterilizer

- Examples:

- Water-main break
- Annual boiler maintenance
- Additional equipment loads
- Installation of new boilers



# Steam Sterilizer Qualification Testing

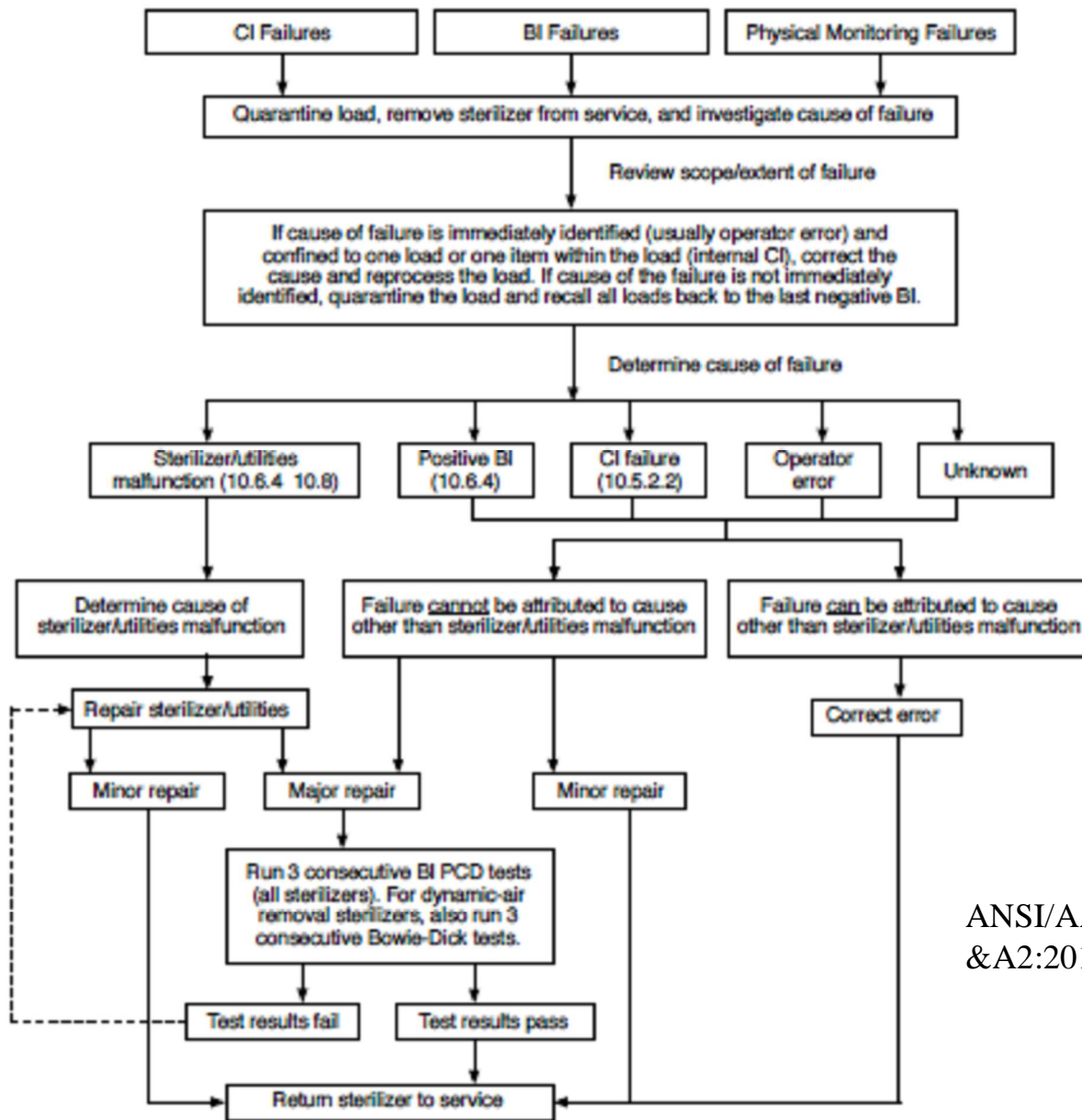
- **Table-top sterilizers**

- BI PCD representative of package or tray routinely processed and most difficult to sterilize
- BI PCD should contain items normally present during routine sterilization
- Full load in cold point (check with sterilizer manufacturer)
- Three consecutive cycles

- **Flash sterilizers**

- BI PCD representative of tray routinely processed
- Select a tray configuration to be tested
  - Perforated, mesh bottom tray, open surgical tray
  - Rigid sterilization container system
  - Protective organizing case
  - Single-wrapped surgical tray
- Empty load on bottom shelf over drain
- Three consecutive cycles

# Investigation Steam Sterilization Process Failures



ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 Figure 12, Table 8

# Sterile Storage

Sterile items should be stored in a manner that reduces the potential for contamination.

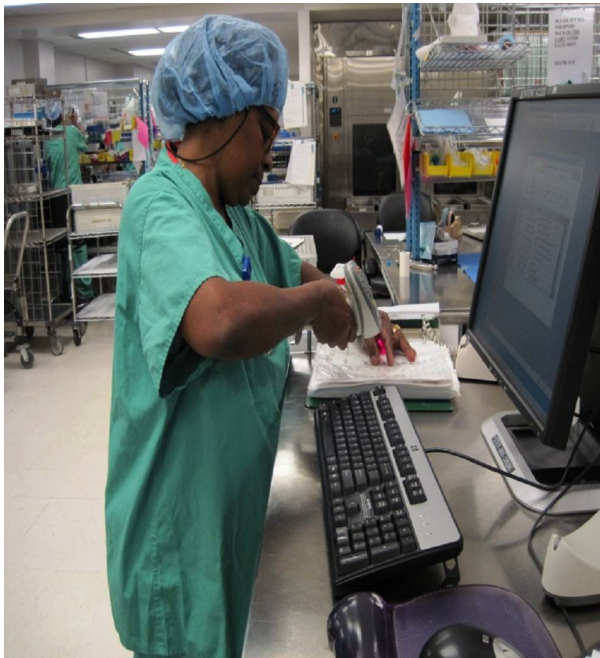
# Sterile Storage

- Separate area with restricted access
- Proper ventilation (at least 4 air changes/hour, positive pressure to corridor) to protect against dust, moisture and extremes of temperature (~24°C /75°F) and humidity (<70%)
- Free of insects and vermin
- Sterile items should be stored away from outside walls (at least 2 inches), off the floor (at least 8-10 inches) and away from the ceiling (18 inches)
- Stored to prevent physical damage (dragging, sliding, crushing, bending, compressing or puncturing)
- Sterile packages should be minimally handled to reduce the risk of contamination of the contents
- Should not be stored next to sinks or under exposed water or sewer pipes or in locations where they may become wet
- Should not be stored on floor or windowsills
- Shelf life is event related
- Sterile packages transported to the point of use should be protected to prevent contamination

# Record Keeping

# Documentation

## Manual or Electronic



### •What?

- Materials that have been processed
- Results of the sterilization process monitoring

### •How?

- Load labels/package
- Paper log systems
- Electronic log systems
- Filed as individual document

# Documentation

## Manual or Electronic

### ❖ Labeling on product

- *Lot or load control number*
  - Date of processing
  - Sterilizer number
  - Cycle number

### ❖ *Expiration date or statement:*

*“Contents sterile unless package is open or damaged. Please check before using.”*

### ❖ Electronic system

- Reduction of human error
- Past records available with a touch of a finger
- Accessibility to all load records at any time
- All load information in one location



# Documentation

## Electronic or Manual



- **Electronic system**
  - Reduction of human error
  - Past records available with a touch of a finger
  - Accessibility to all load records at any time
  - All load information in one location

# Documentation

## Electronic or Manual

- Sterilizer and load records
  - Load contents
  - Date and time of cycle
  - Exposure time and temperature
  - Initials of operator
  - Biological results
  - Chemical indicator results
- Records of sterilizer repair, maintenance and calibration
- Maintain records for time determined by risk manager

# Recall Procedures

**Risk Communication**

# Recall Procedures

- Written policies and procedures for the recall of items from issued or stored loads should be developed in cooperation with the infection prevention and control committee and risk management of the individual health care facility.
- These policies and procedures should be documented, and records should be maintained.

# Sterilization Process Failures

- A processed PCD with a positive BI (BI challenge test pack) or a failed Class 5 integrating CI or Class 6 emulating indicator (CI challenge test pack) is demonstrating a failure for the entire load and **should be immediately reported by phone or messenger to the appropriate supervisor and to the infection prevention and control department.**
- This notification should be followed by a written report.
- Quarantine load, remove sterilizer from service, investigate cause of failure
- Decision tree to assist with the recall

# When To Do a Recall

- If cause of failure immediately identified and confined to one load or item
  - e.g., using incorrect sterilization cycle
  - No recall, correct problem and reprocess load
- If cause of failure not identified
  - Quarantine load, recall all items processed since last negative BI
  - Determine cause of failure

# Areas of Concern



# Areas for Concern for Infection Prevention and Control

- Cleaning Verification
- Toxic Anterior Segment Syndrome (TASS)
- Loaner Instrumentation
- Extended Cycle Times
  
- It is important to collaborate and be an advocate for your Central Sterile Department to address these real issues

# Cleaning Verification

- Test mechanical instrument washers:
  - *Before initial use*
  - *Weekly during service*
  - *After major maintenance*
- Evaluate manual cleaning
  - *When new instruments are reprocessed and periodically*



# Cleaning Verification

- Monitoring of mechanical cleaning equipment
  - Frequency of testing
    - Upon installation
    - Weekly (preferably daily) during routine use
    - After major repairs
  - Review and initial mechanical washer cycle printouts
  - Document results
- Resource: Annex D User verification of cleaning processes

# Areas of Concern

Toxic Anterior Segment Syndrome  
(TASS)

# Toxic Anterior Segment Syndrome (TASS)



- **The Issue:**  
*Serious damage to a patient's intraocular tissue and vision loss as a result of contaminants introduced into the eye during ophthalmic surgery*
- **The Causes:**  
*Contaminated irrigating fluids; antiseptics; antibiotic ointments; powder from surgical gloves; "Most cases of TASS appear to result from inadequate instrument cleaning and sterilization"*
- **Inadequate or inappropriate instrument cleaning**
- *"Detergents"*
- *Heat stable endotoxin from overgrowth of Gram-negative bacilli in water baths or ultrasonic cleaners*
- *Degradation of brass containing surgical instruments from plasma gas sterilization*
- *Impurities of autoclave steam"*

Nick Mamalis, MD, *Toxic Anterior Segment Syndrome* Journal of Cataract and Refractive. Surgery 2006; 32:324-333.

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 7.5.5, Annex N

# Toxic Anterior Segment Syndrome (TASS)

- Follow manufacturing cleaning and sterilization instructions
- Adequate inventory-time for processing
- Designated cleaning area and dedicated equipment
  - Precleaned immediately
  - Transport in closed containers
  - PPE
  - Appropriate cleaning agent & water of appropriate quality as specified by the Mfr.
  - Sterilization according the Mfr's. instructions
- Maintenance of cleaning and sterilization equipment, boilers and water filtration systems
- Training
- AORN Recommendation XIV
  - Special precautions should be taken for reprocessing ophthalmic surgical instruments.
  - Provides a thorough list of recommended practices aimed at preventing TASS

AORN Perioperative Standards and Recommended Practices. Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment, Recommendation XIV, 2012

# Areas of Concern

## Loaner Instrumentation





# Managing Loaner Instrumentation

- Use of loaners has become common practice across U.S.
  - Increasing need to borrow instruments, implants and other devices
  - Vendors
  - Neighboring facilities
- Why?
  - Ever-changing technology
  - Multiple cases in the same day: **block scheduling**
  - Procedures done infrequently
  - Specialty procedures (e.g., pediatrics)
  - Cannot afford to purchase everything
  - Space/storage issues

# Loaner Instrumentation Issues

- Patient Safety
- Timelines (flashing is not recommended)
- Communication (OR, SPD, Vendor)
- Quality
  - **MDM Reprocessing Guidelines**
  - **Adequate time**
  - **Implants**
- Potential for lost items



# Loaner Instrumentation

- Last minute arrivals can result in:
  - Can lead to inadequate processing
  - Lack of processing time
  - Failure to obtain instructions for use.
  - Failure to ensure sufficient processing staff are available.
  - Failure to ensure processing capacity is available.
  - Failure to ensure processing implants can be properly monitored.
  - Failure to ensure staff are in-serviced or trained on how to process sets and to focus on complex medical devices.
  - Failed labeling and set identification.
  - Failure to ensure all loaned instruments and implants are accounted for.
  - Unnecessary stress!!
- Last minute arrivals can have a serious impact on patient outcome and cause major disruption in process flow.

# Where have the trays been?



Loaned instruments are in no condition for use when they arrive. Move in “uncontrolled environments” (planes, trains, automobiles).



Mark Duro, New England Baptist Hospital

# Where have the trays been?



Some vendor transport vehicles are less than ideal. Therefore, all items must be cleaned.



## Loaner Instrumentation – Best Practices to Avoid Impact on Central Sterile and the OR

- ✓ Need to have Manufacturer's written Instructions for Use (IFU) including reprocessing instructions
- ✓ Staff need to be trained on the trays (disassembly, cleaning, inspection, packaging and sterilization)
- ✓ Some IFU provide excellent guidance, while others are poorly written and do not give clear guidance on cleaning issues for specific complex instrumentation and problem areas.
- ✓ Unfortunately, the CSD staff may know or have time to investigate problematic items if trays do not arrive for reprocessing in a timely manner.

# Managing Loaner Instrumentation

- Develop and follow a policy and procedure to manage loaners
- Resources:
  - Joint position paper created and adopted by ASHCSP and IAHCMM – now joined together
  - [http://www.iahcsmm.org/current\\_issues\\_Joint\\_paper\\_loaner\\_instrumentation.htm](http://www.iahcsmm.org/current_issues_Joint_paper_loaner_instrumentation.htm)
  - AORN Recommended Practice
  - Managing Infection Control Journal in-service “Loaner Instrumentation: Keeping Patient Safety First” by Rose Seavey, April, 2007
- Need adequate time to properly reprocess instrumentation: receive loaners at least by the evening before the procedure is scheduled



# Areas of Concern

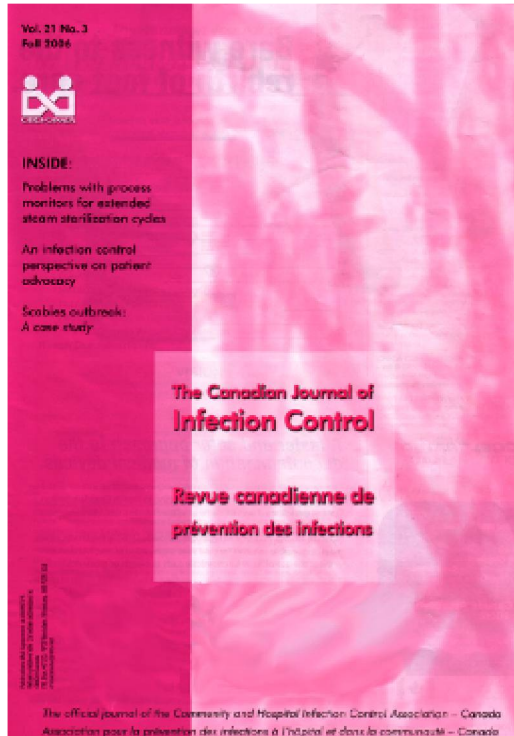
Extended Cycles

# Extended Steam Sterilization Cycles

- What?
  - A steam sterilization cycle that is extended beyond the sterilizer manufacturer's standard cycle time
- Why?
  - Result of medical device manufacturer sterilization validation studies
    - Complex design
    - Lumen size
    - Dense configurations
    - Use of containment devices



# Monitoring Extended Steam Sterilization Cycles



- *“Despite the requirement by the medical device manufacturer for longer cycles, there has not been the concurrent development of the appropriate chemical indicator (CI) and biological indicator (BI) challenge packs to adequately monitor these extended steam sterilization cycles.”*

Dr. Michelle Alfa

Fall 2006 issue of the Canadian Journal of Infection Control

# Monitoring of Extended Cycles

- If a BI PCD for an extended cycle is not available
  - Perform product testing
    - BIs and CIs inside trays
    - Include BI PCD in load - Look for correlation
  - Routinely monitor as would other loads
    - Use same BIs, CIs & PCDs and read the physical monitors

# Product Testing

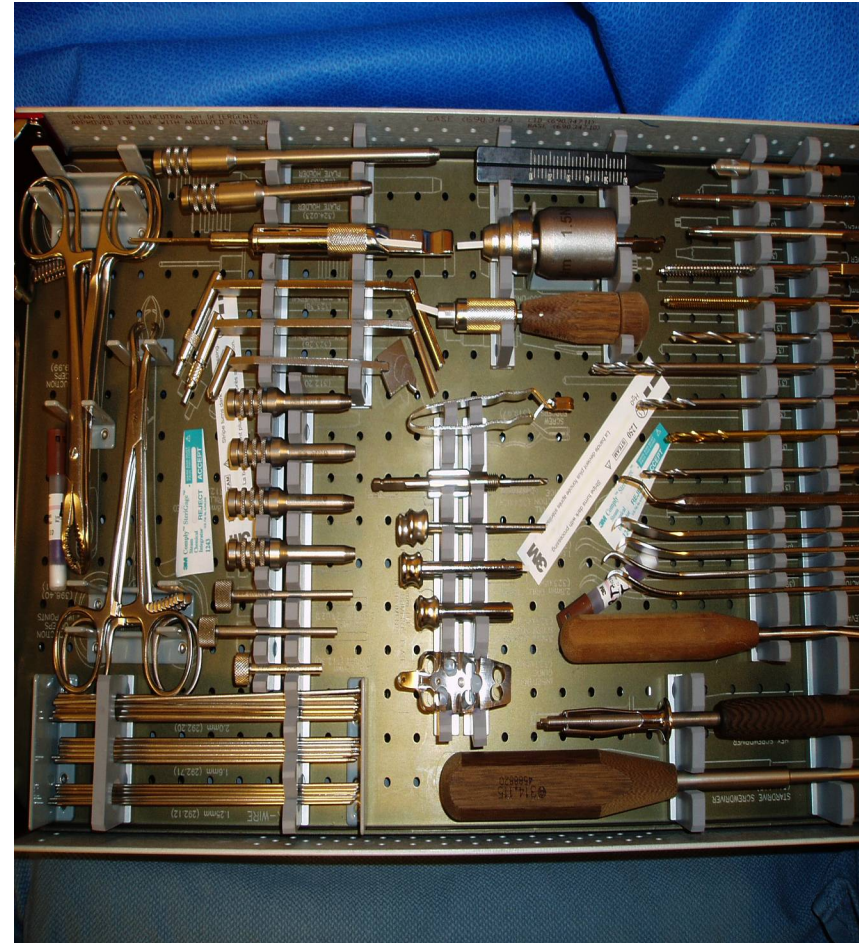
*Product testing should always be performed when major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper.”\**

# Product Testing

- Verify and maintain efficacy after any changes are made in sterilization process
- Changes include:
  - Packaging materials
  - Containers
  - Load contents
  - Packaging dimensions, weight, and load configuration
  - New product to sterilize

# Periodic Product Quality Assurance Testing

- Physical monitoring of cycle
- Multiple BIs and CIs within product test samples
- Verify sterilization effectiveness
- Avoid wet packs



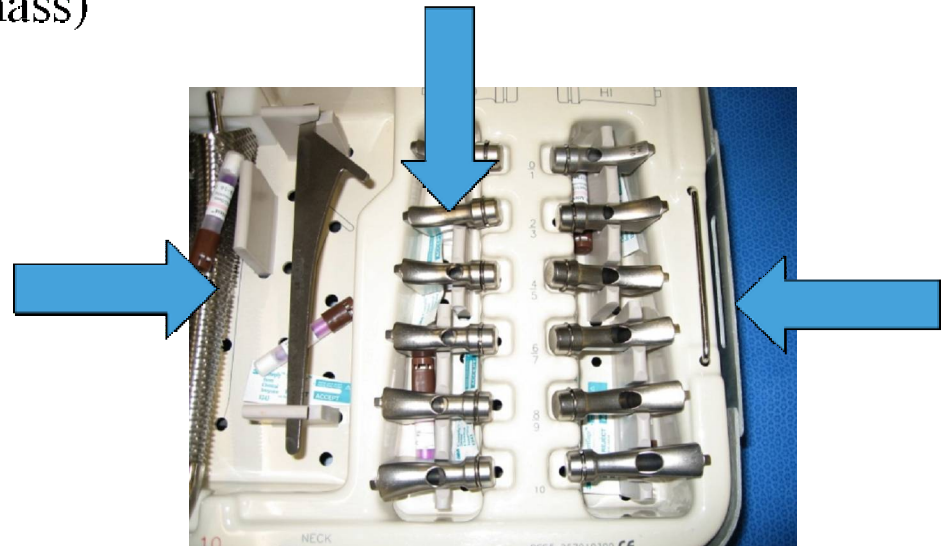


# Product Testing

- Place multiple BIs and CIs into area of packages determined to be the greatest challenge
  - Corners
  - Different layers
  - Next to the heat sink (metal mass)
- Label as product testing
- Place in full load
- Run the appropriate cycle
- Document
  - Date testing performed
  - Name of set, tray or item
  - Placement of all BIs and CIs

(photo)

- Test results
- Results determine routine placement of BI and CI
- Examine for evidence of excess moisture





# Pre-purchase Evaluation of Rigid Container Systems



- Conduct a pre-purchase evaluation of rigid sterilization container system
- Consult container manufacturer for recommended BI and CI placement
  - Test system should contain instruments
  - Filters, if required, must be in place

# Summary

- Collaboration with the CSD / SPD is key
- Include CSD / SPD in your Joint Commission tracer and rounding activities
- Include the function in your risk analysis and perform an FMEA and root cause analysis when issues arise that impact patient safety
- Develop policies and procedures for the management of loaner instrumentation
- Be knowledgeable of the contents of the AAMI standards and recommended practices
- Monitoring of the sterilization process is necessary for maintaining patient safety and infection prevention
- Be aware of the concerns facing the CSD / SPD



Some days we just get stuck, and bogged down.  
Some days all you can do is smile and wait for someone to kindly  
remove your butt from the hole you find it wedged into.

# Acknowledgments

- Staff of the Sterile Processing Department at Sinai Hospital of Baltimore
- Mark Duro, New England Baptist Hospital

## AAMI Standards and Technical Information Reports

- ANSI/AAMI ST79:2010, A2:2010 & A2:2011  
Comprehensive guide to steam sterilization and sterility assurance in health care facilities (Under ongoing review)
- ANSI/AAMI ST77:2006 Containment devices for reusable medical device sterilization (under review)
- ANSI/AAMI ST58:2005/(R)2010 Chemical sterilization and high-level disinfection in health care facilities (under review)
- ANSI/AAMI ST81:2004/(R)2010 Sterilization of medical devices-Information to be provided by the supplier for the processing of resterilizable medical devices



# How to Purchase AAMI Standards for Your Reference Library

AAMI documents can be purchased through AAMI by credit card using the following four options:

Internet: <http://marketplace.aami.org>

Call: 1-877-249-8226

Fax: 301-206-9789

Mail: AAMI Publications, P.O. Box 0211, Annapolis Junction,  
MD 20701-0211

## AAMI Standards and Technical Information Reports

- ANSI/AAMI PB70:2003/(R)2009 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.
- ANSI/AAMI ST41:2008 Ethylene oxide sterilization in health care facilities: Safety and effectiveness, 4ed (if you use EO sterilization; under review)
- Other
  - AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 3ed
  - AAMI TIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices, 2ed
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