STERILIZATION UPDATE

Cynthia Spry RN, MA, MS, CNOR, CSIT

Independent Consultant

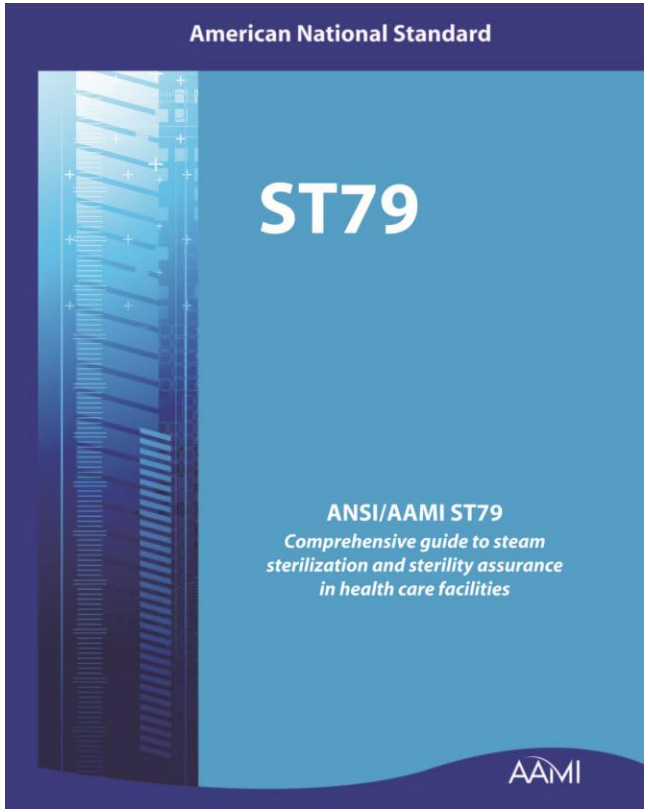
Cynthia350@gmail.com

Current Issues

- AAMI Updates
- Extended Cycles
  - Definition
  - Impact
  - Response
- Immediate use Sterilization
  - Joint Commission
  - FDA
- Loaners
- Monitoring and Class 6 Emulating Indicator
- New Technology - resources

AAMI Updates

- AAMI steam sterilization documents combined into ST79:
  - ST46
  - ST42- Table-top
  - ST 37 – Flash
  - ST 35 Decontamination
  - ST 33 Rigid Sterilization Container Systems

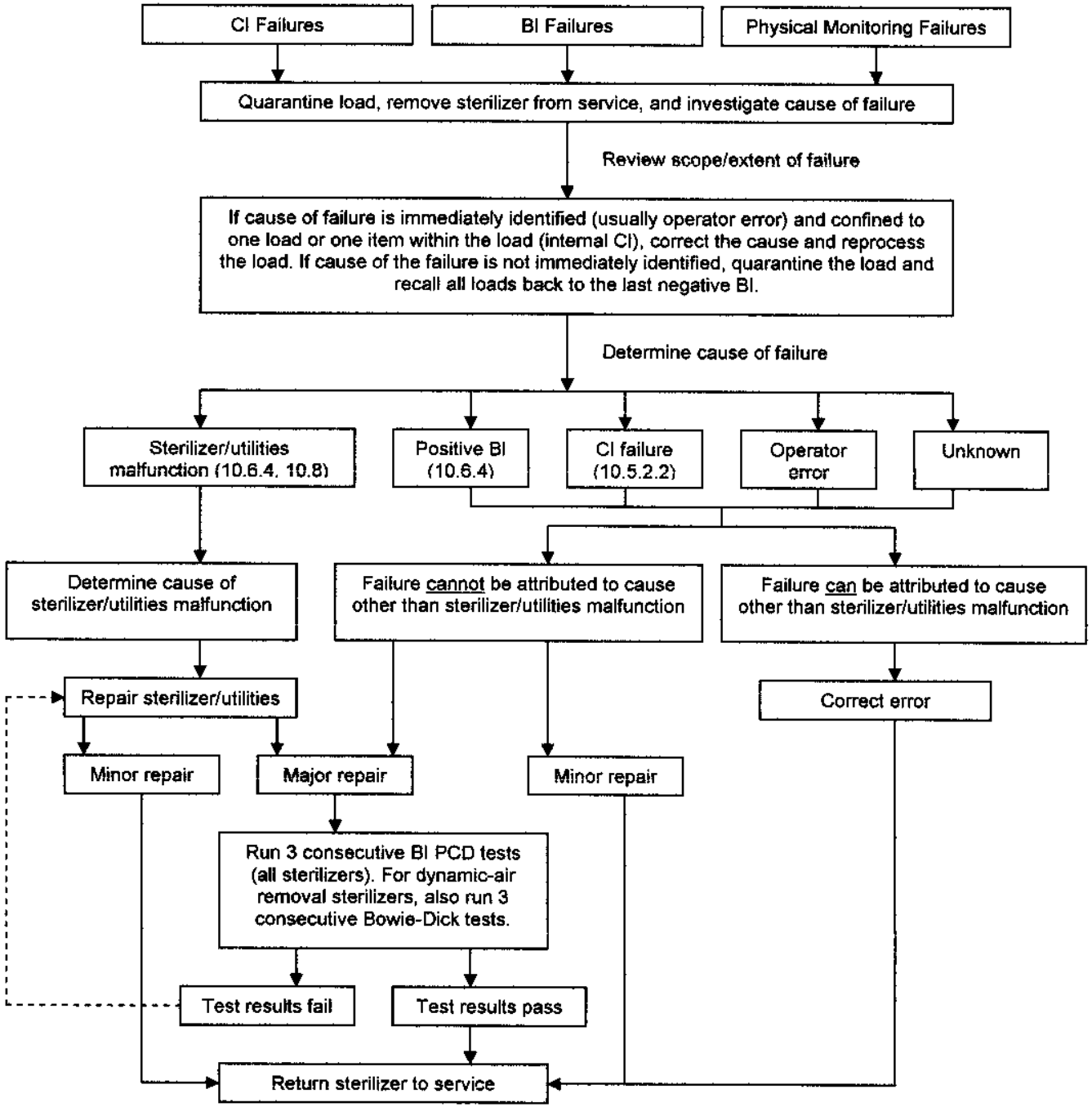


AAMI Updates

- Malfunction of utilities – 3 consecutive test cycles with BI PCD, empty chamber; full chamber if table-top
- Do not moisten lumens unless in IFU
- Filtered, compressed medical grade air to dry instruments
- Enzyme only indicator removed
- Bowie-Dick after shortened cycle
- Flash – test each tray, each type cycle – shortest time

AAMI Updates

- Checklist for possible reasons for process failure
- Algorithm for CI, BI, PI failure


CI Failures
BI Failures
Physical Monitoring Failures
Quarantine load, remove sterilizer from service, and investigate cause of failure
Review scope/extent of failure
If cause of failure is immediately identified (usually operator error) and confined to one load or one item within the load (internal CI), correct the cause and reprocess the load. If cause of the failure is not immediately identified, quarantine the load and recall all loads back to the last negative BI.
Determine cause of failure
Sterilizer/utilities malfunction (10.6.4, 10.8)
Positive BI (10.6.4)
CI failure (10.5.2.2)
Operator error
Unknown
Determine cause of sterilizer/utilities malfunction
Failure cannot be attributed to cause other than sterilizer/utilities malfunction
Failure can be attributed to cause other than sterilizer/utilities malfunction
Repair sterilizer/utilities
Correct error
Minor repair
Major repair
Minor repair
Run 3 consecutive BI PCD tests (all sterilizers). For dynamic-air removal sterilizers, also run 3 consecutive Bowie-Dick tests.
Test results fail
Test results pass
Return sterilizer to service

AAMI Updates

- Guidelines for determining product families for product testing
  - Impossible to test ALL product
  - Test representative product
- “Product testing should be performed whenever there is a change in packaging systems, materials, tray configuration or content density.”

Product Testing

- Testing your product under your conditions in your equipment
- Appropriate when significant changes, e.g.
  - Packaging (blue wrap to containers
  - Loaners
  - New specialty sets
  - New configuration
  - Sterilizer, device and packaging IFU not congruent

Product Testing

- Testing for efficacy
- Testing for moisture

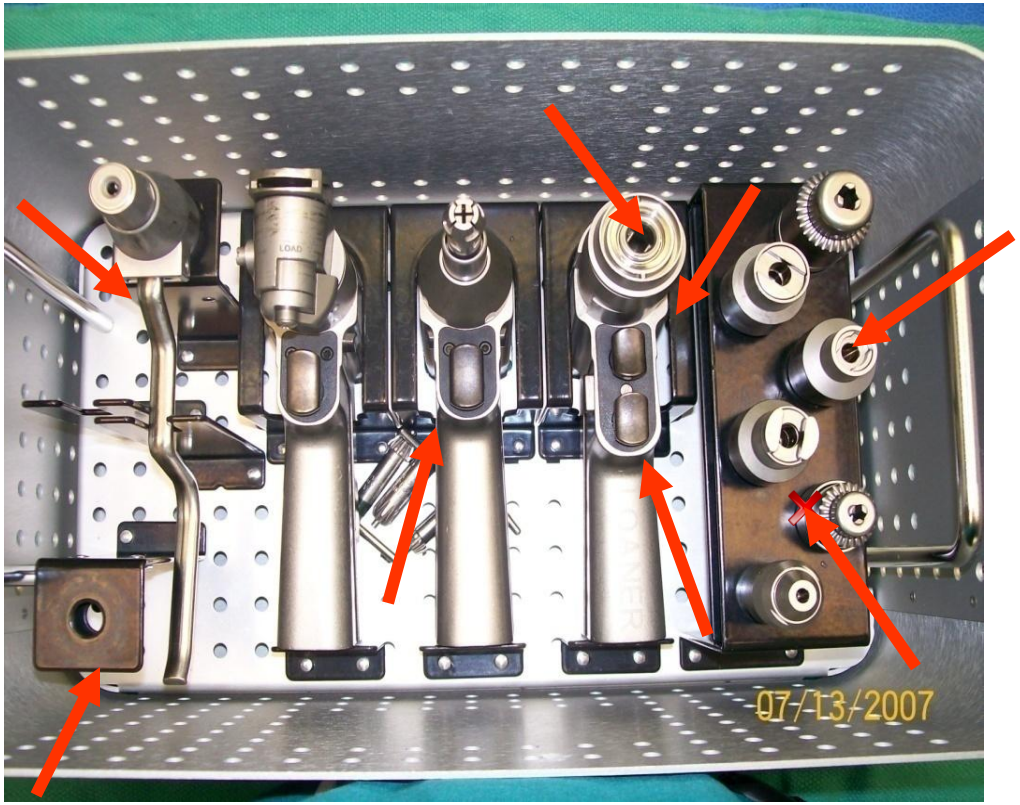
Product Testing

- Instrument sets
  - End of tray, among stringers, near heat sink, each layer

- Containment devices – corners, center, other

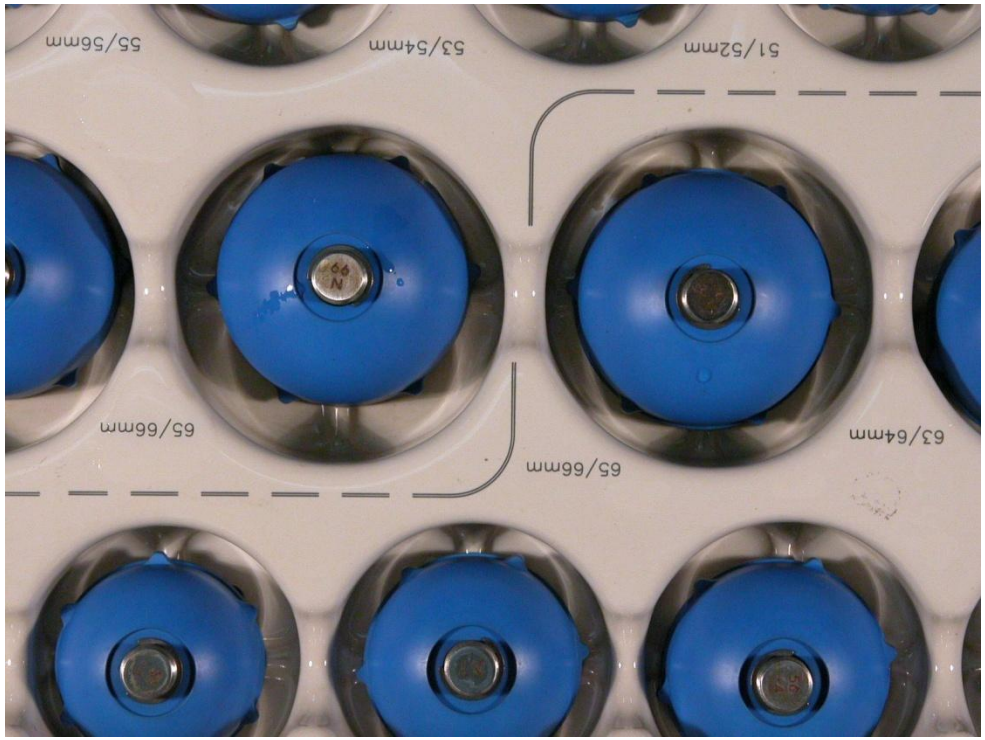
- Basin sets – where air pockets could form

Product Testing



- Place multiple BIs and CIs into areas of packages determined to be the greatest challenge
- Label as “product testing”
- Place in full load
- Run the appropriate cycle

Product Testing



- Examine for evidence of excess moisture
  - Wet or damp absorbent material
  - Water droplets
  - Water stain
    - Do not use, not considered sterile
  - Document and use layout in the future

Product Families, Master Product

- Lumen
- Density – metal mass
- Size
- Materials
- Configuration
- Weight
- Packaging system

AAMI Updates

- Risk Analysis
  - Should be performed annually and whenever significant changes occur
  - Written plan – typically around possible recall

Template – Risk Analysis for Sterilization Failure

1. Select processing component (decontam, prep and pack, storage etc.)

2. Review selected component in AAMI ST 79 and AORN RP 2010

3. Identify issues to analyze within component
   Consider issues that are problem prone, high risk, especially significant

4. Provide rationale for selection – historical data, observation,
   new information, etc.

5. Identify likelihood of failure and how prepared you are in the event of
   failure

6. Identify variables that impact failure

7. Determine what variables need management

8. Develop management plan

9. Implement plan

10. Monitor compliance

11. In the event of a sterilization failure communicate (OR,SPD, ICP, MD, adm., etc. according to policy

Extended Cycles

Extended Cycles

- What are they?
  - Longer than sterilizer manufacturer validation, e.g.
  - 5 to 20 minutes dynamic air removal 270^0C
  - Up to 1 hour gravity 250^0C
- Why?
  - Complexity of design
  - Lumen
  - Dense configuration of the set
  - Material – plastic
  - Layers in set
  - Testing indicates it takes longer to reach 10^{-6}
  - Prion cycle in Europe
- More than 30 different cycles

Extended Cycles - Examples

- Manufacturer's instructions
  - Synthes Graphic Case
    - Pre-vacuum Steam 270-275^{0}F
    - Standard set 8 minutes
    - Spine and maxillofacial – 10 min

    - Gravity 270-275^{0}F
    - Standard set 22 min
    - Spine and maxillofacial – 28 min

SYNTHES®

SYNTHES
1301 Goshen Parkway
West Chester, PA 19380

February 2, 2009

http://mccsp.org/Documents/SYNTHES%20Sterilization%20Parameters.pdf

Re: New Information on the Sterilization Recommendations of Synthes Devices, i.e. Implants, Instruments, and Cases

This letter is to inform you that Synthes has recently re-evaluated our steam sterilization recommendations with the intent of understanding our customer's need for standard hospital steam sterilization processes. The outcome of that review determined that re-qualification of our medical devices for standard sterilization parameters was warranted for the purpose of improving upon previously established sterilization test protocols. Retesting has provided data which supports a sterility assurance level (SAL) of 10^{-6} using a standard hospital Prevacuum cycle, e.g. 4 minute @ 132°C. New test protocols were established utilizing the "overkill method" and sterilization performance criteria outlined in AAMI TIR12:2004 and AAMI ST77:2006. The new test protocols included worst-case devices for sterilization with respect to the device design, device material, case ventilation, and weight.

The new parameters are as follows:

Cycle Type	Minimum Sterilization Exposure Time	Minimum Sterilization Exposure Temperature	Minimum Dry Time
Prevacuum	4 minutes	132°C (270°F)	20 minutes

Notes:

1. *Dry times may be highly variable due to differences in packaging materials (e.g. nonwoven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance, and varying cool down time. The user should employ verifiable methods (e.g. visual inspection) for achieving adequate drying, where differences between the manufacturer's recommendations and the user's results differ.*
2. *These parameters are only valid for devices that are adequately cleaned.*
3. *These parameters are only valid for a properly installed, maintained, and calibrated AAMI compliant healthcare sterilizer.*
4. *These parameters cannot currently be recommended for use with parts: 306.710, 304.754, 304.688, 304.760, 304.771 and 304.686. Re-testing is currently in-progress for inclusion of these case designs. For the interim, please use the recommendations that were issued with the insert for these part numbers.*
5. *These parameters **cannot** be used for the Synthes Power Drive Unit, PN: 530.100.*

Please know that our process for changing our recommended sterilization parameters to standard cycle times is an on-going process that will require further changes within our systems in order to replace older labeling with the new recommendations. This letter may serve as supporting documentation for Synthes current end-user sterilization recommendations.

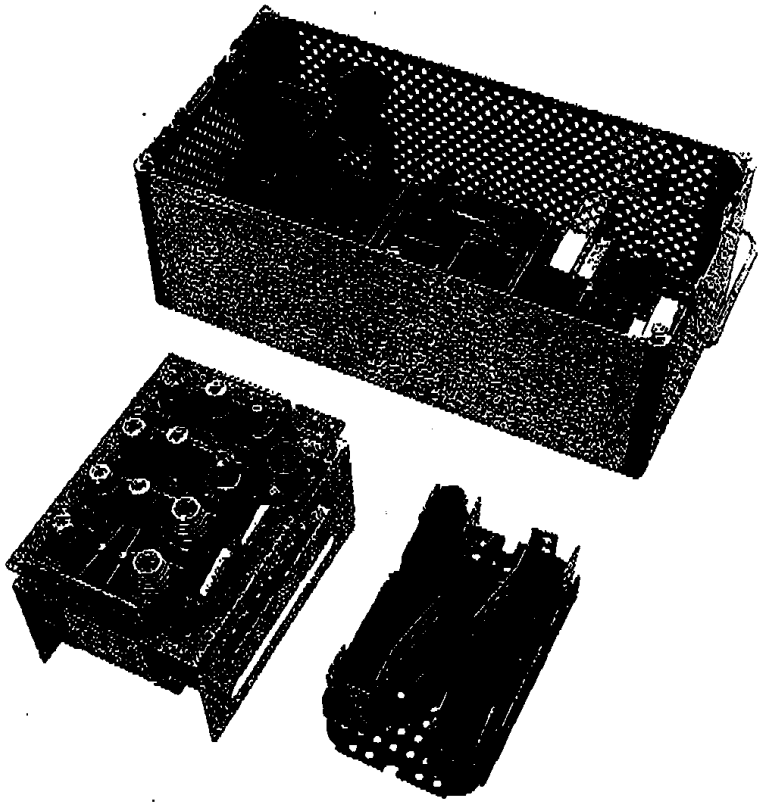
Sterilization Guide for Power Drive Set

http://products.synthes.com/prod_support/Product%20Support%20Materials/User%20Guides%20and%20Manuals/SUSA/SUMANPowerDriveJ2971F.pdf

To sterilize the Power Drive and attachments:

- Disassemble all parts, including attachments, adaptors, instruments and battery packs
- Remove battery pack from drive unit
- Remove battery from casing.
  Battery casing must be open for sterilization

Note: Do not sterilize batteries! Batteries will no longer function.



The Synthes Power Drive Set should be steam sterilized in the graphic case in accordance with the following guidelines:

Wrapped	Temperature	Minimum Exposure Time
Prevacuum	132°–135°C (270°–275°F)	24 minutes
Unwrapped (Flash)		
Prevacuum	132°–135°C (270°–275°F)	24 minutes

Times represent exposure times only, and not total cycle times.


SCIENT'X
STELLA® ANTERIOR CERVICAL PLATE SYSTEM
TO BE STEAM STERILIZED
AFTER CLEANING 134°C - 18 MIN.
31BOI12 (3/3)
PATENT PENDING
SCIENT'X
STELLA® ANTERIOR CERVICAL PLATE SYSTEM
31BOI12 (1/3)
PATENT PENDING

DePuy
a Johnson & Johnson company

CE

Cycle Type	Minimum Temperature	Minimum Exposure Time / Dry Time
Prevacuum	132 - 134º C	8 minutes / 20 minute dry time for metal or metal/poly trays and 45 minute dry time for all poly trays.
	134 - 137º C	5 minutes/ 20 minute dry time for metal or metal/poly trays and 45 minute dry time for all poly trays.

Extended Cycles

- Issues:
  - Awareness
  - Sterilizer tied up for one item – prevents rapid throughput
    - Reduced sterilizer capacity
  - Should not mix devices unless all are cleared for extended cycle times
    - Effect on functionality unknown
  - Packaging, BI and Sterilizer may not be cleared for extended cycles
    - Using products “off label”
  - No PCD for extended cycles
    - Impact on BI accuracy uncertain

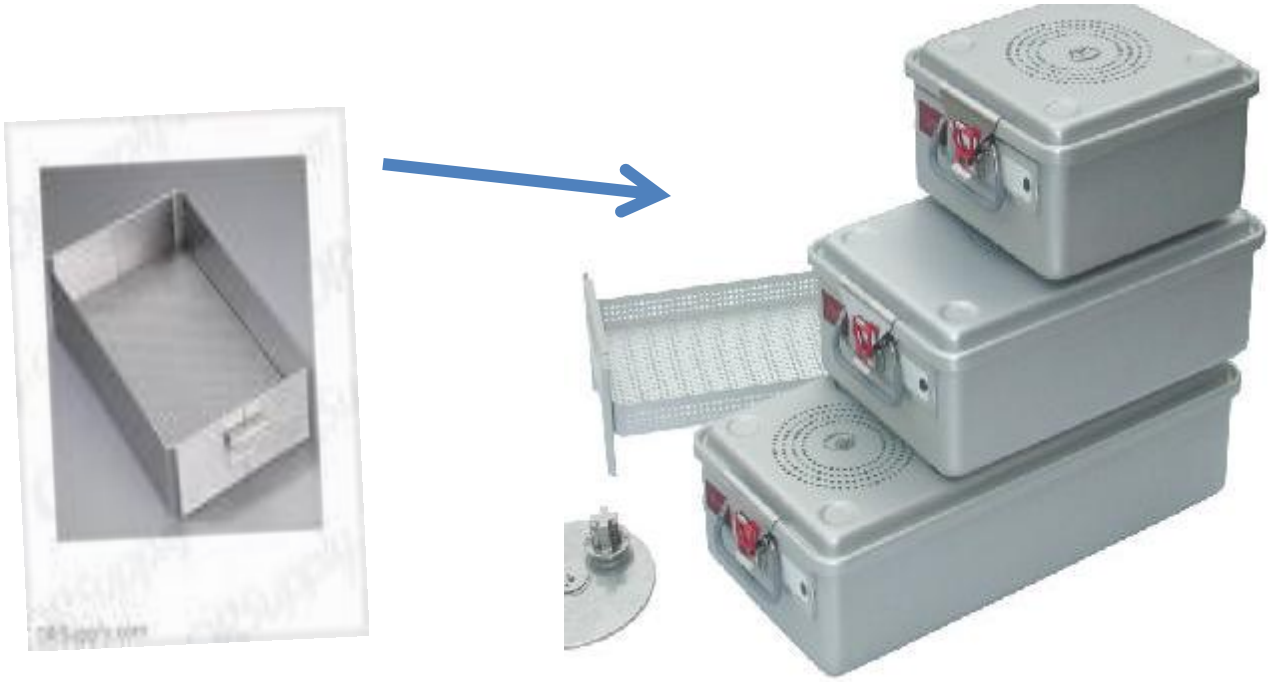
Extended Cycles

- Impact
  - OR schedule impacted
  - Periodic review of IFUs critical
- Response
  - Dedicated sterilizer
  - Communication between CSSD and OR critical
    - Formalized process for schedule review
  - Surgeon awareness
  - Data, data, data - tracking

Immediate Use Sterilization

Immediate-Use Sterilization

- Not your grandmother's flash!
- From open pan to flash container



Immediate-Use Sterilization

- Multiple cycle times and temperatures
  - Some dry times
- Multiple cycle types
  - Gravity
  - Dynamic air removal
  - Pulse-pressure
- Flash can be accomplished in:
  - Gravity sterilizer
  - Combination Dynamic air removal and Gravity sterilizer
  - Pulse-pressure sterilizer

Immediate-Use Sterilization

- As effective as terminal sterilization
- Risks:
  - Preparation for sterilization (cleaning and packaging)
  - Contamination post processing
    - No FDA cleared flash container for subsequent storage of any time

Immediate-Use Sterilization

- CDC and AORN – not to be used for purposes of convenience or lack of sufficient inventory
- Joint Commission – *Steam Sterilization-Update on the Joint Commission's Position* (6/15/2009)
- CMS –*Flash Sterilization Clarification – FY 2010 Ambulatory Surgical Center (ASC) Surveys (9/4/2009)*
- Academy and ASCRS Task Force on Ophthalmic Sterilization – *Statement…Regarding the Joint Commission's…Position on Sterilization Processes*

CDC 1999 Guideline for Prevention of SSI
CDC 2007 Guideline for Dis and Ster in Healthcare Facilities
AORN 2010

Flash Sterilization

- Focus shifted from quantity to quality
- Joint Commission - discussion points
  - Term “flash” no longer used – replace with “less than a full cycle”
  - Statement refers only to cycles of 3 minutes at 270^0 at 27 to 28 lbs pressure
  - Remove all visible soil
- Meeting held with key professional organization representatives to provide additional clarity

Flash Sterilization - JC

- Expects facilities to use sterilizing equipment as specified by the manufacturer
  - Must be able to produce those specifications

    What cycles is the sterilizer cleared to run?

    Can you prove those are the cycles you are using?
  - Will look for use of “flash pans”
  - Will ask staff to describe the process
  - Will ask you to produce IFUs for sterilizer
    - Emphasis on sterilizer IFU

Flash Sterilization - JC

- Does practice reflect policies and procedures?
  - Policies for cleaning, sterilization, storage and transport
- PPE worn?
- Orientation and training

Flash Sterilization - CMS

- Focus on quality of the process rather than quantity
  - However should not be routine practice in ASCs – used only for "urgent and unpredicted need for a specific device"
  - Focus will be on
    - Sterilizer clearance for cycle selected
    - Sterilizer manufacturer load recommendations
    - Containment device cycle recommendations

Flash Sterilization - CMS

- Focus on quality of the process rather than quantity
  - However should not be routine practice in ASCs – used only for "urgent and unpredicted need for a specific device"
  - Focus will be on
    - Sterilizer clearance for cycle selected
    - Sterilizer manufacturer load recommendations
    - Containment device cycle recommendations

Flash Sterilization - ASCRS

- Flash referred to as short cycle
- …"use of a shorter steam sterilization process for unwrapped instruments will no longer be considered ineffective"
- Follow sterilizer and device manufacturer's instructions

Flash Sterilization - Implications

- Staff can explain process and rationale
- IFUs for packaging, sterilizer and device readily accessible
- PPE worn
- Decontamination away from patient care areas
- Resources and processes consistent across facility

Flash Sterilization – Remaining Issue

- Sterilizer, device and packaging instructions for use are not compatible
- Cycles not available
  - Contact device manufacturer
- If differing instructions unresolved and urgent – follow device IFU
- Consider including devices in product testing initiatives

Loaners

Loaners

- CSSD and OR need your help!!!!

Loaners

- Many facilities still experiencing problems
- Policy and procedure to include
  - Delivery process and time
  - Inventory before and after
  - IFU prior to delivery/acceptance
  - Weight and containment
  - Responsibility –contents of consignment and loaner trays
  - Documentation
- Must have support

Monitoring and Class 6 Emulating Indicator

Class 6 Emulating Indicator

- Cycle verification indicator
  - For specific time and temperature
  - Not interchangeable
  - Very appropriate for prion cycle
  - AAMI – Class 6
    - Within package – internal chemical indicator
    - Within PCD to monitor sterilizer loads
    - Part of release criteria for loads containing implants

AAMI - approved 8/2010

Class 6


VERIFY®
LCC003
270°F
132°C
4 mins
SixCess 270F 4 Challenge Pack


VERIFY®
LCC014
275°F
135°C
3 mins
SixCess 275F 3 Challenge Pack


270°F
132°C
4 mins
VERIFY®
STERIS®
SixCess 270F 4 Minute Indicator - Long
For prevacuum and steam-flush pressure-pulse (SFPP) STEAM sterilizers at 270°F/132°C for 4 minutes including the Express Cycle.
Free from lead and other heavy metals. Accept only if yellow circle turns blue/purple.
Reorder No: PCC008
LOT


3
mins
10
mins
270°F
132°C
3/10 mins
VERIFY®
STERIS®
SixCess 270F Flash Indicator
For gravity flash STEAM sterilizers at 270°F/132°C for 3 and 10 minutes.
Free from lead and other heavy metals.
Accept only if yellow square turns blue/purple.
Reorder No: LCC310
LOT


275°F
135°C
3 mins
VERIFY®
STERIS®
SixCess 275F 3 Minute Indicator - Long
For prevacuum STEAM sterilizers at 275°F/135°C for 3 minutes.
Free from lead and other heavy metals.
Accept only if yellow circle turns blue/purple.
Reorder No: PCC034
LOT

Quality Monitoring – Load Release

- **No Implants**
- Monitoring ***optional,*** monitor with:
  - BI PCD
  - CI (Class 5 or 6) PCD
  - BI and Class 5 PCD
- **Implant Load**
- Monitoring ***not optional,*** monitor with:
  - BI and CI (Class 5) in PCD

Quality Monitoring - Trend

- Every load monitoring with BI
  - Potentially reduces quantity of recall items
  - Eliminates having to identify which sets contain implants

Quality Monitoring

- Sterilizer efficacy
  - Steam terminal– weekly, preferably daily with BI in PCD
  - Steam flash – The PCD is the container/tray/pan in which item is sterilized.
    - Must test every type of pan
    - Must test every type of cycle
    - Must test only shortest cycle

New Technology - Resources

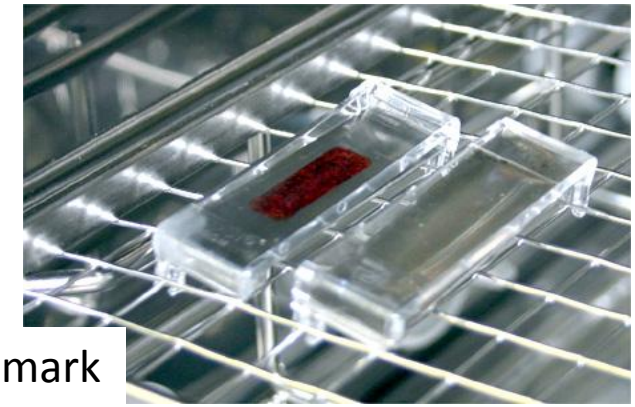
Cleaning

ATP Test

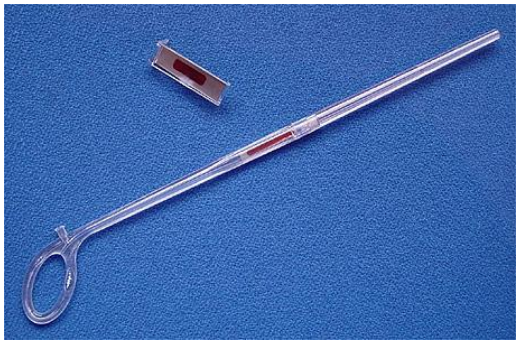
Courtesy Ruhof

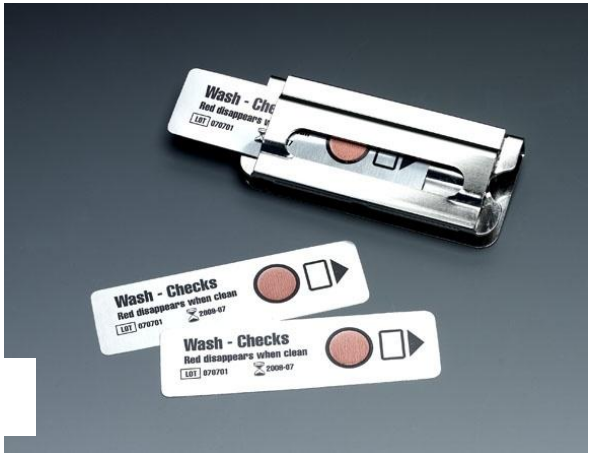
Cleaning

- Washer efficacy tests



Courtesy Healthmark





Courtesy SteriTec

Instructions For Use

- www.Onesource.com
  - Provides manufacturers' instructions for processing
  - More than 10,000 links between MDM and IFUs
  - Updated quarterly