SESSION NAME	**Wet Packs: Are They Sterile?**
SPEAKER	Rose E. Seavey, MBA, BS, RN, CNOR, CRCST
SESSION NUMBER	**0028**
DATE/TIME	**Monday, March 31, 2014, 4-5pm**
REPEAT SESSIONS	0179, 0122
REPEAT DATES/TIMES	Tuesday, April 1, 2014, 7-8am Tuesday, April 1, 2014, 2:30-3:30pm
CONTACT HOURS (CH)	1.0

SESSION OVERVIEW:

One of the most time-consuming and frustrating sterilization issues is troubleshooting wet packs. A package is considered a wet pack if moisture in the form of dampness, droplets, or puddles of water are left in or on a package after sterilization and proper cooling period. Moisture present on or in several packages of a sterilized load is considered a wet load. Explore issues with wet packs. Learn to identify a wet pack. Learn how to troubleshoot to eliminate or avoid wet packs.

OBJECTIVES:

1. Discuss sources of internal and external moisture on sterilized devices.
2. Describe available tools to help guide an investigational process on moisture assessment.
3. Identify ways to help prevent wet packs/loads.

SPEAKER BIOGRAPHY:

Rose E. Seavey, MBA, BS, RN, CNOR, CRCST is president/CEO of Seavey Healthcare Consulting and formerly the director of the sterile processing department at The Children's Hospital of Denver. Rose served on the AORN Board 2008 to 2010 and she is a past President ASHCSP. Rose has received numerous awards, such as AORN's award for Mentorship in 2012 and Outstanding Achievement in Nurse Education in 2001. In addition, she has received the national IAHCSMM Award of Honor, the Industry Leadership Award from the Massachusetts chapter, and the Educator of the Year award from the Golden West chapter. She was one of the Who's Who in Infection Prevention in 2006 by Infection Control Today. Ms. Seavey is the author of the book tilted Sterile Processing In Healthcare Facilities: Preparing for Accreditations Surveys, published by AAMI, and she serves on several AAMI committees writing standards.

SPEAKER CONTACT INFORMATION:

Rose E. Seavey, MBA, BS, RN, CNOR, CRCST
President/CEO
Seavey Healthcare Consulting, Inc.
Arvada, Colorado
rose@seaveyhealthcareconsulting.com

FACULTY DISCLOSURE:

1. 3M Healthcare, Bioseal, Key Surgical, Ultra Clean Systems, AmMed, Kimberly-Clark, Getinge, Steris Microsystems, OneSOURCE
2. Ultra Clean Systems

Objective 1

Discuss the sources of internal and external moisture on sterilized devices.

1

How Many Have Experience Wet Packs/Loads?

2

Wet Packs

- Wet packs are a big concern in sterility quality systems
- Packages should be inspected for external and internal moisture.
- AAMI & AORN – do not use an item that is wet or contains visible moisture

3

ANSI/AAMI ST79

Comprehensive guide to steam sterilization and sterility assurance in health care facilities

- Continuous Maintenance
  - Evolve and updated on a regular basis
  - Proposals for revisions are sought from interested and knowledgeable parties

4

Most Current ST79 Amendment

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

- New wrap drawings
  - Updated pictures
  - Descriptive instructions

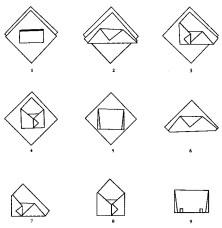
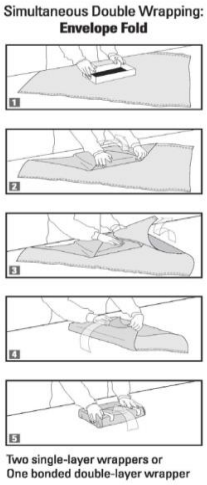


Figure 4—Sequential double-wrapping: envelope fold



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Most Current ST79 Amendment

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

Moisture assessment

- Updates to 8.8.6
  - Handling and inspection
  - Checking for moisture
- New Annex P
  - Check list
  - Flow chart

6

Amendment - A4:2013

- **8.8.6 Handling and inspection**
  - *Rationale*: Items with torn or **wet packaging are considered contaminated.**

    Wet packaging might indicate problems with:
    - Package composition,
    - Loading procedures,
    - Sterilizer performance or operation, or
    - The steam generation and distribution system

7

Moisture Assessment

- Visible moisture left in or on a package after sterilization and proper cooling period should be considered a wet pack.
- Visible moisture present on or in several packages - the load should be considered a wet load.

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

8

Moisture considerations

- Moisture maybe in the form of:
  - Dampness,
  - Droplets, or
  - Puddles of water.
- Reprocessed in a way that ensures excess moisture/condensation does not occur.

AORN Recommended Practices for Packaging Systems – Selection and Use, In: *Perioperative Standards and Recommended Practices.* Denver, CO: AORN, Inc; 2013

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

9

Exterior Moisture

- Moisture on the outside
  - Improperly trapped, sloped, insulated, steam lines,
  - Dripping from the cart, railings, or shelves,
  - Dripping from metal items above other items.

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

10

Internal Moisture

- Moisture on the inside caused by:
  - Positioning items that trap moisture, or
  - Pack preparation techniques:
    - Heavy or dense instrument
    - No absorbent material to wick moisture
    - Putting wet instruments into trays
    - Textile packs wrapped to densely
    - Improperly prepared items (e.g., items or trays wrapped while moist).

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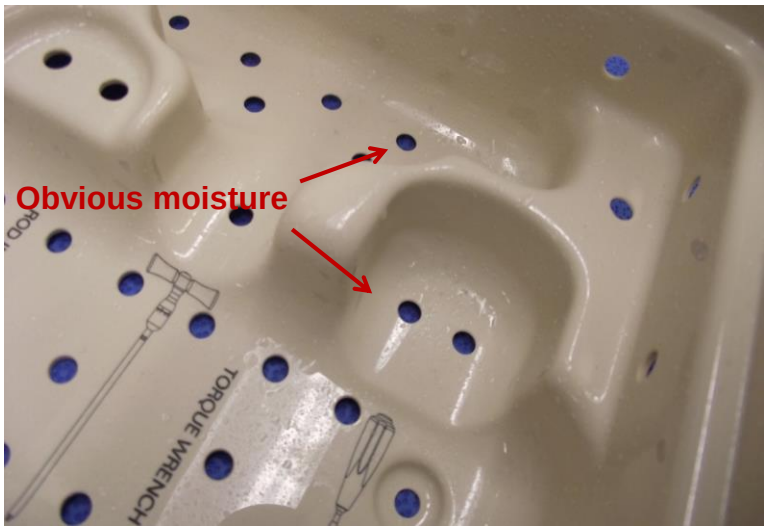
11

Composition materials (e.g., plastic) of containment device may cause wet items.



12

Moisture Issues

- Wet packs are a concern because the moisture on or within a package can create a pathway for microorganisms to migrate from the outside to the inside of a package.

Recommended Practices for Sterilization. In: *Perioperative Standards and Recommended Practices.* Denver, CO: AORN, Inc; 2013
ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012, 8.8.1 and 8.8.2

13

Investigational Process Questions

- Did the wet packs happen:
  - At a certain time of day?
  - At a certain time of the year?
  - Only with certain trays?
  - In a specific sterilizer?
  - On a certain level or location of the sterilizer cart?

- Humidity in the wrapping and assembly area?
- Wetness on the outside or inside?
- Inside and outside at the same time?

14

Objective 2

Describe available tools to help guide an investigational process on moisture assessment.

15

Wet Loads are Complex Issues

- Form a team
  - Sterile processing technicians and managers
  - OR personnel
  - Infection prevention and control
  - Facilities management
  - Equipment repair personnel
- Document all moisture incidents
  - Illustrate occurrences - loading procedures (pictures)

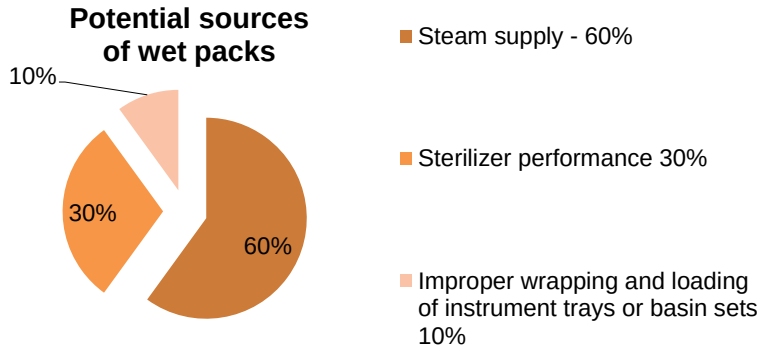
16

Table P.1

Moisture Assessment Check List

- Processing Errors
  - ✓ Practice Issues
  - ✓ Load Content and Configuration
  - ✓ Sterilization Process
- Sterilizer or Utility Malfunctions
  - ✓ Boiler System
  - ✓ Steam Delivery System (Piping)
  - ✓ Sterilizer Performance
  - ✓ Environmental Issues

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013 Table 1



Moore T C. Wet Packs: Improved Communication Leads to Improved Response Time. *Biomedical Instrument & Technology*, September/October 2008

18

Practice Issues

Processing		
Clinical Practice	**Interior**	**Exterior**
Major changes in packaging, wraps, or load configuration	X	
Wrapper too tight or too loose		X
Manufacturer's packaging IFU not followed	X	X
Rigid organizing trays or rigid sterilization container systems not used according to the manufacturer's written IFU	X	
Flat trays not placed on the sterilizer cart at an angle	X	
Solid bottom trays placed incorrectly	X	
Absorbent material may be needed for heavy trays	X	
Multiple part instruments requiring disassembly are not disassembled	X	
Incorrect use or placement of liners and other protective devices	X	
Wrappers not allowed to come to room temperature/humidity levels before use	X	
Humidity above 70% in sterile storage area	X	X
Sterilizer load not at room temperature	X	
Transportation without protection from moisture or excessive heating and/or cooling		X
Instruments or containment devices not dry before packaging	X	X

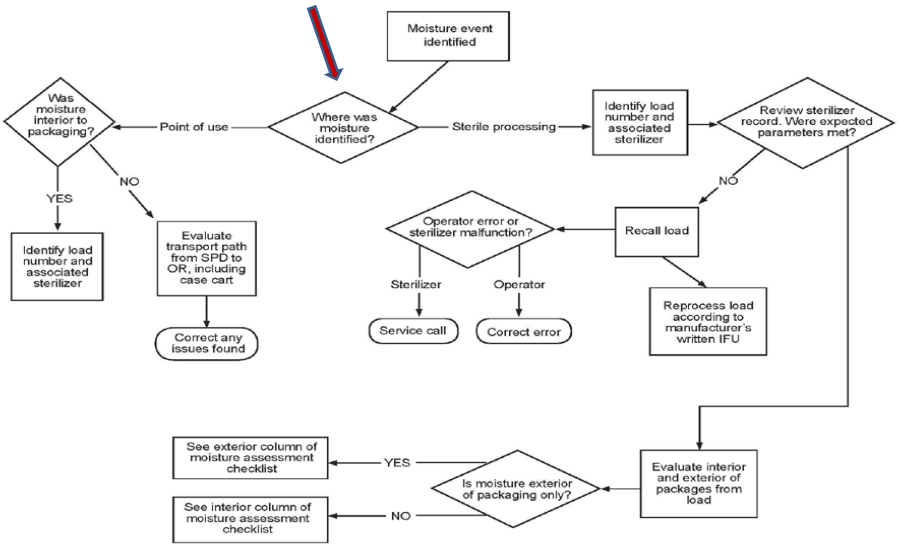
19

Equipment or Utility Issues

Sterilizer or Utility Malfunctions		
Boiler System	**Interior**	**Exterior**
Steam dryness not between 97% and 100% (i.e., too much water in the steam)	X	X
Boiler feedwater that contains too many noncondensable gases (such as air)	X	X
Water treatment affecting the level of noncondensable gases	X	X
Changed (e.g., seasonal), unusual, or increased demands placed on the steam system	X	X
Boiler not properly maintained	X	X
Improper insulation of steam lines	X	X
Malfunction of trap in steam line or no trap in steam line	X	X
Malfunction of drain check valve or no drain check valve	X	X
Steam Delivery System (Piping)	**Interior**	**Exterior**
Improper or insufficient insulation of steam lines	X	X
Blocked or partially blocked steam lines	X	X
Blocked or partially blocked chamber drain line	X	X
Steam pipework designed so condensate cannot flow properly	X	X
Condensate not appropriately trapped and drained	X	X
Air vents and steam trap not fitted at each vertical rise	X	X
Dead legs in the steam piping	X	X
No steam lines from the top of the main lines, resulting in condensate carryover	X	X
Accumulation of condensate when the sterilizer is not in operation	X	X

20

Moisture Assessment Flow Chart



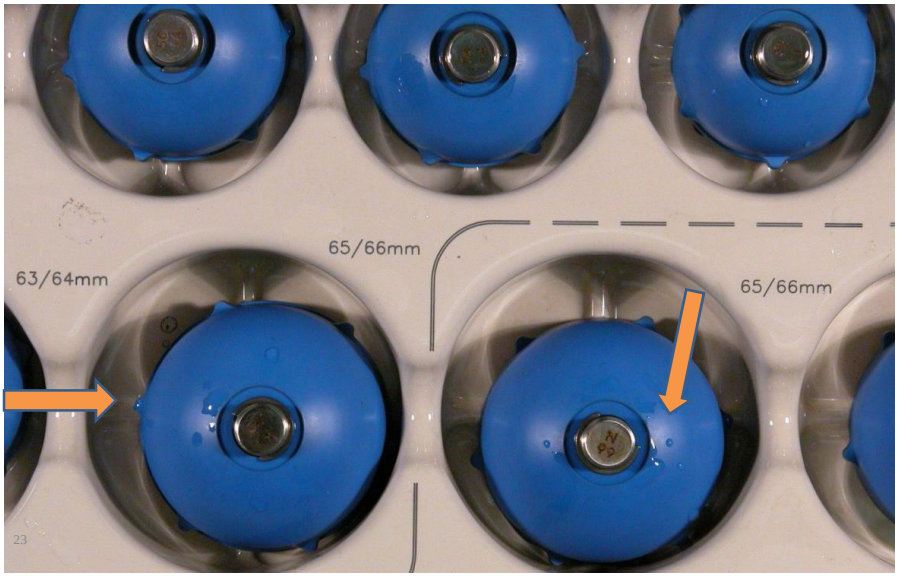
21

Practice Issues Examples

- Interior Moisture examples
  - Major changes in packaging or load configuration
  - Insufficient dry time
  - No absorbent material used for heavy trays
  - Concave or convex surfaces
  - Incorrect placement of liners (misalignment)
  - Sterilizer load not at room temperature before moving

AORN Recommended Practices for Packaging Systems – Selection and Use, In: *Perioperative Standards and Recommended Practices.* Denver, CO: AORN, Inc; 2013
ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

Loaner Tray After Product Testing
Enough dry time?



23

Multiple Layers in Plastic Caddy

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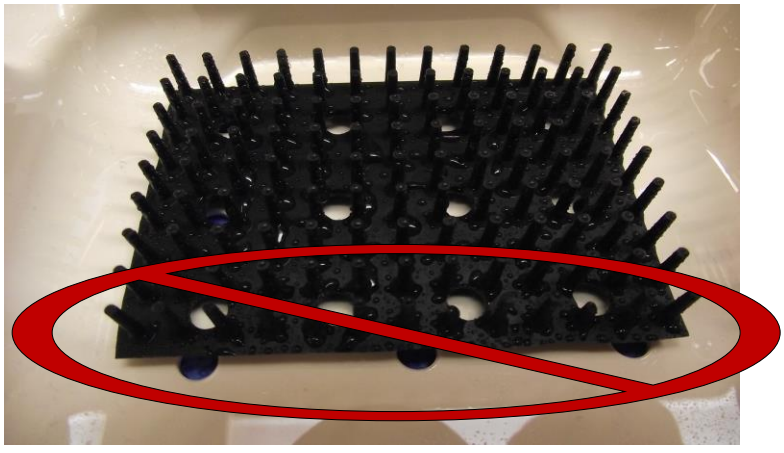
Low Linting Absorbent Material

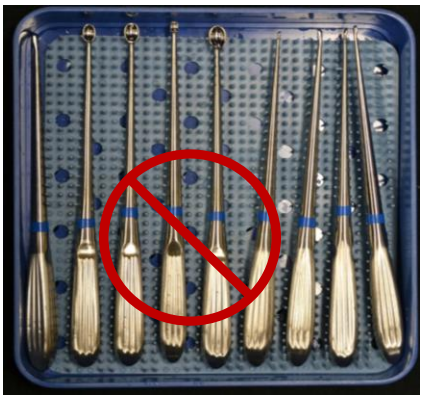
25

Protective Mats Must be Aligned

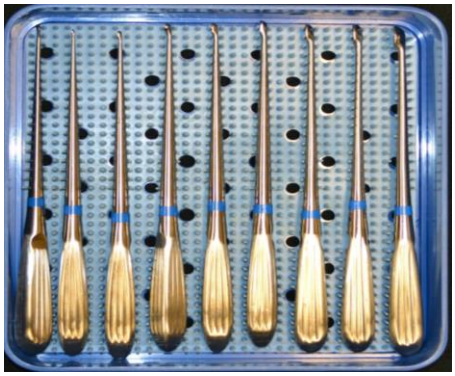


26

Misalignment May Cause Wet Packs



Misaligned liner/mat



Correctly aligned liner/mat

27

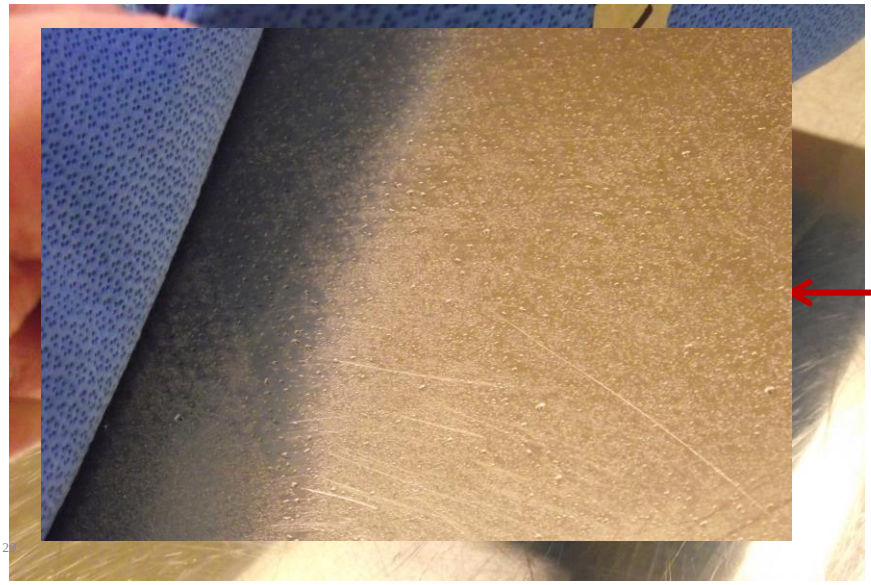
Sterile Items Must Be Cool

- Retained moisture may wick bacteria on hands of personnel
- Cooling time will vary according to:
  - How hot items are at end of cycle
  - Density and composition
  - Packaging material
  - Temperature and humidity of the ambient environment
- 30 minutes to two hours may be necessary

Recommended Practices for Sterilization. In: *Perioperative Standards and Recommended Practices.* Denver, CO: AORN, Inc; 2013
ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012, 8.8.1 and 8.8.2

28

Hot/Warm Packs on Cold Surface



Infrared Temperature Guns

- Available products to measure package temperature

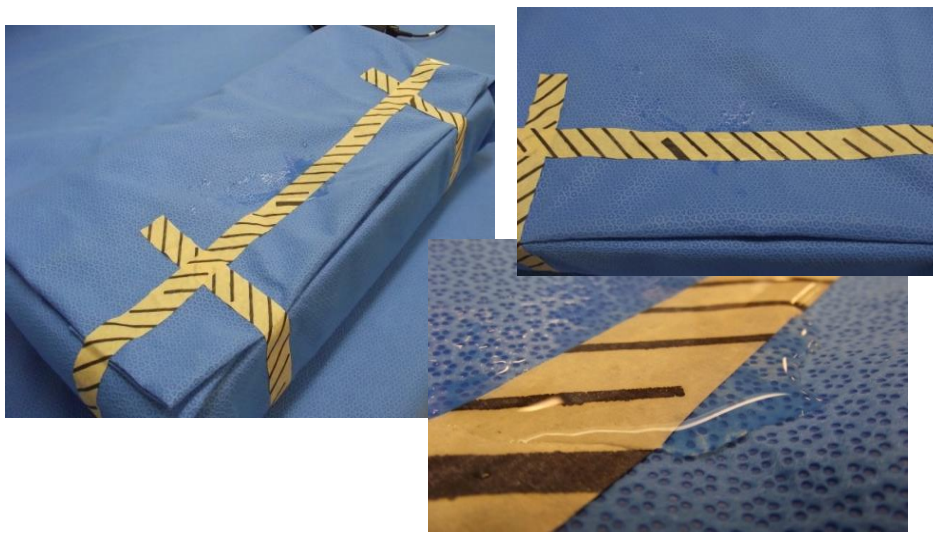
Processing Practice Issues

- Exterior Moisture examples
  - Wrapper
    - Too tight
    - Too loose
  - Incorrect packaging
  - Improper loading (heavy metal over wrapped sets)
  - Transportation not conducive to maintaining package integrity

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

31

Moisture Pooled in a Low Point of a Poorly Wrapped Tray



32

Load Content and Configuration

- Interior Moisture
  - Tray too small
  - Metal mass not evenly distributed
  - Instruments or containment devices not dry before packaged
  - Tray not allow easy air removal, steam penetration or drying
  - Instrument set too heavy or dense (25 total pounds*)

*AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization Recommendation 2013
*ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

33

Metal Mass or Heat Sink Too Excessive

34

Containment Device Not Dry Before Packaging

35

Load Too Dense

36

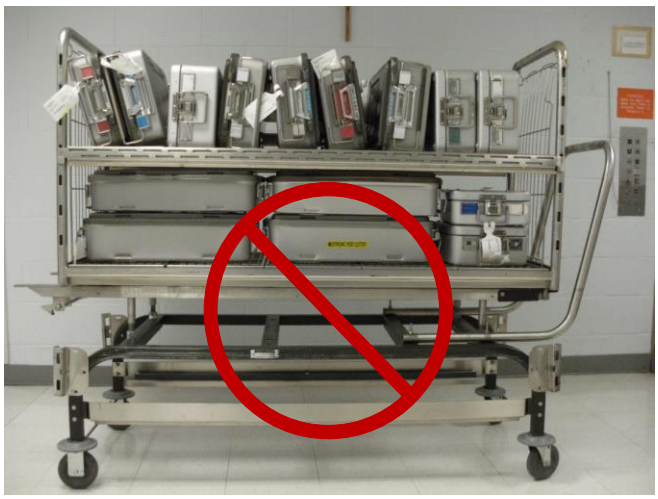
Sterilization Processing Issues

- Interior or Exterior Moisture examples
  - Inadequate dry time
  - Sterilizer cart shelf lined with non absorbent material
  - Sterilizer not loaded according to manufacture IFU
  - Improper stacking of trays or rigid containers
  - Heavy items placed above lighter items

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

37

Sterilizer Not Loaded According to Manufacturer IFU



38

Heavy Items above Lighter Items

39

Sterilizer or Utility Malfunctions Boiler System

- Interior or Exterior Moisture
  - Too much water in steam
    - Dryness of steam should be between 97% and 100%
  - Noncondensable gases caused by
    - Water treatment, or
    - Insufficient de-aeration of boiling feed water
  - Boiler not properly maintained
    - Improper insulation of steam line
    - Malfunction of trap or drain check valve
  - Unusual demands placed on the steam system

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

40

Boiler System

41

Super Saturated or Dirty Steam?

42

Rust-Colored Stains Post Sterilization

Rust-Colored Stains Post Sterilization

- Possible causes
  - Large demand for steam from the boiler
  - Condensate from pipe work – failed steam traps
  - Steam filters not installed correctly
  - Iron from boiler or plumbing system
  - High iron oxide levels in water going to boiler
  - Boiler water additive dosage too high
- Steam and water quality are usually the cause

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

44

Sterilizer or Utility Malfunctions Steam Delivery System

- Interior or Exterior Moisture
  - Improper or insufficient insulation of steam lines
  - Steam trap not fitted to each vertical rise
  - Accumulation of condensate when sterilizer not in use
  - Clogged lines
  - Failed steam traps

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

45

Clogged Pipe

46

Steam Pipe Missing Insulation

47

Sterilizer Insulation in Poor Shape

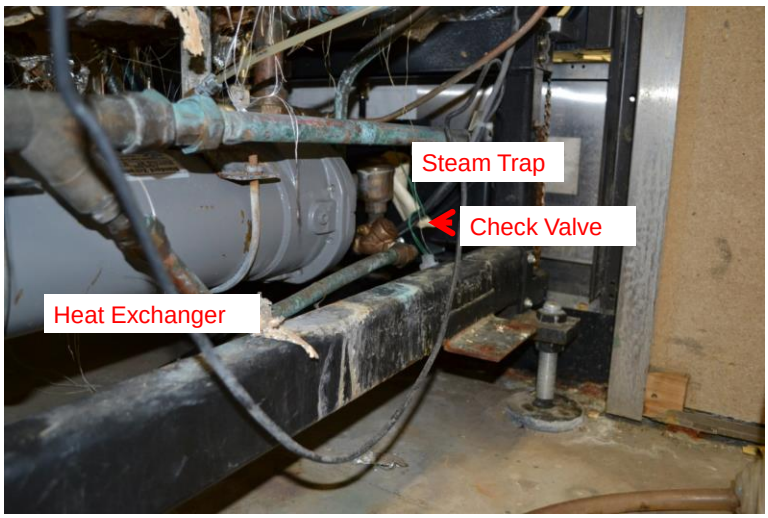
Sterilizer or Utility Malfunctions
Sterilizer Performance

- Interior or Exterior Moisture
  - Drain check valve malfunction of
  - Malfunction or no trap in steam line
  - Temperature or pressure sensors out-of-calibration
  - Clogged strainer or drain screen
  - Non-intact gasket

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

49

Sterilizer Components



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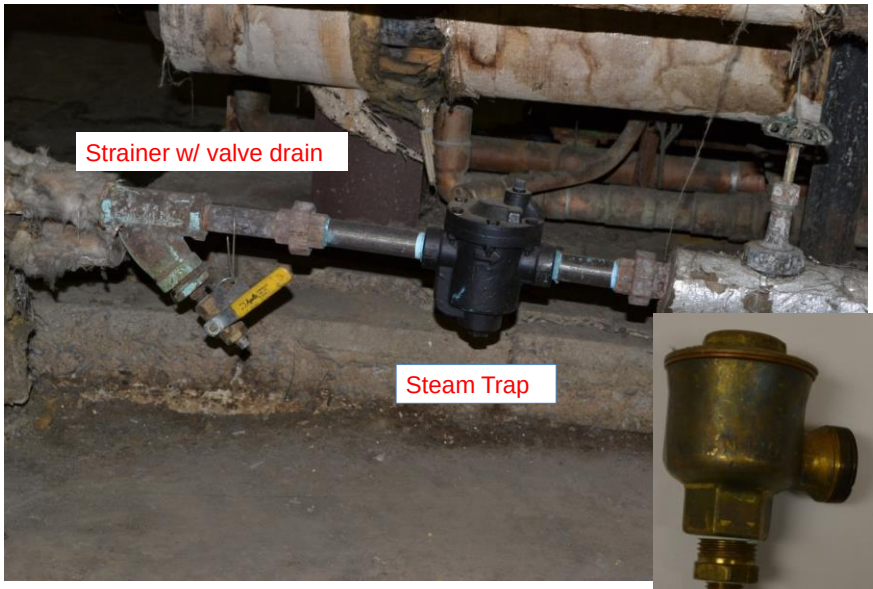


Close up of steam trap →

51

Steam Valve Corrosion

Steam Engineering Tutorials

- For more information on the principles of steam engineering and heat transfer
  - http://www.spiraxsarco.com/resources/steam-engineering-tutorials.asp
    - Covers all aspects of steam and condensate systems:
      - Boiler house,
      - Steam distribution system
      - Condensate recovery system, and
      - Returning to the boiler.

53

Objective 3

Identify ways to help prevent wet packs/loads.

54

Measures to Resolve Wet Packs

- Package weight, density and configuration,
- Materials and methods used for packaging
- Load contents and configuration
- Placement of package on the sterilizer cart,
- Compliance with Mfr. IFU - containers, instrument and wrap
- Load removal process from sterilizer
- Temp and humidity in cool down area
- Location of air conditioning vent
- Water and steam quality
- Sterilizer performance

AORN Recommended Practices for Packaging Systems – Selection and Use, In: *Perioperative Standards and Recommended Practices.* Denver, CO: AORN, Inc; 2013

55

Minimize Practice Errors

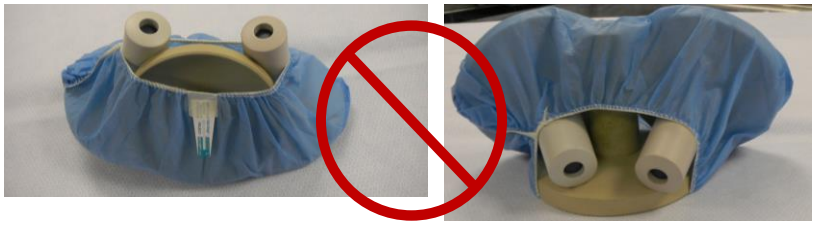
- Guidelines for qualifications (4.2)
  - Minimum criteria for training, education, personnel health, hygiene and attire
  - Sterile processing personnel (4.2.2)
    - Qualified individuals
      - Initial orientation
      - On-the-job-training
      - Competency-based knowledge
        - ✓ Demonstrated and documented competencies in all aspects

Recommended Practices for Sterilization. In: *Perioperative Standards and Recommended Practices.* Denver, CO: AORN, Inc; 2013
ANSI/AAMI ST79:2010 & A1:2010 & A2:2011, A3:2012 & A4:2013

56

Follow Manufacturer's IFU Devices, Packaging and Sterilizer

- Wraps, peel packs and rigid container systems
  - Obtain and keep on hand
    - MFG test data,
    - Instructions for use (IFU), and
    - Care and handling instructions



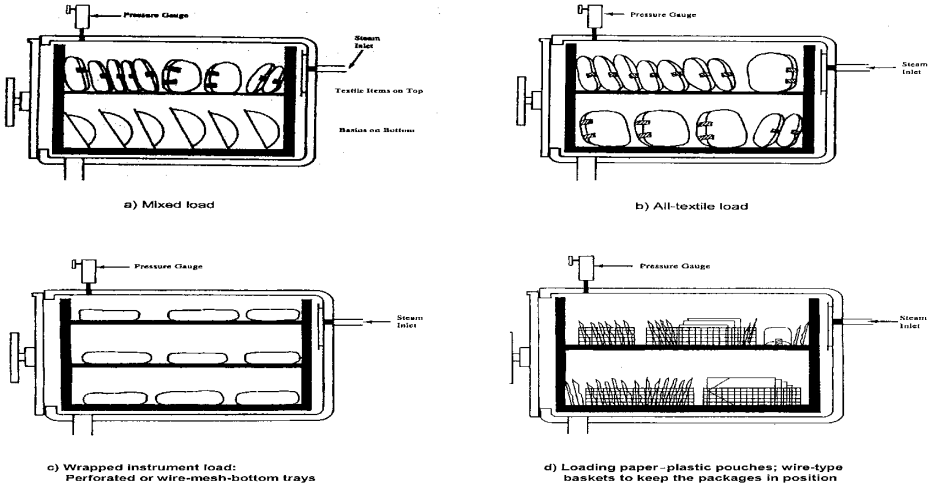
57

Preparation, Assembly and Sterilization

- Multiple parts – disassembled
- Excessive moisture removed
- Maximum weight limit
- Loading the sterilizer
  - Pouches and textiles on edge and loosely loaded
  - Tilt items capable of holding water
  - Heavy metal items below wrapped items
  - No stacking without MFG IFU
- Sterilization parameters same for all items

58

Loading the Sterilizer



59

Figure 9—Loading the sterilizer

Follow Sterilizer MFG IFU for Loading

- Sterilizers validated to a specific number of trays and weight
- Follow IFU for number of trays or weight for the specific sterilizer
- Do not exceed the design
  - For every 16 lbs of metal, 12 oz of condensation is created during the heat up phase*

Moore, T K C. Wet Packs: Improved Communication Leads to Improved Response Time. *Biomedical Instrument & Technology*, Sept/Oct 2008

60

Tilt Items Capable of Holding Moisture

61

Concave Devices Properly Positioned

62

Sterilizer Shelf Liners Can Help Wick Moisture

Use only absorbent sterilizer shelf covers recommended by the manufacturer

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A32012 Annex I

63

Precondition the Load

- "Heating of the instruments before injection of steam may resolve wet pack issues not associated with steam quality or packaging/loading errors."
  - Place instruments inside sterilizer 10 to 15 minutes with the door closed prior to starting.

AORN Recommended Practices for Packaging Systems – Selection and Use, RP X . In: *Perioperative Standards and Recommended Practices.* Denver, CO: AORN, Inc; 2013

64

Periodic Product Testing

- QA product testing performed:
  - Routinely processed items, and
  - Before new or loaner items placed into use
  - Major changes made in packaging, wraps or load configuration
    - Dimensional changes,
    - Weight changes, or
    - Changes in the type of material of packaging or wrapper.

Recommended Practices for Sterilization. In: *Perioperative Standards and Recommended Practices.* Denver, CO: AORN, Inc; 2013
ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013

65

Minimize Sterilizer or Utility Malfunctions

- Maintain equipment
  - Proper installation
  - Routine care
    - Inspect and clean daily according to Manufacturer's IFU
    - Preventative maintenance (by a qualified individual)
    - Periodic calibrations preformed and documented
- Record-keeping
  - Maintenance record for each sterilizer
  - Sufficient information to establish a history of service repairs

66

67

Clean Drain Screens

68

Steam Quality

- ST 79 Annex M - Steam quality
  - Provides guidelines on how to achieve and maintain adequate steam quality for steam sterilization processes.
  - Have your steam quality professionally tested to include the point of connection to the sterilizer.

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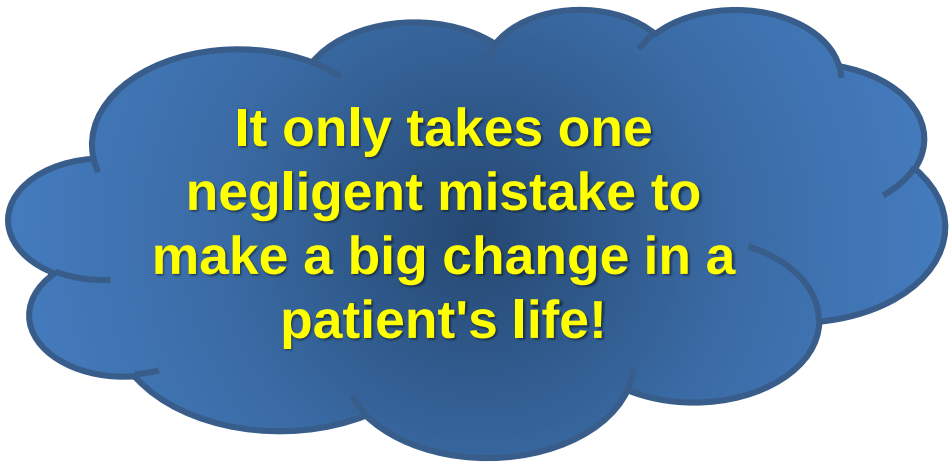
69



Safety isn't expensive – It's priceless.

Acknowledgment

Pictures and expertise

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- Steve Kovach, Healthmark
- Chip Moore, Sterilization Answer Man
- Ray Taurasi, Healthmark
- Jonathan A. Wilder, H & W Technology, LLC/Stericert Co.
- Martha L. Young, Martha L. Young, LLC

71

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- Moore, T K C. Wet Packs: Improved Communication Leads to Improved Response Time. *Biomedical Instrument & Technology*, Sept/Oct 2008

72

ANSI/AAMI ST79 Documents

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74