Wet Packs
Causes & Solutions

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Time to Reprocess

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Connecticut Central Service Association
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Middlesex Hospital

- Number of Beds: 300
- Number of ORs serviced: 10 + 3 offsite
- Number of Shifts in Central Services: 3 with 18 FTE’s
- Number of complaints 0*

*3rd shift when no one is there!
Objectives:
- Identify wet pack causes
- Identify specific products to alleviate problem
- Identify common CSS/SPD mistakes
- Set configurations
- Packaging considerations
- Loading the sterilizer
- Unloading the sterilizer
- Storage and handling

Reference materials:
- AAMI ST79:2013
- Good old fashioned 21 years of experience

Focus on CSS/SPD issues today
- Set Configuration problems and solutions
- Packaging problems and solutions
- Loading the sterilizer problems and solutions
- Steam cycle. Processing the load
- Post cycle Unloading problems and solutions
- Storage and Handling problems and solutions
IFU’s quickly..

- How to build and maintain a library
- Digital
- Outsource...onesource
- They are NOT just for instruments.. They are for Equipment and containers etc

What are wetpacks?

“Wet packs” are when there is a presence of moisture in a set or item (post sterilization) in steam or ETO. This is not good because a wet pack or wrapper could permit surface organisms to migrate, penetrate the pack and contaminate the item.

Who is involved?

- Sterilizer Manufacturers
- Service reps
- Hospital Engineering
- CSS/SPD staff
- Surgical Instrument Manufacturers
- Sterilization Container Manufacturers
Set configurations:

- Heat Sinks/ Metal Mass and layout
- Textile Packs and configurations outlined in Section 8.3.5
- Basins
- Devices with Lumens. Irrigate? MFGR IFU

What's a Heat Sink?? How's this!

Weight and density of sets. 8.4.2

- Body mechanics
- Equally distribute the mass
- Help ensure dry sets
- Total number of sets per load should be evaluated.
- 25 lbs with containment device (container)
- Controlled random sampling and opening
- MFGR IFU for containment devices
Equipment Manufacturers helping us?

IAHCSMM Orthopedic Council

- Working with Ortho vendors
- Starting dialog between CSS/SPD needs and equipment manufacturers

So what does the future hold?

FDA Draft Guidance Document issued May, 2011:

- Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
FDA Draft Guidance on Reprocessing

- FDA recommends:
  - Sterilization parameters be technically feasible for end-users
    - i.e., recommended sterilization parameters should be consistent with cycle parameters found on sterilizers commonly available in health care facilities
  - Device manufacturers generate validation data in FDA-cleared sterilizers and with FDA-cleared accessories.

The FDA recognizes the challenge extended cycles pose to health care facilities

“FDA advises against including extended cycle recommendations in product labeling for a number of reasons.”

Appendix provides examples of cycles used in health care facilities

<table>
<thead>
<tr>
<th>Item</th>
<th>Exposure Time at 132°C (270°F)</th>
<th>Exposure Time at 134°C (275°F)</th>
<th>Drying Times</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped Instruments</td>
<td>4 minutes</td>
<td>3 minutes</td>
<td>16 minutes</td>
</tr>
<tr>
<td>Sterile Pads</td>
<td>4 minutes</td>
<td>3 minutes</td>
<td>5 - 26 minutes</td>
</tr>
<tr>
<td>Wrapped Linens</td>
<td>4 minutes</td>
<td>3 minutes</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Unwrapped-nonporous items (e.g., instruments)</td>
<td>3 minutes</td>
<td>3 minutes</td>
<td>N/A</td>
</tr>
<tr>
<td>Unwrapped-nonsor and porous items in novel load</td>
<td>4 minutes</td>
<td>3 minutes</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Good lay out??

Better but why?
Scrub preference or science?

Basins
- 7 pound total weight limit (AAMI ST79 8.3.6)
- Proper wicking.
- Weight and size
- Proper placement and arrangement in cycle
- Offset technique
- Water flow analogy, in sets and on cart
- Consider total amount per cycle
Offset basins with Crepe paper liner

Packaging Materials:
Problems and solutions

Set Configurations

AAMI ST79

**8.2** selection of packaging materials
a) Allow adequate air removal and steam penetration of the package contents
   New Kimberly Clark package insert

**8.3.1** General considerations
Before use materials should be held at room temperature 68-73F and at a relative humidity ranging from 30% to 60% for a minimum of 2 hours
8.3.1 General considerations

- "Wrappers should be kept snug to prevent low spots that could collect condensate on the exterior of the package"
- More in Rational section...
  “Adherence to established policies and procedures is important in ensuring proper sterilization and drying”

Use of Tray liners or containment devices

AAMI 8.4.5
“Absorbent material wicks condensate away from the instruments and disperses it over a greater surface area for more efficient drying. However, an excessive amount or incorrect type can impede air removal and sterilant penetration and interfere with proper drying”
Notice the blue tray liner to prevent holes.

Problems!

- If used during the sterilization cycle they can collect condensate
- At Middlesex hospital we use them post sterilization after cool down is complete

New Technology Better Solutions
TrayBelt!
TrayBelt

Tray wick (No Drip). Are they totally dry before processing?

Approved tray liner NoDrip
NoDrip continued..

Approved corner guard made of Crepe paper. Two for one purpose. Dry and holes

Approved Crepe paper for autoclave truck
Approved Crepe paper liner in set.

Sometimes bandaids are bad!

Steam Demands & Quality
- Onsite linen?
- Times of the day.
- Spring and summer. Heating cooling
- Wet steam? Drysteam? 97% magic #
- Steam at source vs into machine
Sterilizer

- Service and PM. Cleaning per IFU
- Verification vs signing printouts
- Things to look for when random wetpacks are occurring: Patterns. Logs. Same time of day? Tech? sterilizer? Pictures

Sterilizer continued....

- Proper install and utility requirements
- Subcontracted plumbing work? It's a problem
- 97-100% steam is desired.
- No more than 3% of the steam/condensate mixture supplied should be condensate (water)
- Hosp engineers. Boiler maintenance is there even a relationship with dept or heads up.
- CSS staff. Many opportunities for mistakes
- FDA approved containers and pre purchase verification testing done in dept

Sterilizers 101

How they work (in 2 minutes)
Variables Affecting the Outcome of Steam Sterilization Process

![Diagram of steam sterilizer chamber](image)

Ref: Personal Communication, Charles Hancock, President, Charles O. Hancock Associates, Inc.

How do we eliminate the 15%? 3 steps

- **Steam Quality monitoring**
  - Utilized Stericert. Dr. John Wilder. I.D. steam quality issues. Measured steam from plant at autoclave and just before "in chamber".
- **Chamber Mapping**
  - Utilized Pryce Consultants (Chip Moore) for in chamber testing. Data logger.
- **Cleaned interior chamber surface**
- **Set up schedule for upkeep**
- **Get to know your facilities person on a first name basis. They need to know what your needs are.**
My Autoclaves IFU

- Getinge 733 IFU
- 20ea -16lb trays max
- Who has 16 lb trays??!!
- Also Aesculap IFU
Loading of cart makes huge difference (hand-space rule)

Rigid container over wrapped good

Pack’ em in- ride’ em out rawhide!
Items can absorb excess moisture by touching chamber walls during cycle

Unloading the sterilizer and cool-down

- AAMI 8.8.1 Large Chamber sterilizers
  - Remain on cart until adequately cooled minimum 30 min. Could be 2hrs! Hands act as "wicks"
  - Rigid containers until cool to the touch
  - Door may be opened at end of cycle for period of time and items left inside to reduce condensation formation. See MFG IFU
How do know when its “cool”?

Unloading the sterilizer and cool-down

AAMI 8.8.1

“Place the cart in a low traffic area where there are no air-conditioning or other cold air vents in close proximity. Warm items should never be transferred from the cart to cold metal carts racks or shelves for cooling or placed in dust covers before completion of cooling process”

Our customers..

We often set ourselves up for failure by telling our customer that a device will be out of the autoclave at “12” and we do not add cool down time. Safety is a factor and damage to instruments by a rapid cool down with sterile water.
AAMI 8.9.2 Storage Facilities

- 75°F
- Humidity should not exceed 70%
- If leaving dept items must be dust covered
Food for thought on the future state

- Device on the market that is FDA approved with "0" dry time.
- Difference between rigid and wrapped sets
- Notion of immediate use moving forward.
- Following Instrument IFU dry times
- AAMI ST79 section on new products

Questions? Comments? Thank you!