Preparation and Packaging Best Practices Wet Pack Problem Solving Guide
# Table of Contents

- Introduction ............................................................................................................. 2
- Steam Sterilization of Instrument Sets ................................................................. 2
- Utensil sets .............................................................................................................. 6
- Textiles .................................................................................................................... 9
- Tips for Improving Your Steam Sterilization Techniques .................................. 12
- Wet Pack Problem Solving Guide ....................................................................... 17
- Guideline for Determining Wet Packs ................................................................. 33
- Guideline for Solving Wet Pack Problems ......................................................... 40
- References and Suggested Reading ...................................................................... 48
Introduction
The information provided in this booklet is intended to be a quick reference for the preparation and sterilization of wrapped instrument and utensil sets and textile packs. In addition, three important papers on wet pack problem solving are included to assist with troubleshooting when wet packs occur.

All operators and department heads should carefully review and become familiar with the warnings, cautions and instructions contained in the operator manual applicable to the sterilizer being used.

Steam Sterilization
Instrument Sets
An instrument set should weigh no more than 25lbs., including the set containment device (instrument tray, rigid sterilization container, etc.) Trays should be large enough to distribute the metal mass within the tray without piling instruments on top of each other.

1. Preparing and wrapping for sterilization
   a. Inspect instruments to make sure they are clean, DRY, and functioning properly.
   b. Open, unlock, or disassemble instruments to permit steam to contact all surfaces (Figure 1). Steam will only sterilize the surface it can touch.

   Figure 1:

   c. Use a mesh-bottom tray or equivalent (Figure 2) see section at end) large enough to equally distribute instruments in a single layer.

   Figure 2:

d. For heavier trays, it is acceptable to have two layers of instruments. Distribute the metal mass and separate the bottom layer (heavier instruments) from the top layer (lighter instruments) with an open 100% cotton surgical towel. The towel should be similar in size to the tray, any excess should be minimal and folded over the top of the instrument layer. **Special note:** Instrument trays must be designed for easy air removal, sterilant contact, drainage of condensate and drying.

e. Place a fully opened (single layer) 100% cotton surgical towel or validated disposable tray liner in the bottom of the tray (Figure 3) see section at end). This will help facilitate drying. **Special note:** Use a towel that covers the bottom of the tray with minimum excess overhang.

   Figure 3:

   f. Place instruments on the towel (Figure 4) see section at end). Use the appropriate size tray to enable even distribution of instruments. **Special note:** Concentration of metal mass in one area of the tray can cause formation of localized moisture and increase the possibility of a Wet Pack. Some heavy metal instruments (e.g., weighted speculums) may need to be wrapped in a 100% cotton surgical towel to absorb moisture for more efficient drying.

   Figure 4:
g. Fold the excess towel over the instruments (Figure 5)

h. Place an internal chemical indicator in the instrument tray (Figure 6) in the area least accessible to the sterilant. Multiple indicators may be necessary.

i. You may choose to wrap the instrument tray sequentially in two single layer instrument wrappers or simultaneously using one bonded double layer wrapper, using either the **envelope method** or **oblong method** (Figures 7 and 8). Secure the package with sterilizer (indicator) tape and identify the contents of the tray by either writing on the sterilization tape with a permanent marker or affixing a computer generated adhesive label to the package. Never write directly on the sterilization wrap. **NOTE:** Wrapper size should be appropriate for the desired method of wrapping but not too large. Excessively large wrappers may cause moisture to pool in the folds.
j. The combined weight of a properly prepared tray of instruments including the tray contents, containment device, and any accessories or wrappers should not exceed **25 pounds** (Figure 9) for a better probability of steam contact and drying.

k. Manufacturers of rigid sterilization container systems should provide the user with total container weight and drying information. The manufacturer will also indicate what types of steam sterilization cycles are appropriate for use with the container.

2. **Preparing paper/plastic pouches for sterilization**
   a. Peel pouches are designed for small, lightweight, low profile items.
   b. Ensure size allows for at least 1 1/2 inches from the item to all seals (Figure 10).
   c. Packages may be sealed using a heat sealer, indicator tape, or self-seal pouches.
3. **Loading the steam sterilizer**
   a. Place all instrument trays flat on the loading cart shelf (Figure 11) to ensure even distribution of metal mass, air removal, sterilant penetration, condensate drainage and drying. **Special note:** If a loading car is not used, then loosely place items into sterilizable wire baskets or on sterilizer shelves.

   ![Figure 11: Instrument Trays (Wrapped)](image)

   b. In loads that combine textiles and metal items, place metal items below textiles on sterilizer cart. (Figure 12).

   ![Figure 12: Instrument Trays (Wrapped) Fabric Packs](image)

   c. Place paper/plastic pouches standing on edge with plastic side of one facing the paper side of the one next to it. Use instrument trays, wire baskets, pouch organizers, or other sterilizable stabilizers if necessary, to hold the packages in proper position for sterilization.

   d. **Do not overload shelves.**
   **Do not compress packages.**

   e. **Do not allow wrapped instrument set(s) to contact the sterilizer chamber wall.**

   f. **Provide at least three inches** between the sterilizer chamber ceiling and the topmost package of the load to facilitate air removal, sterilant circulation, and drying.

   g. **Never place instrument tray(s) or other packages on the floor of the sterilizer chamber.**

4. **Steam Sterilization Cycles**
   a. Prevacuum cycle

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Exposure Time (recommended minimum)</th>
<th>Dry Time (recommended minimum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>270-274°F (132-134°C)</td>
<td>4 Minutes</td>
<td>20 - 30 Minutes</td>
</tr>
</tbody>
</table>

   b. **Gravity cycles***

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Exposure Time (recommended minimum)</th>
<th>Dry Time (recommended minimum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>270-274°F (132-134°C)</td>
<td>15 Minutes</td>
<td>15 - 30 Minutes</td>
</tr>
<tr>
<td>250-254°F (121-123°C)</td>
<td>30 Minutes</td>
<td>15 - 30 Minutes</td>
</tr>
</tbody>
</table>

   **Special note:** The information contained here is based on basic instrument sets. Specialty surgical instruments e.g. including but not limited to orthopedic, neuro and ortho spine loaner trays may require different exposure and drying times. Manufacturers of specialty surgical instruments should provide specific sterilization recommendations for these sets/devices.

5. **Unloading the Steam Sterilizer**
   a. **Loading car**

   1) **Remove loading car from sterilizer and place it in a low-traffic area where there are no air conditioning or other cold air vents in close proximity.**

   2) **Do not touch packages until they are cool.**

   3) **Visually check outside wrapper for moisture.**
   A wrapped tray of instruments is considered unacceptable if there are water droplets or visible moisture on the outside of the package or on the tape used to secure it.
4) Remove instrument tray(s) from the loading cart when the load has reached ambient room temperature. The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used. A minimum cooling time of 30 minutes is recommended. (ANSI/AAMI ST79:2010 8.8.1)

b. Wear heat-protective gloves to carefully remove hot wire baskets of sterilized items from the sterilizer. Wear sterile gloves and use sterile towels as pot holders if you must touch hot items to remove them from the sterilizer shelves.

1) Visually check outside wrapper for moisture. A wrapped tray of instruments is considered unacceptable if there are water droplets or visible moisture on the outside of the package or on the tape used to secure it.

2) Transfer acceptable items to wire cart shelving that has been covered with a clean 100% cotton surgical towel to cool. Do not place on a solid cold surface; condensation will occur. Be sure there are no air conditioning or cold air vents in close proximity.

3) Remove instruments from the wire cart when they have reached ambient (room) temperature. The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used. A minimum of 30 minutes is recommended. (ANSI/AAMI ST79:2010 8.8.1)

c. Arrange utensils so that the bottom of each is parallel to the one beneath it (Figure 14). This allows air to escape from the utensil(s) and helps promote drying when properly positioned for sterilization. Arrange utensils with curled edges (emesis basins) so that water will drain from that edge as well as from within the item.

b. Wear heat-protective gloves to carefully remove hot wire baskets of sterilized items from the sterilizer. Wear sterile gloves and use sterile towels as pot holders if you must touch hot items to remove them from the sterilizer shelves.

1) Visually check outside wrapper for moisture. A wrapped tray of instruments is considered unacceptable if there are water droplets or visible moisture on the outside of the package or on the tape used to secure it.

2) Transfer acceptable items to wire cart shelving that has been covered with a clean 100% cotton surgical towel to cool. Do not place on a solid cold surface; condensation will occur. Be sure there are no air conditioning or cold air vents in close proximity.

3) Remove instruments from the wire cart when they have reached ambient (room) temperature. The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used. A minimum of 30 minutes is recommended. (ANSI/AAMI ST79:2010 8.8.1)

d. Place an internal chemical indicator in the area(s) of the package which is least accessible to steam penetration, usually between two large-nested basins and among other utensils in the top basin.

e. You may choose to wrap the utensil set sequentially in two single-layer instrument wrappers or simultaneously using one bonded double-layer wrapper, using either the oblong method or the envelope method (Figures 15 and 16). Secure the package with sterilizer (indicator) tape and identify the contents of the set by either writing on the sterilization tape with a permanent marker or affixing a computer generated adhesive label to the package. Never write directly on the sterilization wrap. **NOTE:** Wrapper size should be appropriate for the desired method of wrapping but not too large. Excessively large wrappers may cause moisture to pool in the folds.

**Utensil Sets**

1. **Preparing and Wrapping for Steam Sterilization**

   a. When placing utensils in a set, separate each clean, dry basin or component from the one beneath it with a 100% cotton surgical towel.

   b. Open towel fully and “pie crust” it into the basin (Figure 13). **NOTE:** The towel assists in air removal, sterilant contact, and drying between basins.

   ![Figure 13:](image)

   ![Figure 14:](image)
Figure 15: Oblong Method - Utensils

Step 1
Step 2
Step 3
Step 4
Step 5
Step 6
Step 7

Figure 16: Envelope Method - Utensils

Step 1
Step 2
Step 3
Step 4
Step 5
Step 6
Step 7
Step 8
f. Total weight of utensil set and wrapper should not exceed seven pounds (Figure 17).

2. Loading the Steam Sterilizer
   a. Place wrapped utensil sets on edge, top side tipped slightly forward, so that air will not be trapped and condensate (water) can drain out of sets (Figure 18). **NOTE:** When sterilizing any dry solid container, imagine it filled with water and then position it so that water would drain out freely.

   b. Place utensil set(s) on the lower shelf of a loading cart in loads which combine textiles and metal items (Figure 19). **NOTE:** If loading cart is not used, it is preferable to loosely place items into sterilizable wire baskets or on sterilizer shelves.

   c. Do not overload shelves. Do not compress packages. Load to facilitate air removal, sterilant circulation, and drying.

   d. Never place utensil set(s) or other packages on the chamber floor.

3. Steam Sterilization Cycles
   a. Prevacuum cycle

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Exposure Time (recommended minimum)</th>
<th>Dry Time (recommended minimum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>270-274°F (132-134°C)</td>
<td>4 Minutes</td>
<td>20 - 30 Minutes</td>
</tr>
</tbody>
</table>

   b. Gravity cycles

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Exposure Time (recommended minimum)</th>
<th>Dry Time (recommended minimum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>270-274°F (132-134°C)</td>
<td>15 Minutes</td>
<td>15 - 30 Minutes</td>
</tr>
<tr>
<td>250-254°F (121-123°C)</td>
<td>30 Minutes</td>
<td>15 - 30 Minutes</td>
</tr>
</tbody>
</table>

4. Unloading the Steam Sterilizer
   a. Loading car

   1) Remove loading car from sterilizer and place it in a low-traffic area where there are no air conditioning or other cold air vents in close proximity.

   2) Do not touch packages until they are cool.
3) Visually check outside wrapper for moisture. A wrapped utensil set is considered unacceptable if there are water droplets or visible moisture on the outside of the package or on the tape used to secure it.

4) Remove utensil set(s) from loading cart when the load has reached ambient room temperature. The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used. A minimum cooling time of 30 minutes is recommended. (ANSI/AAMI ST79:2010 8.8.1)

b. Wear heat protective gloves to carefully remove hot wire baskets of sterilized goods from the sterilizer. Wear sterile gloves and use sterile towels as pot holders if you must touch hot items to remove them from the sterilizer shelves.

1) Visually check the outside wrapper for moisture. A wrapped utensil set is considered unacceptable if there are water droplets or visible moisture on the outside of the package or on the tape used to secure it.

2) Transfer acceptable items to wire cart shelving that has been covered with a clean 100% cotton surgical towel to cool. Do not place on a solid cold surface; condensation will occur. Be sure there are no air conditioning or cold air vents in close proximity.

3) Remove textile packs from the wire cart when they have reached ambient (room) temperature. Depending upon the sterilized items and environmental conditions in the area, this may take a minimum of (1) hour.

Textile Packs

1. Preparing and Wrapping for Sterilization*
   a. Place two wrappers on work surface. **NOTE:** ALL textiles must be laundered, delinted and inspected for holes, worn spots, breaks in or separation of the fabric and stains between sterilization cycles.

   b. Place contents on wrappers. A pack should be prepared with clean, preconditioned textiles. It might be necessary to separate tightly woven, liquid-resistant textile items in the pack with absorbent, less dense fabrics (e.g. surgical towels) in order to allow adequate air removal, steam penetration, and steam evacuation. Wrapper size should be appropriate for the desired method of wrapping but not too large. Excessively large wrappers may cause moisture to pool in the folds. All textile packs should be equilibrated, held at room temperature (20 deg C – 23 deg C- 68 deg F – 73 deg F) and at a relative humidity ranging from 30% - 60% for a minimum of 2 hours. (AAMI ST79 – 8.3.5/8.3.1)

   c. Place internal chemical indicator in the center of the pack (the area hardest to reach by the steam).

   d. You may choose to wrap the contents sequentially in two single layer instrument wrappers, or simultaneously using one bonded double-layer wrapper, using the oblong method (Figure 20). Secure with sterilizer (indicator) tape and identify pack contents by either writing on the sterilization tape with a permanent marker or affixing a computer-generated label to the package. Never write directly on the sterilization wrapper.

   **Special note:** The wrapper should be securely applied but not pulled in such a way that the contents are compromised. Wrap only tightly enough to hold contents together for a reasonable amount of handling. Pulling the wrap too tightly can create a pack that is too dense for proper air removal, sterilant penetration and drying.

   e. Limit the size, weight and density of the all-cotton textile pack (maximum weight of 12 pounds, maximum size of 12” x 12” x 20,” and density factor not in excess of 7.2 pounds per cubic foot (see Figure 21)). This provides a liberal margin of safety for sterilization and is also necessary for drying.

* This guideline is only appropriate for all-cotton textile packs. Manufacturers of water-repellent/resistant textile blends and combinations must be consulted for their specific pack preparation instructions for effective sterilization and drying information.
2. **Loading the Steam Sterilizer**
   a. Place textile pack on edge so that the layers of textile within are perpendicular to the shelf to facilitate air removal, steam penetration and drying (Figure 22).

   ![Fabric Packs](Image)
   **Figure 22:**

   b. Place textile packs on top shelves of a loading car when combining load with metal items (Figure 23). **Special note:** If loading cart is not used, it is preferable to loosely place textile packs into sterilizable wire baskets. Otherwise, place packages on the sterilizer shelf.

   ![Fabric Packs Instrument Trays (Wrapped)](Image)
   **Figure 23:**

   c. Do not overload shelves. Do not compress packages.

   d. Do not allow pack(s) to contact the sterilizer chamber walls.

   e. Provide at least three inches between the sterilizer chamber ceiling and the topmost package of the load, to facilitate air removal, sterilant circulation and drying.

   f. Never place wrapped pack(s) or other packages on the chamber floor.
3. **Steam Sterilization Cycles**
   
a. Prevacuum cycle

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Exposure Time (recommended minimum)</th>
<th>Dry Time***(recommended minimum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>270-274°F (132-134°C)</td>
<td>4 Minutes</td>
<td>5 Minutes for a single fabric pack in a small chamber sterilizer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20 minutes for up to six fabric packs</td>
</tr>
</tbody>
</table>

b. Gravity cycles

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Exposure Time (recommended minimum)</th>
<th>Dry Time (recommended minimum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>270-274°F (132-134°C)</td>
<td>25 Minutes</td>
<td>15 Minutes</td>
</tr>
<tr>
<td>250-254°F (121-123°C)</td>
<td>30 Minutes</td>
<td>15 Minutes</td>
</tr>
</tbody>
</table>

***If instruments and/or utensil sets are sterilized with textiles, extend minimum dry time to the minimum time needed to dry the metal load. Textile packs usually dry more readily than do instrument and utensil sets.

4. **Unloading the Steam Sterilizer**
   
a. Loading car

1) Remove loading car from sterilizer and place it in a low-traffic area where there are no air conditioning or other cold air vents in close proximity.

2) Do not touch packages until they are cool.

3) Visually check outside wrapper for moisture. A textile pack is considered unacceptable if there are water droplets or visible moisture on the outside of the package or on the tape used to secure it.

4) Remove textile packs from the loading car when they have reached ambient (room) temperature. The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used. A minimum cooling time of 30 minutes is recommended. (ANSI/AAMI ST79: 2010 8.8.1)

b. Wear heat-protective gloves to carefully remove hot wire baskets of sterilized goods from the sterilizer.

Wear sterile gloves and use sterile towels as pot holders if you must touch hot items to remove them from the sterilizer shelves.

1) Visually check outside wrapper for moisture. A textile pack is considered unacceptable if there are water droplets or visible moisture on the outside of the package or on the tape used to secure it.

2) Transfer acceptable items to wire cart shelving that has been covered with a clean 100% cotton surgical towel to cool. Do not place on a solid cold surface; condensation will occur. Be sure there are no air conditioning or cold air vents in close proximity.

3) Remove textile packs from the wire cart when they have reached ambient (room) temperature. The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used. A minimum cooling time of 30 minutes is recommended. (ANSI/AAMI ST79: 2010 8.8.1)
Tips for Improving Your Steam Sterilization Techniques

(Revised 2014)

Textiles ................................................................. 12
Instruments ............................................................. 13
Utensils ................................................................. 14
Glass syringes ......................................................... 14
Solutions In Containers ................................................. 14
Pack Density ........................................................... 16
The Formula ............................................................. 16

These tips are a quick reference to help you determine probable causes. They also offer preliminary suggestions for correcting some problems you may encounter during sterile processing. Use these tips along with other resources and references, including your sterilizer operator’s manual, to improve your steam sterilizing techniques.

### Textiles

<table>
<thead>
<tr>
<th>Probable Causes</th>
<th>Corrections</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Damp/Wet</td>
<td>See “Wet Pack Problem Solving Guide” in this booklet</td>
</tr>
<tr>
<td>2. Stained</td>
<td></td>
</tr>
<tr>
<td>• Dirty chamber walls and loading shelves, cars or carts</td>
<td>Clean (cool) chamber walls periodically to maintain sterilizer cleanliness and appearance. Immediately clean sterilizer chamber when spills or other soiling has occurred. Never use strong abrasives, steel wool, scouring powders, sharp instruments, etc. to remove stubborn stains. Consult sterilizer manufacturer for specific recommendations.</td>
</tr>
<tr>
<td>• Chemical reaction between residual laundry compounds in textiles and steam</td>
<td>Laundry chemicals and steam additives should be appraised by responsible management for proper mixtures. Textiles must be thoroughly rinsed.</td>
</tr>
<tr>
<td>• Boiler compound carry-over in steam supply</td>
<td>Notify hospital maintenance.</td>
</tr>
<tr>
<td>• Debris in steam lines (most likely after installation of new steam lines)</td>
<td>Notify hospital maintenance.</td>
</tr>
<tr>
<td>3. Torn Wrappers</td>
<td></td>
</tr>
<tr>
<td>• Rough surfaces on loading shelves, cars, or carts</td>
<td>Repair or replace damaged equipment. Use absorbent covers.</td>
</tr>
<tr>
<td>• Improper loading and unloading techniques</td>
<td>Carefully lift, do not PUSH, PULL, or DRAG wrapped packages when positioning or removing them on sterilizer shelves, cars or carts.</td>
</tr>
<tr>
<td>Probable Causes</td>
<td>Corrections</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>1. Damp or wet instruments</strong></td>
<td>See “Wet Pack Problem Solving Guide” in this booklet.</td>
</tr>
<tr>
<td><strong>2. Pitted/corroded instruments</strong></td>
<td>Clean instruments carefully and according to the manufacturer’s instructions. Do not delay cleaning. Remove gross soils at the point of use by simply using a wet sponge. Promptly transfer instruments to the decontamination area for immediate cleaning. Chloride ions in blood and bodily fluids attack instrument surfaces in the same way as saline solution does. Keep instruments moist with a pre-enzymatic cleaner or a moist towel.</td>
</tr>
<tr>
<td>• Damage to the passivation layer</td>
<td></td>
</tr>
<tr>
<td>• Poor cleaning or delayed cleaning of blood and bodily fluids or tissue on instruments</td>
<td></td>
</tr>
<tr>
<td>• Exposure to hard or caustic highly acidic or highly alkaline solutions or chemicals such as acids, iodine, sodium chloride detergents</td>
<td>Rinse instruments thoroughly and immediately after contact.</td>
</tr>
<tr>
<td>• Damage to instrument surface by abrasive scouring compounds, steel wool, sandpaper, metal brushes, scalpel scrapes, or soaking in bleach</td>
<td>Use only the cleaning tools and agents recommended by the instrument manufacturers. Use cleaning compounds e.g. rust remover per manufacturer’s instructions.</td>
</tr>
<tr>
<td>• Inferior instruments e.g. floor grade, Pakistani etc.</td>
<td>Use only surgical quality instruments.</td>
</tr>
<tr>
<td>• Instrument surfaces previously damaged and exposed to moisture</td>
<td>Avoid soaking instruments for prolonged periods and dry them thoroughly.</td>
</tr>
<tr>
<td>• Metallic deposits resulting from galvanic reaction with sterilizer components or cleaning agents</td>
<td>Clean the sterilizer chamber, accessories and trays only with cleaning agents recommended by the sterilizer manufacturer.</td>
</tr>
<tr>
<td><strong>3. Spotted and/or stained instruments</strong></td>
<td>Wash with appropriate detergent and good quality water. Use treated rinse water e.g. distilled or demineralized.</td>
</tr>
<tr>
<td>• Mineral deposits on instruments</td>
<td>Inform laundry services management and ask for evaluation of rinsing procedures.</td>
</tr>
<tr>
<td>• Laundry compound from instrument wrappers</td>
<td>Clean and thoroughly rinse instruments immediately after exposure.</td>
</tr>
<tr>
<td>• Deposits or stains from strong dyes or chemicals</td>
<td></td>
</tr>
<tr>
<td><strong>4. Stiff hinges or joints (box locks)</strong></td>
<td>Thorough cleaning and lubrication is only a “band-aid.” The instrument should be sent for repair or replaced.</td>
</tr>
<tr>
<td>• Corrosion</td>
<td>An enzymatic presoak and/or ultrasonic cleaning can help remove hard-to-reach soil. Clean and rinse thoroughly.</td>
</tr>
<tr>
<td>• Soil</td>
<td>Realignment by a qualified instrument repair service</td>
</tr>
<tr>
<td>• Jaws or shanks out of alignment</td>
<td></td>
</tr>
</tbody>
</table>
## Utensils

<table>
<thead>
<tr>
<th>Probable Causes</th>
<th>Corrections</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Damp or wet utensils</td>
<td>See “Wet Pack Problem solving Guide.” in this booklet</td>
</tr>
<tr>
<td>2. Misshapen heat-resistant plastic utensils</td>
<td></td>
</tr>
<tr>
<td>• Loaded too tightly</td>
<td>Load loosely and do not place heavy objects against them.</td>
</tr>
<tr>
<td>3. Broken suction bottles</td>
<td></td>
</tr>
<tr>
<td>• In-rush of cool air when sterilizer door is opened</td>
<td>Open the chamber door a few inches and allow bottles to remain in the chamber for 15-20 minutes before handling.</td>
</tr>
<tr>
<td>• Soft glass</td>
<td>Use heat-resistant glass bottles</td>
</tr>
<tr>
<td>• Chipped or defective bottles</td>
<td>Inspect bottles for defects before sterilizing</td>
</tr>
</tbody>
</table>

## Glass Syringes

<table>
<thead>
<tr>
<th>Probable Causes</th>
<th>Corrections</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Sticky syringes</td>
<td></td>
</tr>
<tr>
<td>• Residual detergent or soil</td>
<td>Clean and rinse thoroughly and use distilled water for the final rinse.</td>
</tr>
<tr>
<td>• Sterilized while fully assembled</td>
<td>Separate barrels and plungers before sterilizing</td>
</tr>
<tr>
<td>2. Excessive breakage</td>
<td></td>
</tr>
<tr>
<td>• Rough handling</td>
<td>Handle carefully</td>
</tr>
<tr>
<td>• Sterilized while fully assembled</td>
<td>Separate barrels and plungers before sterilizing</td>
</tr>
<tr>
<td>• Poor quality syringes</td>
<td>Use good quality syringes</td>
</tr>
<tr>
<td>• Steam erodes glass</td>
<td>Sterilize with dry heat</td>
</tr>
<tr>
<td>• Cracked or chipped</td>
<td>Inspect syringes for defects before sterilizing</td>
</tr>
</tbody>
</table>

## Solutions In Containers

<table>
<thead>
<tr>
<th>Probable Causes</th>
<th>Corrections</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Caps blow off</td>
<td></td>
</tr>
<tr>
<td>• Exhausting the sterilizer too rapidly</td>
<td>Use a slow exhaust cycle.</td>
</tr>
<tr>
<td>• Slow exhaust valve; out of adjustment</td>
<td>Notify the sterilizer service provider</td>
</tr>
<tr>
<td>• Worn or damaged caps or collars</td>
<td>Inspect before using and replace as necessary, or use appropriate disposable closures.</td>
</tr>
<tr>
<td>2. Loss of more than 5% of fluid volume during sterilization</td>
<td>Use a slow exhaust cycle.</td>
</tr>
<tr>
<td>• Exhausting sterilizer too rapidly</td>
<td>Notify the sterilizer service provider</td>
</tr>
<tr>
<td>• Slow exhaust valve; out of adjustment</td>
<td>Sterilize at 250-254°F (121-123°C) using the sterilizer’s liquid cycle.</td>
</tr>
<tr>
<td>• Excessive sterilizing temperature</td>
<td></td>
</tr>
</tbody>
</table>
## Preparation and Packaging Best Practices and Wet Pack Problem Solving Guide

### Solutions In Containers

<table>
<thead>
<tr>
<th>Probable Causes</th>
<th>Corrections</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3. Cracked flasks</strong></td>
<td></td>
</tr>
<tr>
<td>• Cracked before sterilization; indicates poor inspection after cleaning</td>
<td>Inspect thoroughly after cleaning and discard chipped or cracked flasks.</td>
</tr>
<tr>
<td>• Containers not heat-resistant or have screw caps</td>
<td>Use only borosilicate Type 1 containers and automatic sealing and venting closures or appropriate disposable closures.</td>
</tr>
<tr>
<td>• Sterilizer exhausting too rapidly</td>
<td>Notify sterilizer manufacturer.</td>
</tr>
<tr>
<td><strong>4. No vacuum</strong></td>
<td></td>
</tr>
<tr>
<td>• Worn or damaged caps or collars</td>
<td>Inspect closures thoroughly after cleaning and discard any damaged ones.</td>
</tr>
<tr>
<td>• Applying cap and collar to flask separately</td>
<td>Assemble caps and collars before placing on flasks.</td>
</tr>
<tr>
<td>• Slow exhaust valve; out of adjustment</td>
<td>Notify sterilizer manufacturer.</td>
</tr>
<tr>
<td><strong>5. Discoloration</strong></td>
<td></td>
</tr>
<tr>
<td>• Prolonged exposure period</td>
<td>Exposure should be according to the size of the flasks (fluid volume); do not combine flasks requiring different exposure times in the same load.</td>
</tr>
<tr>
<td>• Impure ingredients or dirty flasks</td>
<td>Check the purity of ingredients and clean the flasks thoroughly.</td>
</tr>
<tr>
<td>• Excessive temperature</td>
<td>Sterilize only at 250-254°F (121-123°C) using the sterilizer’s liquid cycle.</td>
</tr>
<tr>
<td><strong>6. Solutions are boiling when chamber door is opened</strong></td>
<td></td>
</tr>
<tr>
<td>• Door was opened too quickly or was fully opened at the end of the cycle.</td>
<td>Open the sterilizer door no more than ONE inch and wait at least 10 minutes before unloading the sterilizer. Do not touch or move a load of boiling solutions.</td>
</tr>
<tr>
<td>• Slow exhaust valve; out of adjustment</td>
<td>Notify sterilizer service provider.</td>
</tr>
<tr>
<td><strong>7. Black particles or “snowstorm” in solution</strong></td>
<td></td>
</tr>
<tr>
<td>• Particles indicate deteriorated caps and/or collars</td>
<td>Replace caps and/or collars or use appropriate disposable caps.</td>
</tr>
<tr>
<td>• Snowstorm indicates clumping of chemicals</td>
<td>Use only chemically pure ingredients.</td>
</tr>
<tr>
<td>• Snowstorm indicates use of “soft glass” containers</td>
<td>Use only borosilicate Type 1 containers.</td>
</tr>
<tr>
<td>• Snowstorm indicates chemicals are incompatible with routine sterilization temperatures</td>
<td>Get specific instructions from the chemical manufacturer.</td>
</tr>
</tbody>
</table>

**Special note:** “Primarily for personnel safety reasons, in-hospital preparation and sterilization of parenteral and irrigation liquids is discouraged. When solutions are processed in the hospital (i.e., in emergency situations), processing should be performed only by trained personnel familiar with the [following] guidelines.” (ANSI/AAMI – ST79: 2010 & A4:2013)
Pack Density

This formula can be used to determine the density of cotton/linen textile packs and assess whether a pack is too tightly wrapped for its weight. Consult manufacturers of water repellent/resistant textile blends/combination for appropriate methods for pack density determination.

A textile pack, small or large, can be so dense or tightly wrapped that it can prohibit proper air removal and/or steam penetration for sterilization and drying. In general, a cotton/linen textile pack should weigh no more than 12 pounds (5.44 kg) for ease of handling and assured sterilization. At this weight, the pack should measure 12” high by 12” wide by 20” long (30.5 cm x 30.5 cm x 50.8 cm) to achieve a pack density no greater than 7.2 pounds per cubic foot (1.15 kg per cubic meter).

Remember, however, that for all practical purposes density relates to how the textile contents are arranged and how tightly the pack is pulled together. The tighter it is, the more dense it is and therefore, the more difficult to sterilize.

This is the formula, using US values:

**Step 1**
Size of pack ÷ 1728\(^{(1)}\) = cubic feet of pack

**Step 2**
Weight of pack ÷ Cubic feet of pack = DENSITY

Example # 1 – Using a standard 12” x 12” x 20” pack weighing 12 pounds with US values:

| Step 1 | 12 x 12 x 20 = 2880 = 1.666 cubic feet |
| Step 2 | 12 pounds = 7.2 pounds per cubic foot |
|        | 1.666 cu. ft.                           |

Here is the formula using metric values:

**Step 1**
Size of pack ÷ 1,000,000\(^{(2)}\) = Cubic meters of pack

**Step 2**
Weight of pack ÷ Cubic meters of pack = Density
(in kilograms per cubic meter)

Example # 2 -- Using a standard 30.5 cm x 30.5 cm x 50.8 cm pack, weighing 5.44 kilograms:

| Step 1 | 30.5 x 30.5 x 50.8 cm = .0473 cubic meters |
| Step 2 | 5.44 kilograms = 115 kilograms per cubic meter |
|        | .0473                                      |

\(^{(1)}\) 1728 is the number of cubic inches in a cubic foot. This is a constant.

\(^{(2)}\) 1,000,000 is the number of cubic centimeters in a cubic meter. This is a constant.
### Wet Pack Problem Solving Guide

(Revised 2014)

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is a Wet Pack? Why Are Wet Packs a Problem</td>
<td>18</td>
</tr>
<tr>
<td>Where the Moisture Comes From</td>
<td>18</td>
</tr>
<tr>
<td>Looking for Causes and Remedies</td>
<td>18</td>
</tr>
<tr>
<td>Finding and Documenting Wet Pack Occurrences</td>
<td>19</td>
</tr>
<tr>
<td>Examining Individual Packs</td>
<td>19</td>
</tr>
<tr>
<td>Who is Preparing the Packs That You Sterilize and When Did You Last Audit Them?</td>
<td>20</td>
</tr>
<tr>
<td>Have You Audited Your Own Department’s Preparation Practices Lately?</td>
<td>20</td>
</tr>
<tr>
<td>Preparation Techniques</td>
<td>21</td>
</tr>
<tr>
<td>Choosing the Correct Tray</td>
<td>21</td>
</tr>
<tr>
<td>Instrument Set Assembly</td>
<td>21</td>
</tr>
<tr>
<td>Basin Set Preparation</td>
<td>23</td>
</tr>
<tr>
<td>Textile Pack Preparation</td>
<td>24</td>
</tr>
<tr>
<td>Other Important Considerations</td>
<td>26</td>
</tr>
<tr>
<td>Appendix A- Wet Pack Prevention and Investigation Audit</td>
<td>28</td>
</tr>
<tr>
<td>Appendix B- Guideline for Determining Wet Packs</td>
<td>33</td>
</tr>
<tr>
<td>Appendix C- Guideline for Solving Wetpack Problems</td>
<td>40</td>
</tr>
<tr>
<td>References and Suggested Reading</td>
<td>48</td>
</tr>
</tbody>
</table>
What is a “wet” pack?

Perhaps the most frustrating and confounding dilemma we face as sterilization professionals is the occurrence of wet packs. While wet packs can also result from ethylene oxide sterilization, they most frequently occur during steam sterilization, which is the method that is the mainstay of hospital processing throughout the world. This section will focus on wet packs that occur with steam sterilization.

Packs are considered to be “wet” when moisture in the form of dampness, droplets, or puddles are found on or within a textile pack, instrument, or basin set after a completed sterilization cycle and at least a one-hour cooling period. External moisture would be visible immediately after the sterilization cycle, whereas internal moisture will not be noticed until the pack is opened for use.

Why are wet packs a problem?

Wet packs have the potential to provide a pathway for microorganisms to enter the just-sterilized package and then contaminate it.

Moisture found on the outside of a package may be the result of condensation dripping from a sterilizing shelf or cart rail above the items; condensation blowing through the steam lines into the chamber; or metal items loaded on the shelf above that may drip condensate onto the items below. These seem to be the most common sources of exterior wetness. If this moisture is not dried by the time the integrity of the sterilization chamber is broken (by opening the door at the end of the cycle), the textile or non-woven disposable wrapper’s biobarrier may be considered penetrated and the items inside it contaminated.

Moisture found inside a package is often the result of metal items positioned in a way that enables water to pool, or that traps steam, which later condenses. Instrument and basin sets are often overloaded and lack absorbent surgical towels to absorb moisture for more efficient drying. Textile packs also retain moisture when they are too tightly wrapped. All of these items, when properly prepared but improperly loaded for sterilization, can contribute to moisture forming and remaining within the set-up. Internal moisture can “wick” its way to the outside of the pack, providing a pathway for microorganisms to enter.

Some question why we need to be concerned about internal moisture such as a droplet found well within a set or pack. Certainly that small amount can’t contact the outer surface, can it? The fact is that a pack prepared with an absorbent wrapper must always be considered contaminated if there is any internal moisture. This is because the outside of the wrapper may also have been wet, and the moisture found inside the pack could be all that remains after the outside dries first.

On the other hand, moisture found inside a rigid sterilization container may not be contaminated. Rigid metal or plastic sterilization container systems that are used in place of textile or nonwoven disposable wrappers may or may not allow such a pathway for microorganisms to be established, depending upon their design. You should discuss the likelihood with the rigid sterilization container manufacturer and then establish a facility policy regarding moisture within rigid sterilization containers based on the information gained from the manufacturer’s testing and documentation.

Where the moisture comes from

During the steam sterilization cycle, air is removed from the sterilizer either by gravity displacement or a mechanical air removal device. Steam (water vapor) heats the load up to the temperature required for sterilization by transferring its latent heat energy to the items. As that happens, the steam condenses and becomes water. Metal items, in particular, require a great amount of heat energy transfer to reach sterilization temperature because of their mass or density. Therefore, the more metal mass in the load and/or the greater density of the load, the more water produced when the steam condenses (or collapses).

In a “normal” steam sterilization cycle, much of the condensate drains from the chamber before exposure timing begins. The remaining water is re-vaporized at the end of the exposure period and is then exhausted, or evacuated, from the chamber at the end of the cycle. Wet packs result when there is so much condensate present that it cannot be fully re-vaporized.

Looking for causes and remedies

Once they are discovered, finding the cause and remedy for wet packs is not always easy. There are many factors involved that must be individually considered.

First, we all recognize that this very frustrating problem involves many disciplines and that the sterile processing manager has a number of areas to examine. Many sterile processing consultants have found that items improperly prepared and loaded for sterilization are the most common contributing factors to the occurrence of wet packs. However, these are by no means the only probable cause.
A routine review or quality assessment of the basic techniques of preparing and loading items for sterilization is a first step at correction, and certainly a good idea for prevention as well. Sterile processing personnel involved in the process should be audited to assure that they are following department procedures.

Finding and Documenting Wet Pack Occurrences

Finding the incorrect preparation practice is not always an easy task, particularly when wet packs occur sporadically. The first step in investigating the problem must be to clearly and completely document the actual occurrences. Using a simple format like this one can be helpful:

<table>
<thead>
<tr>
<th>STERILIZER LOG*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilizer number:</td>
</tr>
<tr>
<td>Location in load</td>
</tr>
</tbody>
</table>

* Please see full-page log in Separate M1844EN

Wet packs found by the department opening the pack can also be documented in this form. The users can provide information for the comment section while the load documentation system in the sterile processing area provides the rest. The wet packs should be immediately returned to the sterile processing department intact for examination.

Once the wet pack log data is analyzed, patterns may emerge that give clues to the root cause. Perhaps the problem exists only with the heaviest of instrument sets, or those items coming to you already wrapped from another department, or items prepared by a particular worker, or specialty instruments (multilayered trays of orthopedic instrumentation or combination metal and plastic trays).

Examining individual packs

External wetness on packs is usually immediately noticed when they are removed from the sterilizer. Internal wetness will not be noticed until the packs are opened for use unless it wicks through the wrap.

1. As a general rule, do not check packs for wetness until they are thoroughly cooled.

2. If you choose to check packs before they have finished cooling, realize that warmth goes hand-in-hand with some vapor that will be present immediately after sterilization and will normally re-vaporize during cooling.
   - Take particular notice of how items were prepared and positioned for sterilization and where the moisture is in relation to it all.
   - When examining warm fabrics just removed from the sterilizer (whether from textile packs or instrument/basin sets), open them up, shake them out, and then feel for moisture. A hot/warm towel can feel moist at first, but with one or two good shakes to eliminate the vapor, you may find it is completely dry or you may find real wet spots. If that is the case, be sure to leave similar packs/sets to thoroughly cool before examining them to see if the wetness remains. If so, you have a legitimate wet pack.
Who is Preparing the Packs That You Sterilize and When Did You Last Audit Them?

<table>
<thead>
<tr>
<th>ITEMS STERILIZED FOR OTHER DEPARTMENTS*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dept. Name</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Dept. Name</td>
</tr>
</tbody>
</table>

All departments that expect you to sterilize their packs must be expected to adhere to your requirements if your department is to assume responsibility for successful sterilization and drying. List where the items you sterilize come from, using the following criteria to complete the log:

1. Is preparation of these items done in part or wholly by that area?
2. Has the staff been provided an in-service program regarding proper cleaning, assembly/disassembly, and packaging for sterilization?
3. Is each individual item audited?
4. When were that department’s instrument sets last examined or audited by your department for continued compliance and/or updates? Audits at least every six months is recommended.

Have You Audited Your Own Department’s Preparation Practices Lately?

Perform random audits of items being prepared by your sterile processing staff for sterilization. Do they understand that the probability of sterilization and efficient drying is improved when everyone follows directions carefully? Every detail of preparation should be performed essentially the same way by each individual to assure a consistent outcome and easy problem solving.

Survey the sterile processing department and ask your personnel a few questions:

1. Are all protocols, policies and procedures clearly documented, updated, and easy to understand and follow? Consider that photographs and simple diagrams may be helpful.
2. Are you assured that all personnel have been thoroughly oriented to their area of responsibility?
3. Is orientation documented for each person?
4. Were the employees required to do a demonstration of each process, for example; instrument, basin set or textile pack assembly, packaging, and sterilizer/cart loading techniques to assure their understanding?
5. Are the supervisors closely monitoring the performance of the workers?
6. Do staff members understand that items improperly prepared might not be properly sterilized and/or a wet pack could result? Does the staff understand the consequences of a wet pack?
7. Is the staff taking short cuts? A few examples:
   - Not placing an absorbent surgical towel properly within a basin or instrument set.
   - Agreeing to a request from surgical personnel to put all of the instruments into one tray instead of dividing them among two or more. Dividing instruments between two or more trays increases the probability of sterilant contact and drying.
   - Overloading the sterilizer shelves with properly prepared packs, creating a tight, dense load that prevents proper air removal and steam penetration for sterilization, and steam evacuation for drying.
   - Improperly positioning items on the sterilizer shelf to get more in the load.
   - Using inappropriate trays for sterilizing heavy instrument sets; for example, those with no holes, too few holes, or holes in incorrect places for efficient drainage of condensate.

Only after ascertaining that procedures and technique are not the cause of the wet packs should you investigate potential steam quality issues.
Preparation Techniques

Always ensure that industry-recommended practices are followed when preparing instruments, basin sets and textile packs for sterilization. Compare your current practices to the instructions below to determine if any changes to current practices should be considered.

Choosing the Correct Tray:

1. Always use a “standard” surgical instrument tray that has multiple perforations or a wire-mesh bottom (or its equivalent used in rigid sterilization container systems) for surgical instrument set assemblies (Figure 1).

![Figure 1: Correct Tray Example](image1)

2. Always choose a tray that is large enough to distribute the mass of metal instrumentation evenly in a single layer. Rectangular “cake pan” type or flat trays with holes are not preferred for heavy surgical instrument sets but if they must be used, be certain that the holes in the tray are large enough and in the correct position to promote drainage. These trays are more appropriately used for small instrument trays used at the bedside (e.g., chest tube insertion, cut-downs, suture, etc.) These trays generally contain fewer metal instruments, so less steam condenses on the instruments and they are more easily dried.

![Figure 2: Incorrect Tray Example](image2)

Instrument Set Assembly

1. Line the tray with an absorbent surgical towel or its disposable equivalent before arranging instruments. Moisture formed during sterilization dries more readily from absorbent materials than from droplets or moisture pooling on solid metal surfaces (Figure 3).

![Figure 3: Correct Liner and Absorbent Example](image3)

   a. Do not use a water-repellent textile or nonwoven disposable wrapper or thick super absorbent textile, as they may pool or trap moisture and make it very difficult, if not impossible, to dry the set. Some foam products can also hold condensate. As with any product used in sterilization, be sure to check with the manufacturer regarding proper use and/or test it yourself to see that you are getting a sterile and dry pack.

   b. Do not use a tray liner with rigid sterilization container systems unless validated by the liner or container manufacturer.

2. Open all instruments and evenly distribute them throughout the tray. Ensure that all instruments are disassembled following the device manufacturer’s instructions for proper steam contact and to avoid trapping steam that can condense and contribute to a wet pack.

   a. Consider alternating the position of the heavy handle instruments such as orthopedic chisels, osteotomes and gouges, whether you are placing them flat in trays and/or in organizing pouches to ensure even distribution of the metal mass. When pouches are used, avoid rolling them tightly. Instead, fold the pouch in thirds loosely before wrapping to provide for more efficient drying (Figure 4).

![Figure 4: Correct Instrument Placement Example](image4)

   b. Avoid piling instruments on top of one another. The more metal mass, the more condensation you can expect and the harder the set is to dry (Figure 5).
Preparation and Packaging Best Practices and Wet Pack Problem Solving Guide

Figure 6:  
d. Do not use paper/plastic peel pouches or water repellent nonwoven disposable wrappers to contain groups of instruments, use only pouches that have been validated for that use. Separate and arrange them within an instrument set. This, too, can be the cause of pooling condensation and can prohibit sterilization (Figure 7).

Figure 7:  
3. Experience has shown that a properly assembled set weighing no more than 25 pounds has a better probability of drying. Remember, when steam heats up a load, each item must reach sterilization temperature. As steam contacts the cool item, it transfers its heat energy to it, the steam collapses (condenses), and becomes water. Consequently, the more metal mass in a set, the more water created. Consider that:

a. A light set, perhaps just ten pounds, assembled in an unlined tray that is too small to distribute the metal mass could result in a wet pack.

b. Just one medical device made of heavy, dense metal can weigh several pounds by itself, and can require a great deal of heat energy to heat it to sterilizing temperature. Thus, a great deal of condensation will be created, resulting in wet packs. Wrapping a heavy device in an absorbent towel before placing it in the tray aids re-vaporization and drying.

c. It is generally not wise to exceed 25 pounds when preparing a set for sterilization. Heavy sets are often difficult for workers to handle besides being more difficult to dry after sterilization.

c. In some instances, an absorbent surgical towel can be used to separate layers of instruments within the tray (heavy instruments on the bottom, lighter ones on the top). However, the addition of absorbent material should not be considered a substitute for removing some instruments from a heavy or over-loaded tray. The additional towels may absorb so much condensate that they may be difficult to dry (Figure 6).
Wrapping the Instrument Set

1. Before applying sterilization wrap, consider placing an absorbent surgical towel between the bottom of the tray and the wrapper (Figure 8).

![Figure 8: Wrapping the Instrument Set](image)

a. This is particularly helpful when using nonwoven disposable wrappers, because excess moisture will usually dry more readily from the textile and prevent pooling inside the wrapper.

b. An absorbent surgical towel may be placed on top of the set before wrapping if necessary. The top towel should contact the top surface of the instruments to absorb moisture. Figure 8 shows the wrong way to apply the top towel.

2. Instruments prepared in paper/plastic peel pouches can be double-packaged. Slide one pouch into the other - paper to paper, plastic to plastic. This allows air and steam to easily pass through the paper during the sterilization process (Figure 9). Ensure that the inner pouch is smaller than the outer. Avoid folding a large inner pouch over and onto itself to fit into a smaller outer pouch. This practice can prohibit steam penetration and/or trap moisture.

![Figure 9: Basin Set Preparation](image)

Basin Set Preparation

Assembling the Basin Set

All personnel who assemble, wrap, and load basin sets for sterilization must use the same technique. Standardizing basin set assembly techniques ensures that anyone who picks up a set prepared by someone else will know exactly how to load it properly for sterilization. In general:

1. A basin set should not exceed seven (7) pounds, primarily to limit condensation from the solid metal surfaces.

2. All nested utensils should be separated or “wicked” using absorbent surgical towels. This helps to separate surfaces for steam contact and evacuation for drying (Figure 11).

a. When separating large solution basins, be sure to fully open the surgical towel and “pie-crust” it well into the bottom basin before placing another basin on top. The moisture that will be formed between them will cling to the inner surface of that bottom pan, and the towel will absorb it for more efficient drying (Figure 10). If the top basin is the same size or only slightly smaller in diameter than the lower one, use a folded absorbent surgical towel to provide space between the basins, preventing a tight fit that could trap moisture between them.

b. Position utensils that have “curled” or turned rims, such as emesis basins on edge within a basin set to prevent water from pooling on the rim which can be a wet pack source.

c. Hollow surgical light handles should be inverted with the handle-end down into the basin so that when the set is tilted on edge for sterilization the handles will drain.

d. Small items like a medicine glass/cup should be eliminated from basin sets if they cannot be secured in a position that will promote drainage. Small items such as medicine cups often reposition during sterilization and can retain moisture.
Wrapping the Basin Set

1. Consistent assembly and wrapping techniques go hand in hand. Sets assembled exactly alike should then be positioned exactly the same. This way, an external landmark, such as sterilization tape can indicate to the loader which way the basin set should be positioned in the sterilizer. For example, the taped side may indicate the “standing edge” (Figure 13).

![Figure 13:]

a. Before applying the sterilization wrap, ensure that the “curled” rim usually found on large solution basins are tilted so that water can drain. Make sure the rim is positioned on the wrapper so that some of the absorbent towel used to wick the basins will wrap around the edge that the wrapped basin will stand on in the sterilizer. The towel will absorb that condensate and aid in drying (Figures 12 and 14).

![Figure 12:]

Textile Pack Preparation

1. A textile pack should weigh no more than 12 pounds (5.4 kg) and be 12” high x 12” wide x 20” long (30.5 cm x 30.5 cm x 50 cm) to achieve a pack density no greater than 7.2 pounds per cubic foot (115 kg per cubic meter). See pages 29-30 of the section “Tips for Improving Your Steam Sterilizing Techniques” for the pack density formula. This is important to ensure proper air removal, steam penetration and evacuation during the sterilization cycle.

a. Textiles have, however, changed over the years. The linen/textile pack density formula is not appropriate for use with water repellent textiles, only cotton/linen textiles. Always keep in mind that density relates to how the textile contents of a pack are arranged and how tightly they are wrapped. A simple gown or towel pack could be pulled together so tightly that sterilization and drying could be compromised (Figures 15 and 16). Follow the advice of manufacturers of newer textiles for a pack density formula appropriate for their products.
b. Multiple layers of tightly woven or water-repellent textiles may need to be rearranged within the pack and/or separated by absorbent, less dense fabrics to promote drying.

c. Ensure that pack preparation instructions and sterilization parameters are provided by the textile manufacturer. Documentation from the manufacturer should show that sterilization testing was performed using standard hospital cycles.

Packaging Methods

Wet pack difficulties have become more frequent following the introduction of nonwoven disposable sterilization wrap, newer, less absorbent textiles, and rigid sterilization container systems. This does not indicate that these products are responsible for wet packs, but rather that the woven textiles have been more forgiving of improper preparation techniques. Those porous textiles absorbed the excess moisture from overloaded trays and sets, and they often (but not always) dried more readily.

For successful packaging:
1. Always choose sterilization wrap, etc. that’s designed and tested for the type of sterilization cycle (gravity or pre-vacuum) to be used. Always consult sterilization wrap, peel pouch, and rigid sterilization container manufacturers for their instructions for use.

2. Avoid using sterilization wrap for a dual purpose (e.g., a large table drape).

3. Avoid using too large a wrap, the excess layers or folds of wrap could prohibit steam penetration and/or trap moisture.

Loading the Sterilizer

1. An absorbent shelf liner may be used and can be helpful in drying a load, particularly when disposable wrap and rigid containers are used. The shelf cover will absorb moisture that might otherwise drop onto items on the shelf below.

   Do not use nonwoven disposable wrap as a shelf liner. Condensate more readily dries from absorbent materials.

2. It’s better to sterilize textiles and metal items, e.g., instrument sets, basin sets, etc., in separate loads.

   a. If mixed loads are necessary, textiles should be placed on top shelves and metal items below, to avoid condensate run-off to items below.

   b. Surgical instrument trays should be placed flat on the shelf to maintain even instrument distribution and facilitate proper drainage. Placing sets on edge permits moisture to collect at the standing edge (Figure 17).

   c. Basin sets should stand on edge, tilted for drainage (Figure 18).
d. Position textile packs so that the layers within are perpendicular to the shelf (not sitting flat, one upon the other) for more efficient air removal, steam penetration, and evacuation for drying (Figure 19).

e. Stand paper/plastic peel pouches on edge using a basket or rack for sterilization. Placing the package flat, “plastic side down” may cause moisture to remain inside. Placing the package flat, “plastic side up” may result in water droplets on top of the plastic (Figure 20).

1. Do not allow items to touch chamber walls where they could contact condensate. Use sterilizable baskets to contain small items on sterilizer shelves/carts.

2. Use sterilizer carts whenever possible and allow items to remain on them untouched until thoroughly cooled. For each sterilizer, ideally, there should be one cart cooling, one in the sterilizer, and one that is being prepared for loading.

3. Examine the position of each item on the cart and avoid overloading. If overloaded, the cart will not allow efficient air removal, steam penetration, and evacuation, even if the items were prepared appropriately. Consider maximizing available cart space by adding another shelf to the sterilizer cart and rearranging the load.

Unloading the Sterilizer

1. Always allow items to thoroughly cool on the cart before handling.
   a. Do not place hot items on cold surfaces, into boxes/bins, or stack them one upon the other. Condensation will occur beneath and/or between them.
   b. Do not place warm packages in plastic dust covers. Condensate will be trapped and remain there until opened, and might damage the items within.

Other Important Considerations

1. Instrument lubricants should be used in accordance with the manufacturer’s instructions, including proper dilution (if necessary). The lubricated items should be dry before they are wrapped for sterilization.
   a. Use a lubricant that is compatible with the method of sterilization to be used.
   b. Packs that are wet before sterilization may also be wet at the end of the cycle.
   c. Lubricants that are inadequately diluted may leave instruments slippery and/or give the false impression of wetness.
2. Inspect and clean the sterilizer chamber drain screen \textit{at least daily}. An obstructed screen can prohibit not only proper air removal, but also steam removal at the end of the cycle.

3. Finally, be sure to keep the sterilizer clean. Radiant heat from clean chamber walls will provide for more effective drying.

The preparation information provided so far is very important in the wet pack investigative process and provides a logical place to start an investigation. You may find that this is all you need to determine your problem and you simply have a few things to correct in your process to reach a solution.

On the other hand, you may confirm that you are preparing items properly, and you need to expand the investigation to other areas to discover the origin of wet pack occurrences - steam quality, plumbing, trapping, etc. The Equipment, Process and Environment Audit checklist in Appendix A will help you with a broader assessment.

Wet packs represent an economic loss to the institution because goods must be reprocessed. If unrecognized, they can be a patient safety risk. Resolving the problem takes patience, critical thinking and observation, and most importantly, cooperation among all concerned.

References and Suggested Reading:

- Association for the Advancement of Medical Instrumentation (AAMI), 1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795 (800-332-2264) AAMI Standards and Recommended Practices:
  - Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ST79)
  - Containment devices for reusable medical device sterilization (ST77)
  - Ethylene oxide sterilization in health care facilities: safety and effectiveness (ST41)

- Association of periOperative Registered Nurses (AORN), 2170 S. Parker Rd., Suite 300, Denver, CO 80231-5711, 800-755-2676

- AORN Standards, Recommended Practices & Guidelines:
  - Sterilization in the Practice Setting

- ASPEN Publishers, Inc., Gaithersburg MD, 800-638-8437
  - Sterilization Technology for the Health Care Facility, Reichert, M., Young, J.

- American Hospital Association (AHA), One North Franklin, Chicago, IL 60606,800-AHA-2626
  - Ethylene Oxide Use in Hospitals: A Manual for Health Care Personnel, Danielson, N.E.

For specific assistance from STERIS Corporation, please call 800-548-4873.
Appendix A

Wet Pack Prevention and Investigation Audit

Wet packs are commonly recognized when there have been changes within the overall conduct of the sterilization process or environment. The following statements are arranged as a checklist, under their appropriate responsible party. As you read along, place a “√” next to the item that you want to remember to investigate. The comment column is provided for you to record what you specifically intend to check and/or the results of your audit.

<table>
<thead>
<tr>
<th>Audit Points</th>
<th>√</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sterile Processing Personnel</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. <strong>Review work practices:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Ensure all personnel have been adequately trained.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Policies and procedures for sterilization preparation, packaging, and sterilization must be accurate, easily understood, and disseminated to all department personnel.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Investigate whether new staff members might be a factor in the wet pack occurrences.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. <strong>Isolate wet pack occurrences:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Sterilizer(s) involved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Location of packs on cart (top, middle, bottom)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Wet packs on the bottom of the cart may be the result of a leaking check valve or a PRV issue.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Wet packs on the top of the cart may be the result of excessively wet steam.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Location of moisture on pack (inside or outside)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) External moisture may be the result of saturated steam condensing on packs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Internal moisture may be the result of poor preparation/packaging technique.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Note the time of day wet packs are occurring. Wet packs may occur at times during the day when units are coming back on line after a period of inactivity and could result in excess water in the steam lines being picked up and carried to the sterilizer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Ensure that the design of a new medical device or new containment device is not contributing to the wet pack occurrence (e.g., heavy metal mass inside a metal containment device with plastic inner organizing trays and a plastic lid).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Ensure that the processing instructions from the device manufacturers are carefully followed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit Points</td>
<td>✓</td>
<td>Comments</td>
</tr>
<tr>
<td>--------------</td>
<td>---</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Sterile Processing Personnel</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. Check to see if changes in packaging (non-woven sterilization wrap, non-absorbent textile wrap, or rigid sterilization containers) prompted the discovery of wet packs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Check the instructions from the container or wrap manufacturer regarding appropriate sterilization cycle parameters and drying time.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Follow the container manufacturer’s instructions for container use, valve or filter cleaning and maintenance, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Assure that the containers or wraps are compatible with the sterilization process and cycle used.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) Check to see if absorbent towels are recommended by the container or wrap manufacturer to assist in absorbing moisture during sterilization.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5) Check to see if the use of absorbent towels is discouraged by the wrap or container manufacturer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6) Follow manufacturer’s instructions for rigid sterilization container stacking.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7) The total weight of the tray should not exceed the recommended maximum weight from the container manufacturer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8) Consult with the container or wrap manufacturer for specific reasons for wet packs related to their product.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9) If reusable textiles wrap is used and absorbent towels, check with the laundry facility to ensure the excess fabric softener is not being used. (Overuse of fabric softener can diminish absorbency of cotton textiles, which may contribute to wet packs.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10) Follow manufacturer’s instructions for use of accessories e.g. foam corner protectors etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit Points</td>
<td>✓</td>
<td>Comments</td>
</tr>
<tr>
<td>--------------</td>
<td>---</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Sterile Processing Personnel</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Environmental conditions that contribute to wet packs:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. The cool down area must be maintained at a temperature between 68-73°F and humidity should not exceed 30-60%.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Sterilization loads should not be placed under air conditioning vents during cool down.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Do not place near doors or windows where drafts can impact condensation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Review cycle printout tapes for deviations in the temperature and pressure on loads with wet packs with those in non-wet pack loads. Temperature and pressure discrepancies can indicate superheat or calibration issues.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Facility Maintenance Personnel:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Steam must be regulated at the proper dynamic steam pressure (50-80psi) from the steam generator to each sterilizer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Steam entering the sterilizer must be regulated to between 36-40 psig of steam pressure to the sterilizer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Incoming water pressure must be between 20-50 psig.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Incoming water temperature should be less than 70°F (21°C). Water temperature in excess of the recommended range can affect the function of the water ejector or vacuum pump.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Steam line trapping must be sufficient and maintained in good working order.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Plumbing lines are as direct as possible from steam generator to sterilizer with the appropriate incline, and properly trapped to prevent carry over of condensate in the lines.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Steam must be of acceptable quality. A minimum quality of 97% and moisture content of no more than 3% is considered ideal.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Steam lines must be covered with insulation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit Points</td>
<td>✓</td>
<td>Comments</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
<td>---</td>
<td>----------</td>
</tr>
<tr>
<td>9. Other pieces of equipment (washer-disinfectors or dietary dish washing equipment) that require steam from the same steam source when the sterilizer(s) are in operation may result in steam pressure challenges.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Water quality and boiler treatment chemicals must be compatible with the sterilization process and may vary with seasonal changes.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Performing maintenance or moving the steam generation or distribution system may impact sterilization and drying.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Determine if any changes have been made to the facility piping, boiler or other steam-related equipment in the same time frame that the wet packs began occurring. Changes in any of these can affect drying.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Sterilizer Service Provider

| 1. Steam separators, if in use, should be properly installed and maintained. Verify last service date and who is responsible for changing the filters. |   |          |
| 2. The PRV adjustment of the disk-to-seat gap must be verified at 1/16". An incorrectly adjusted PRV can contribute to wet packs. |   |          |
| 3. The sterilizer must be level to ensure that water drains effectively. Water should never be seen inside the chamber and staining of the chamber floor may indicate excessive pooling. Excessive water in the chamber can also be a result of a leaking check valve, blocked drain line, or excessively saturated steam. |   |          |
| 4. Verify sterilizer configuration with respect to other sterilizers:  
a. Verify how sterilizers are plumbed.  
b. Check to see if any sterilizers were recently installed.  
c. Check on whether the sterilizer(s) involved in the wet packs are located at the beginning or the end of the steam supply line. Sterilizers at the beginning of the line may serve as condensation traps to sterilizers toward the end of the line. |   |          |
5. **Verify how the feeds from the header are configured.**
   a. Check to see whether they located at the top or the bottom of the header. Feeds located at the bottom may contribute to wet packs because condensate is sent down the piping as water slugs.

6. **Perform a leak test on the sterilizer.**
   a. Rates more than 1mmHg/min (higher than normal) could indicate a performance problem.
   b. Leak rate that is normally 0 to .1, but is now .7 - still represents a passing result, but may indicate something that is affecting the overall performance of the machine.

7. **Wet packs occurring following installation of a new sterilizer:**
   a. Make sure the sterilizer was correctly installed.
   b. Make sure that steam pressure from the generator, water pressure, water temperature and inlet steam pressure are within acceptable ranges.
   c. Ensure that plumbing connection sizes are correct.

---

### References and Suggested Reading

1. *Good Hospital Practice: Steam Sterilization and Sterility Assurance* (Arlington, VA: Association for the Advancement of Medical Instrumentation).
Appendix B

Guideline for Determining Wet Packs*

Wet packs are commonly recognized when there have been changes within the overall conduct of the sterilization process or environment. The following statements are arranged as a checklist, under their appropriate responsible party. As you read along, place a “√” next to the item that you want to remember to investigate. The comment column is provided for you to record what you specifically intend to check and/or the results of your audit.

CONTENTS

Causes of Wet Packs ........................................................................................................... 34
Evaluation of Pack Conditions ........................................................................................ 35
  Water Droplets on the Exterior of a Pack ................................................................ 35
  Water Droplets within a Pack ................................................................................ 36
  Absorbed Moisture within a Pack ........................................................................... 37
Summary ............................................................................................................................. 38

*This paper was reprinted in edited form in the August 1983 AORN Journal.
Causes of Wet Packs

Aseptic techniques for surgical procedures require all supplies coming in contact with the surgical field to be sterile. A “state of dryness” is part of the definition for sterility. Wet materials transmit bacteria; therefore, a “state of wetness” would compromise the sterility of processed packs and instruments presented to the sterile field.

“Wet packs” have created concern for users of in-hospital sterilized items since the earliest days of hospital sterilizers. They are a source of frustration for both central services and operating room personnel. Wet pack problems can lead to considerable investments of time, supplies and money to reprocess packs and result in serious disruptions to surgical and diagnostic department schedules.

Hospital personnel have become increasingly aware of wet packs occurring in hospital-sterilized supplies in recent years. For those of us who examine many of these occurrences, it is clear that there are several factors that deserve equal consideration when evaluating the causes of wet packs.

Wet pack conditions can occur:

• In different types of loads and processes (i.e., instrument sets, utensil sets, textile packs, and steam or gas sterilization cycles)

• In various types and sizes of wrappers (i.e., reusable textiles of all thread counts and materials, disposable cellulose-based, and disposable polypropylene-based, Tyvek® and paper/plastic peel pouches).

• In different types and sizes of sterilizers (i.e., prevacuum steam, gravity steam, and ethylene oxide gas sterilizers)

• When using different pack preparation and sterilizer loading techniques.

The fact that wet packs can and do result from so many different factors complicates resolution of the problem. It is not uncommon for hospital engineering personnel, central service personnel, operating room personnel, the packaging manufacturer and the sterilizer manufacturer to all be involved to some extent in trying to correct a particular instance of wet packs. Each of these groups has an important role to play in assuring that items are acceptable from a sterility assurance viewpoint.

*Tyvek® is a registered trademark of DuPont.
sterilization efficacy have been established and promulgated by such groups as the Association for the Advancement of Medical Instrumentation (AAMI),1 Association of peri-Operative Registered Nurses (AORN),2 and Center for Disease Control and Epidemiology (CDC).3 Similar information concerning wet packs and pack drying is not available, nor has it yet been formulated. Consequently, hospital personnel have had to use their own judgment and establish their own criteria for how much moisture constitutes a “wet pack.”

Probably the most common criteria used in hospitals are “look and feel.” They visually examine the exterior of the pack and feel the pack for indications of moisture. Common descriptions of a wet pack include: “the pack has water droplets on it,” “the pack feels cold,” or “the pack feels damp to the touch.”

In the case of polyethylene bags evaluated immediately after ethylene oxide gas sterilization, or the plastic side of plastic-paper pouches following removal from a prevacuum sterilizer, one hospital will consider a bag with visible moisture on the inside surface of the plastic as an acceptable pack, while a second hospital will consider the same pouch an unacceptable wet pack. Before a hospital can formulate a set of guidelines by which to evaluate packs for acceptable drying, it is important to review some basic physical properties of packaging.

The purpose of packaging materials is to provide an effective biobarrier; i.e., the packaging must protect the sterile contents from sources of potential contamination. Most sterilization packaging accomplishes this by acting as a tortuous pathway that inhibits the penetration of microorganisms through the packaging.

The use of multiple layers of muslin, when dry, does maintain a limited biobarrier to airborne bacteria and particles even though the openings are significantly larger than a bacterium or particle of debris. However, when the muslin becomes wet and a continuous liquid pathway exists through the wrap, bacteria can easily be carried into the pack and the tortuous pathway is lost. A similar situation exists to a lesser extent for wrappers other than 140 thread-count muslin and for rigid sterilization containers. Therefore, the critical question to ask when determining if a wet pack condition exists is: Can the observed moisture cause, or have caused, a loss in the biobarrier properties of the packaging? The answer to this question depends on the type of packaging, its individual biobarrier properties, where the moisture is located, and the quantity of moisture present.

**Evaluation of Pack Conditions**

When evaluating a load for wet packs, the packs should be examined for three conditions that can make packs questionable for safe use: water droplets on the exterior of a pack, water droplets within a pack, and absorbed moisture in a pack.

1. **Water Droplets on the Exterior of a Pack**

Water droplets on the external surface of the packaging are usually found:

- On the indicator tape of absorbent muslin or paper-wrapped packs
- On the plastic side of plastic-paper pouches
- On polyethylene bags used in ethylene oxide sterilizers
- On exterior surfaces of rigid sterilization containers that are set on water-repellent, nonabsorbent wraps.

Water droplets on surfaces have occurred more frequently with the increased use of disposable non-woven, water-repellent wrap. This type of sterilization wrap does not create the droplets (unlike 140 thread-count muslin, which absorbs and disperses any steam condensate that falls on the wrap surface), but it does retain droplets of moisture. These droplets of steam condensate are extremely difficult to dry because of the low surface-area-to-volume ratio, and have added significantly to the observable incidences of wet packs. To illustrate this point, 0.1 ml of water was placed on a muslin wrapper and on a water-repellent wrapper. It took three minutes in a dry heat oven at 160°F to dry the wet area on the muslin wrap, whereas the water-repellent wrapper required sixteen minutes to dry the water droplets retained on the surface of the material.

To determine the sterility breakdown risk of an external water droplet on a particular sterilization wrap, one must evaluate if such a droplet could establish a liquid pathway for bacteria to enter the pack and result in the loss of the packaging’s biobarrier properties. To this end, several commercially available sterilization wrap materials were evaluated for bacterial penetration by subjecting each wrap to actual sterilizing conditions of heat and humidity before testing with a spore inoculum. A double layer of each test wrap was folded around the exterior of a small metal tray which simulated a
Although current water-repellent wrap materials provide significantly better biobarrier characteristics than muslin, they cannot be considered to be water-impermeable. Therefore, external water droplets could result in loss of wrap biobarrier properties and are considered unacceptable.

### The following guideline applies for water droplets on the exterior of a pack:

- Packs wrapped in water-permeable materials and sterilized with steam should be considered unacceptable if there are water droplets on the exterior of the pack.
- Droplets on the exterior of packs wrapped in water-impermeable films (such as polyethylene) are not considered wet packs. However, caution must be used to ensure that such droplets are not displaced onto packs wrapped with water-permeable wraps.

#### 2. Water Droplets Within a Pack

Water droplets are not observed on the interior surface of wrapped packs as frequently as external wetting, probably due in part to less visibility. Most often the wrapping material is opaque and the interior of the pack is not visible to hospital personnel until the pack is opened for use. It is generally only after external wetting is noticed that a wrapped load is opened and inspected immediately after sterilization. Packs wrapped in absorbent material may feel dry on the surface but have droplets of moisture on the interior contents. The circulating nurse, who most frequently opens the outer wrap, may not perceive any area of wetness. Additionally, the scrub nurse, who opens the inner wrap, also may not perceive any droplets or areas of wetness since her hands are enclosed in water-impermeable rubber gloves. Thus, it is possible for water droplets and moist areas to escape detection.

Internal wetting, like external moisture, must be evaluated according to the type of packaging material used. Moisture, in the form of droplets that occur on the interior surface or between the inner and outer wraps of water-permeable wraps, must be judged with the same criteria as are used for external wetting. The only difference between these two conditions is in the source of the liquid pathway.

When water droplets are present inside the pack, although sterile by virtue of the completed processing cycle, they may have created a liquid pathway to the contaminated exterior of the pack. Water droplets on instruments or on hard-good items in the interior of the pack may become dislodged and drop onto the surface of a permeable inner wrap. For this reason, the presence of water droplets on pack contents must be considered unacceptable.

A condition called "fogging" can occur within plastic-paper pouches or plastic-film pouches when the pack is removed from the warm, humid environment of a steam or ethylene oxide sterilizer into a cooler room. A very fine mist, or fog, may form within the pack on the plastic surface or on metal goods. If the mist is not of sufficient volume to form droplets, it may not be considered a wet pack. If there is a danger of droplets forming and dislodging, the pack must be rejected. The formation of fogging can be minimized by immediate transfer of the sterilized goods from the ethylene oxide sterilizer to a property filtered aerator.

25 pound instrument tray. The test trays, with the exception of those wrapped in polyethylene, were subjected to a 270°F prevacuum cycle and dried in the sterilizer for 15 minutes. Those wrapped in polyethylene were not subjected to any sterilization process since this material is unable to withstand the extreme temperatures associated with steam sterilization.

Immediately after removing the pack from the sterilizer, an inoculum of 108 Bacillus subtilis per ml was applied in 1 ml droplets to the surface of the wrap material. After 10 minutes and 60 minutes, the wraps were evaluated for bacterial penetration by pressing a rodac plate containing trypticase soy agar, against the outer surface of the inner wrap of each for a 15-second period. The plates were then incubated at 37°C for seven days. Even after a brief ten-minute period, all of the materials tested, except the 3-mil polypropylene film and 2-mil polyethylene film, showed some bacterial penetration through the single-thickness outer wrap. Bacterial penetration was observed 100% of the time on the outside surface of the inner muslin wrap. No penetration was observed for the plastic films. Although no attempt was made to quantify the moisture barrier properties of the several wraps tested, the three new water-repellent disposable and one water-repellent reusable wraps showed significantly less penetration than the muslin wrap, but did show penetration through the single-thickness outer wrap.

Continuous plastic films provide an effective barrier against bacterial penetration. From a strictly bacterial efficacy standpoint, water droplets on the surface of these materials do not result in a wet pack that could compromise the sterility of the contents. However, since droplets on these plastic films could be dislodged and fall onto other packs that have water-permeable wraps, the existence of droplets on plastic surfaces is not desirable.

Although current water-repellent wrap materials provide significantly better biobarrier characteristics than muslin, they are not desirable.
The following guideline applies for water droplets within a pack:

- A wrapped pack, sterilized by ethylene oxide or steam, is considered wet if there are water droplets within the pack.
- Water droplets within peel pouches are unacceptable, but a very fine mist may be acceptable if it is not of sufficient volume to form droplets which could wet the water-permeable side of the pouch.

3. Absorbed Moisture within a Pack

The discussion to this point has focused on the effect of moisture in the form of liquid droplets. A second form of “wet packs” involves moisture absorbed or entrained within a portion of the pack or its wrapper. It is important to remember that all moisture-absorbent materials contain some amount of moisture when stored at normal room conditions. For example, muslin wrappers contain approximately 6% moisture at 70°F and 50% relative humidity. This amount of moisture is bound to the muslin by physical forces and does not compromise microbial barrier properties (i.e., it does not provide a liquid pathway for bacteria).

Absorbed moisture becomes a concern for hospital personnel when it occurs as a localized area of dampness in muslin wrappers, huckaback towels or other moisture-absorptive goods within a pack. The questions then become how much moisture is permissible, and should the pack be considered a wet pack. These questions will be considered first with respect to absorbed moisture within wrappers and then with respect to absorbed moisture within pack contents.

As mentioned previously, in order to determine whether a wet pack condition exists, one must determine if the biobarrier characteristics of the wrapper have been, or potentially could be, compromised. In the case of water droplets on the wrapper, simple tests can be performed to see if water penetrates the wrap. However, it is significantly more complex to determine acceptable levels of absorbed moisture in wraps.

One of the major problems is the lack of recognized standardized tests for determining adequate biobarrier properties for wraps. Current shelf-life testing methods are inadequate in their methodology and do not provide quantitative guidelines for acceptable contamination levels. If appropriate tests were devised, then maximum percent weight gain for various wrappers at the end of a sterilization cycle could be established.

In addition, there is a problem with using weight gain measurements: a wrapped pack can exhibit an overall weight loss after being removed from a sterilizer, but can still have small, localized wet areas. This results from the major portion of the wrap having lost some of its initial 6% moisture, while small, localized areas may still have significantly more moisture than 6%. Until more and better data is available, the appropriate measures for determining acceptable “dryness” levels are the current practices of ensuring that the external wrapper has no visual damp spots (usually determined by color differential of the wrap material) and that it “feels dry” after the pack has completely cooled to room temperature.

Absorbed moisture may also cause localized areas of dampness in pack contents. The most common occurrence of localized dampness is in huckaback towels (or their equivalent) used to line instrument trays and utensil sets. These areas are not detectable by visually examining or feeling the exterior of the pack and are only found where a large amount of condensate can accumulate. There are two ways that moisture in a huck towel might be transferred to the wrap: by dripping or by evaporation and re-condensation.

A 100% cotton huck towel is an extremely absorbent material that is capable of holding approximately twice its weight, or about 200 grams, of moisture. Consider, for instance, that the weight gained by a towel after a prevacuum sterilization cycle is 2 to 5 g, or about 1/40 of the total amount capable of being withheld. A small, localized area containing the moisture is what is commonly referred to as a wet pack condition. The 2 to 5 g is bound to the towel by physical attachment between the water molecules and the fibers of the towel. Therefore, direct transfer from the huck towel to the wrapper is not possible under normal drying conditions. The small amount of moisture held by the huck towel vaporizes until the towel reaches equilibrium with the room environment.

For a wet pack to result, water must vaporize and re-condense on the wraps or pass through the wraps and condense on a cold surface outside the pack, thus establishing a liquid pathway through the wrap. When the moisture in the huck towel vaporizes, it exits the pack via the wrap, which is permeable to water vapor. As an illustration, if we assume that all the moisture condenses uniformly on the upper and lower wrap surface of a pack such as an instrument tray, 5 g of moisture in the huck towel will result in 0.01 g per square inch of moisture on the wrap. In the case of a muslin wrap, this 5 g of moisture is small compared to the 2% to 6% normally contained within the wrap when it has been equilibrated to room conditions.
To prevent condensation on cold surfaces outside the pack, standard recommendations are:

- Allow hot packs to cool on the sterilizer loading car
- If it is necessary to transfer them, use wire-type shelving well padded with absorbent material for cooling.

These recommendations eliminate the possibility of external re-condensation and formation of liquid pathways that can result in contamination of the packs.

When establishing recommendations for packs of soft goods or metal hardware containing absorbed moisture, criteria must be developed for acceptable moisture levels, both within the processing area and at the point of use. Within the processing area, the sterilizer operator is able to control both the handling and cooling process of sterilized packs, so small amounts of moisture are acceptable in packs in this area. However, since no quantification of the acceptable or safe level of moisture has been established, the sterilizer operator must establish a drying time for each type of load that assures dry packs by the time they are removed from this area for storage or use. If a pack contains moisture at the point of use that is observed as the pack is opened, there is no way to determine if the biobarrier has been compromised, because the pack has been handled multiple times and subjected to several storage conditions from the time it leaves the sterilizer until it is opened for use.

For this reason, the general guideline is that a drying time be established for each steam sterilizer that results in dry packs after cooling at room temperature for a minimum of one hour.

The following guideline applies for absorbed moisture within a pack:

A wrapped pack that has been sterilized by steam should be considered unacceptable if it is wet when opened for use. A general guideline suggests that the pack be completely dry after cooling at room temperature (i.e., 68-75°F) for a minimum of one hour after removal from the sterilizer.

Summary

The first step in the resolution of hospital wet pack problems is the acceptance of a single set of criteria by which packs are to be evaluated for acceptable moisture levels. These criteria need to be agreed upon by hospital personnel, wrap manufacturers and sterilizer manufacturers. The lack of established quantitative standards for what constitutes a wet pack has caused significant confusion, blame, frustration and expense for hospital personnel and wrap and sterilizer manufacturers.

This paper has established the following guidelines by which hospital personnel can evaluate their packs for acceptable drying:

1. External droplets or visible moisture on the exterior of the pack, or on the tape, are unacceptable unless that wrap is completely impermeable to water (e.g., plastic film).
2. Water droplets on the interior of a wrap (unless it is completely water-impermeable), or on the items within the pack, are unacceptable.
3. A pack is unacceptable if the pack is damp or wet when opened for use. A general guideline is that the pack be completely dry after cooling at room temperature (70°F) and at 50% relative humidity for a minimum of one hour following removal from the sterilizer. If the room temperature and relative humidity vary from these recommendations, a longer drying time and increased cooling time may be necessary before the packs are handled or stored.

These guidelines are not intended to be the final word in establishment of wet pack criteria. They should serve as a starting point for developing criteria and test methods that are scientifically defensible and at the same time are practical for implementation in the hospital. The effort to address these important issues requires the cooperation of hospital personnel, sterilization packaging manufacturers and sterilizer manufacturers. Only through such joint effort can the importance of the interrelated factors, such as pack preparation techniques, sterilizer operation techniques, and drying characteristics of various packaging materials, be put into proper perspective.
References and Suggested Reading

4. Good Hospital Practice: Steam Sterilization and Sterility Assurance Arlington, VA: Virginia Association for the Advancement of Medical Instrumentation, 1981.
# Appendix C

## Guideline To Solving Wet Pack Problems

## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>41</td>
</tr>
<tr>
<td>Moisture Formation</td>
<td>41</td>
</tr>
<tr>
<td>Drying</td>
<td>41</td>
</tr>
<tr>
<td>Troubleshooting External Moisture</td>
<td>42</td>
</tr>
<tr>
<td>Troubleshooting Internal Moisture</td>
<td>44</td>
</tr>
<tr>
<td>Absorbed Moisture</td>
<td>45</td>
</tr>
<tr>
<td>Summary</td>
<td>47</td>
</tr>
</tbody>
</table>
Abstract
A major responsibility of every healthcare sterile processing department is to provide consistently sterile products to the user departments within the facility. To do this, sterile processing professionals must have a thorough understanding of proper pack preparation, packaging material characteristics, and proper sterilizer loading techniques. This knowledge and the use of proper techniques assure sterilization and minimize the formation of moisture, which can compromise sterility during storage.

Consistent successful sterilization of packaged devices requires cooperative effort of the personnel within the sterile processing department as well as collaboration with other departments within the facility. Failure by one or more departments to ensure good work practices could result in the condition commonly referred to as a “wet pack.”

The manufacturers of sterilization equipment, hospital products and sterilization packaging materials also have a responsibility to the healthcare facility. They must see to it that their products are reliable and easy to use, and that they function well with other products commonly used in conjunction with their product.

If a wet pack situation does arise and it has been established that a pack or load may be unacceptable, the cause must be determined and corrected. Identification of the cause requires a basic familiarity with the mechanism of moisture formation and of drying in the sterilizer, on careful observation of the location and volume of wetness, and on the form in which moisture occurs (i.e., droplets, absorbed, or dispersed moisture).

Moisture Formation
Moisture is formed at the beginning of the cycle as the product is being heated to the sterilizing temperature. In this phase, steam entering the chamber heats the materials and any loading equipment on which the materials are placed. As the steam gives up its heat of vaporization a phase change from steam to liquid water occurs. As a result, a substantial amount of heat (980 BTU per pound of steam condensed) is imparted to the materials and loading equipment. As the contents continue to heat up, additional steam is collapsed and more water is formed. The process continues until everything in the chamber ultimately reaches the temperature of the incoming steam.

Once the desired temperature is reached, no further heating or condensation occurs. However, the moisture that has formed remains in the chamber during the “sterilize” phase of the steam cycle. It may be entrapped in the moisture-absorbent products or may remain as droplets on the surfaces of nonabsorbent products.

The equation for the amount of moisture formed is:

\[ C = 0.566 \cdot W \cdot C_p \cdot \Delta T \]

where \( C \) = Quantity of condensate formed (ml), \( W \) =Weight of product (lb.), \( C_p \) = Specific heat of the product (BTU/lb °F), and \( \Delta T \) = Sterilization temperature minus initial product temperature, in degrees Fahrenheit.

As an example, consider a tray of stainless steel instruments weighing 15 pounds and wrapped in two double-thick muslin wrappers weighing 2 pounds. Specific heat values for stainless steel and muslin are 0.1 and 0.31 BTU/lb °F, respectively. Initial product temperature is 70°F before sterilization; sterilization temperature is 270°F. In this example, the amount of condensate that is formed totals 240 ml. As the weight of the tray increases, so does the amount of moisture formed.

The nature of the moisture formed (i.e., droplets, dampness, etc.) is dependent upon the materials that comprise the product. Absorbent items such as 100% muslin retain moisture by absorbing it into the material. Often, no droplets of water can be seen on these materials, but they may feel wet or damp. Water-repellent materials such as non-absorbent wraps may absorb some of the water, but most of it lies on the surface as beads of water or rolls off the material.

Hard goods and equipment made of metal or rubber do not absorb any of the moisture that forms during heat-up. Instead, the moisture either accumulates and lies on the surface or rolls off depending on the surface condition. Because the potential for wetting of items below these materials is so great, absorbent products are often placed beneath them to retain the accumulated moisture so it will dry later in the cycle.

Most of the moisture formed during sterilization must be removed later in the cycle in order to maintain a sterile environment within the pack after it is removed from the sterilizer. Water in the wrap of a pack could provide a pathway for bacterial migration, so an effective drying system must be employed to prevent wet packs.

Drying
Effective drying relies on a method for removing condensate. To remove the condensate, energy must be supplied to the water in sufficient quantity to vaporize it. The vapor is then withdrawn from the chamber.
Drying begins immediately after the sterilization phase of the cycle. In the drying phase, the sterilant is exhausted quickly and various techniques such as vacuum, heat from the product, or convective heat from the walls of the sterilizer are utilized to dry the load.

A prevacuum sterilizer relies on the stored thermal energy of the condensate itself to vaporize a portion of that condensate. This is possible because water boils at a lower temperature as the pressure around it is reduced. However, this mechanism has limitations. At a vacuum level of 20 mm Hg absolute pressure, for instance, only 20% of the moisture can be evaporated by this process. Very little incremental benefit can be derived by increasing the vacuum level further. Consequently, other sources of energy must be utilized to remove the remaining condensate. The stored thermal energy from the sterilized products and equipment in the chamber also contribute to the drying cycle by giving up this heat to evaporate moisture as the vacuum continues to be drawn. Finally, radiant heat and convected heat from the sterilizer walls make a contribution.

During the drying phase of a prevacuum sterilizer, tests have shown that approximately 90% of the moisture can be removed from the packs using ten minutes of drying for a full load of instrument trays. Note that only 24 ml or about 10% of the moisture remains in each pack after ten minutes, and only 2 ml remains after 20 minutes. Often the packs are neither uniformly nor completely dried in this process. Much of the remaining moisture is trapped in the interior of the tray with an insulating barrier (the wrap) around it. This moisture is normally bound tightly to the huckaback (huck) towel and is very difficult to evaporate. It can be detected only by opening the packs and examining the huck towel carefully by visual and tactile means.

In contrast to the prevacuum sterilizer, a gravity sterilizer experiences only a shallow vacuum and relies on a flow of sterile dry air over the product to remove the condensate from the load. Drying efficiency is reduced since the vacuum is so shallow that it cannot take full advantage of the internal energy of the condensate nor the heat of the instruments to boil off the moisture. The efficiency of the gravity sterilizer, therefore, is limited in its ability to dry compared to a prevacuum sterilizer. The walls of the chamber contribute to drying primarily by radiation. However, most radiant energy is absorbed or reflected by the outer wrapper of a wrapped pack, with little heat penetrating to the interior of the pack where the moisture remains. The walls are maintained at temperature throughout the processing cycle and continually give off heat. Those items that are closest to the walls benefit the most, while those that are farther away benefit less.

Temperature monitoring thermocouples on the exterior layer of wrapped instrument trays have shown that wrap surface temperatures may vary by as much as 60°F among packs at different locations and by as much as 20°F within the same pack from the side facing the wall to the side facing another pack.

The items being processed in the sterilizer assist in drying by giving up their energy as they cool down. Hot, moist absorbent materials, such as the huck towel, must absorb the heat energy from the hot instruments to dry. Those areas of huck towel that are nearest to the heat source benefit the most, while areas of the towel which are remote to the instruments, such as the corner of an instrument tray, are generally the last to dry.

You can apply the above principles along with sound methods for pack preparation and loading to the resolution of wet pack problems. The process of resolving wet pack problems requires a logical progression of thought from initial discovery of the wet packs until dry loads are achieved. The procedure to follow, regardless of sterilizer size, type, or model, is to evaluate and correct any deficiencies that result in wetness on the exterior surfaces of the packs in the load. After that, the interior problems can be corrected.

Troubleshooting External Moisture

External moisture forms on the outside of a processed load pack. It may appear as droplets of water that bead up on non-absorbent materials such as non-woven wrap, beads of water on plastic bags, or as wet areas on muslin wrappers. This type of wet pack is most often the one that is noticed first.

The following general guideline applies: “A pack is unacceptable if there is external or visible moisture on the exterior of the tape, unless that wrap is completely impermeable to water (i.e., plastic film on peel pouches).” The concern with water-permeable wraps is that the moisture may transmit bacteria through the wrap to contaminate the inner, sterile layer of wrap. With peel pouch plastic films, although bacterial penetration cannot occur unless there is a break in the film, there is still the possibility that the exterior droplets may fall onto absorbent parts of the packaging and compromise them.

There are two ways in which external moisture can be deposited on the sterilizer load: it can occur as localized moisture or as dispersed moisture. The location and concentration of external moisture are keys to determining how it was deposited. Localized moisture is in the form of water droplets or wetness, and occurs on the exterior of packs.
in specific locations in the sterilizer chamber. Localized moisture is usually, but not exclusively, associated with wetting from a source outside the pack.

Consider a load which, when removed from the sterilizer, occasionally has wetness on the exterior of the packs in the upper rear quadrant of the load while the remainder is dry. The port where steam enters the chamber is immediately adjacent to that wet area. A possible cause for wetness in this area is poor steam quality, which can result from several deficiencies. Poor steam quality may result from placing excessive demand on the boiler, from un-insulated pipes, or from improperly trapped lines. Wet steam may occur only at peak operation periods, so these wet packs may occur infrequently or may be a continuous problem.

Improper trapping of the steam line to the sterilizer permits a buildup of moisture in the lines immediately adjacent to the unit. A properly sized thermostatic steam trap or drum trap will correct this deficiency.

An un-insulated line allows the steam in the line to cool, thus producing excessive moisture. Wet pack causes of this type should be discussed with your facility maintenance engineer, who is responsible for assuring that an adequate volume and quality of steam are supplied to your sterilizer. Provide a log of the times wet packs occur and how frequently they occur; this will make it easier to track down the demands on the boiler at different periods of the day.

Wetness that occurs on the exterior (especially on the bottom) of the packs at the bottom front of the chamber is often caused by the failure of a check valve in the drain that permits water to be drawn into the chamber through the drain port. A faulty jacket (layer that wraps around the outside of the sterilizer chamber) trap can also be responsible for this type of wetness. A faulty jacket trap can allow water to accumulate in the bottom of the jacket and wet the pack immediately above this location. Explain the location of the wet packs as they have been observed in detail to your maintenance personnel. If your sterilizer is the type that feeds steam to the chamber through the jacket, a plugged jacket steam trap may also cause this type of localized wetting. Contact your sterilizer service provider for a simple and inexpensive repair.

Localized moisture can also result from water droplets that are displaced from the shelves of some loading equipment. A line of wetness may be evident on the packs (especially nonwoven wrapped packs) immediately beneath the supporting trusses of these shelves. The extent of this moisture may vary from one or two drops to a line of water, depending on loading conditions, type of wrapping material, and length of drying time that was selected. This problem could be solved by draping the product with an absorbent material such as a muslin sheet, or by replacing the shelving with a lighter shelf designed specifically for nonwoven wraps.

Dispersed moisture is distributed over the entire load. It is usually discovered by a feeling of dampness in muslin wrapped items, or by noting uniform beads of water on plastic films or nonabsorbent wraps on all or most of the outside surfaces of the load’s packs. Dispersed moisture is usually associated with either sterilizer malfunction or technique problems. Examples of these are inadequate drying phase of the cycle is inadequate for the size or density of the load, a malfunctioning drying phase, or an improperly loaded sterilizer.

Consider the case of a load that feels damp on the outside surfaces of the packs when they are removed from the sterilizer. The steam quality has been determined to be at 97% during peak periods of the day, and the steam quantity is adequate. The sterilizer vacuum rate and vacuum level have been checked by the sterilizer service provider, using full loads, and have been determined to be operating within specifications.

Now examine carefully the size, density, and loading arrangement of the items being sterilized. It is possible that they are loaded too heavily or packed too densely. Proper pack size, density, weight, and preparation technique are important contributors to efficient sterilization and drying. Specific guidelines have been established by STERIS Corporation, AAMI (Association for the Advancement of Medical Instrumentation) and AORN (Association of peri-Operative Registered Nurses) for maximum size and density of fabric packs. It is recommended that fabric packs have dimensions no greater than 12” x 12” x 20”, a maximum weight of 12 pounds, and a density no greater than 7.2 pounds per cubic foot. These guidelines also recommend that an instrument tray should weigh no more than pounds (STERIS recommends 17 pounds). AAMI ST77 – “Containment devices for reusable medical device sterilization,” recommends a maximum weight of instrument sets, including containment devices, to be no more than pounds. STERIS tests have shown that the addition of just two to three pounds of instruments, or the use of a smaller than required tray for 16 pounds of instruments, could increase the drying time by as much as seven to ten minutes.

For example, a 15 pound tray contains 16 ml of moisture after ten minutes of dry time. After 20 minutes the residual moisture in that tray has been reduced to 1 ml. The same
tray with 17 pounds of instruments would require 13 minutes to reduce the moisture content to 16 ml. As the weight of the instruments increases, the required drying time increases as well.

Limit the size and density of trays. Separate packages in the sterilizer and use adequate sized trays to allow ample room for flow of sterilant to the items during sterilization and for removal of moisture during drying. A good rule of thumb is to permit enough space between trays and packages so that a hand, on edge, may be slid between each pack. Two smaller instrument trays, rather than one large one, have a greater surface area and will dry in a shorter period of time. Similarly, utensil sets should be limited in size and density. Remember that they are placed on edge to prevent air entrapment, and that all of the moisture that forms during the heating of this product concentrates in one place, namely, at the bottom of the basin. Place an absorbent liner between basins, limit the weight of the sets (STERIS tests have shown that seven pounds should be the maximum weight for utensil sets), and allow ample room between individually wrapped sets for steam penetration and efficient drying.

Troubleshooting Internal Moisture

If a pack is opened and moisture is detected on the interior of the wrap, on the item, or in the huck towel; or if a clear plastic wrap (e.g., peel pouch) has moisture on the interior of the wrap, sterilized by steam, is considered wet if there are water droplets within the pack. Water droplets within peel pouches are unacceptable but a very fine mist is acceptable if it is not of sufficient volume to form droplets that could wet the water-permeable paper side of the pouch.”

The majority of excessively wet instrument trays and utensil sets result from pack preparation deficiencies. The first of these was discussed in the review of thermodynamics. If a large concentration of metal is placed in a small area, all of the moisture formed during the heat-up process is localized in a small area directly beneath the metal. A mass of metal will produce a quantity of water relative to its size and density. When too much moisture is formed in a concentrated area, it will not dry within the recommended time periods.

Disperse the mass of metal by using a larger instrument tray of proper construction (e.g., mesh bottom) or divide the instruments into two separate trays to reduce the concentration of metal. If a nonabsorbent wrap is used, a huck towel of adequate size to cover the bottom of the tray must be added. Use of a too-small towel (or no towel) may result in accumulation of moisture on the interior of the wrap at the bottom of the tray. This moisture will not dry within the recommended time.

Another very common problem that occurs when processing utensil sets is entrapment of water in the lip or depression of the utensils. In these instances, the heat from the metal is not sufficient to evaporate the water during drying, and a puddle remains at that site. When the set is removed from the cart and turned over, the moisture is displaced onto the huck towel, and a wet area may appear. Improper loading technique is most often responsible for this wet pack situation, but the design of basins and pans may also result in water entrapment regardless of the orientation of the item. When preparing metal basins for processing invert the set before wrapping and look for places where water could accumulate. Position these items so that no water can collect. If you cannot position them to eliminate all depressions, then place them in a position to collect the least amount of moisture and place a section of the absorbent huck towel into the depression to absorb it.

Manufacturers of metal items are often not aware of the potential problems their designs can create during sterile processing. If you have purchased a product that cannot be oriented in such a way that water is not retained, consider phasing the product out. Also consider that if items are wet when placed in the sterilizer, they are more likely to be wet at the end of the cycle. Moisture on a metal item adds to the total weight and, therefore, to the amount of water condensed. Be sure all items that are to be sterilized are clean and dry.

If the vacuum drying system of a prevacuum sterilizer is malfunctioning and an insufficient vacuum is drawn, then drying efficiency will be reduced. A properly operating system should pull down and hold at a vacuum level specified by the manufacturer for the duration of the drying period. An improperly operating system will cause excessive moisture on both the inside and outside of wrapped items. Two causes of an improperly operating system are constrictions in the drain line and inadequate water pressure. Check to be sure the drain line is not plugged by debris and that adequate water pressure is available to the sterilizer.
Absorbed Moisture

Absorbed moisture is a small, localized area of moisture which is physically bound to the absorbent liners of instrument trays and utensil sets. Absorbed moisture cannot be detected by examination of the exterior of the pack. It is only discernible by observing or feeling the absorbent liner after opening the tray.

A general guideline for absorbed moisture is that packs that are EO or steam sterilized be considered unacceptable if they are wet when opened for use. A pack should be completely dry after cooling at room temperature (70°F and 50% relative humidity) for one hour or until adequately cooled. If huck towels are still damp after the pack is at room temperature, it is usually an indication of sterilizer malfunction or inadequate dry time.

This information was derived from standard Amsco® tests that were conducted using full loads of 17-pound instrument trays wrapped in two layers of non-absorbent, disposable wrap or in 140 thread-count muslin. They were processed, and then vacuum dried for dry times that ranged from 5 to 20 minutes. The packs were removed, weighed immediately, then opened, or held for one hour before weighing and opening. Weight gains and losses and complete drying of the huck towel were compared. The remaining moisture was reduced as the drying time was extended. After 20 minutes, only 2 ml of water could be detected. The exteriors of all of these packs were completely dry. Yet when the packs were opened and examined, there was a feeling of dampness on localized areas of the huck towel liner. This absorbed moisture could be eliminated by allowing the pack to remain on the loading cart for a period of one hour or more in an area of the room that was free from direct drafts from air conditioning vents. The best drying results were achieved if during this period, handling was minimized and care was taken not to place load contents on cold surfaces. It was also noted that if a sterilizer loading cart was used, it was best to allow the packs to remain on the warm loading cart during this period of time.

If visible moisture is evident after the packs are cooled, first review the drying time you have selected. If it is adequate, then have the sterilizer checked for drying malfunction. If an adequate drying time has been selected for the size and weight of the products that are being processed, the items will be damp overall in the earlier portion of the dry cycle and localized dampness will remain as the dry cycle is extended. Follow the guidelines for pack sizes and weights.

Large, heavy instruments confined to a small tray may require preheating if processed in a gas sterilizer; or they can be placed in a larger tray if steam sterilization is used.

Sterilizer malfunction must be tested by a qualified sterilizer service provider. An analysis of the vacuum level should be done with both an empty chamber and a full load of items in the chamber. The service provider must determine if a sufficient vacuum is being drawn and held throughout the drying period. If a malfunction exists and the vacuum is not acceptable, the malfunction should be corrected before further testing is done.

Dispelling the Myth of Cracking the Sterilizer Door

It is fairly common practice for a sterile processing staff member to routinely open the steam sterilizer door at the end of a cycle and leave the door cracked six inches open for approximately 15 minutes. This is a process that has been used for many years to help dry loads after steam sterilization, but is it a necessary process, or even a good one?

A bit of sterilization history

Back in the 1950s and 60s the only steam sterilizers in use were gravity-displacement models and the primary barrier product used at that time for packaging instruments was reusable muslin sterilization wrap. Gravity-displacement sterilizers were able to sufficiently dry these muslin-wrapped packs with reasonable success. When an operator identified a wet pack problem (usually wet towels), the natural inclination was to let the packs bake in the sterilizer by leaving the load in the sterilizer with the door cracked for a period of time. This process took a while, but it was basically effective.

It is interesting to note that wet packs with muslin wrappers were almost universally wet inside the pack, while the outer wrapper was completely dry. Without a wet spot on the muslin wrapper, any organism, if present when the door was cracked, would not be able to penetrate the wrapper, so using the cracked door technique was not really a problem from a sterility maintenance standpoint.

In the late 1960s vacuum-assisted steam sterilizers became available and, with them, a much improved drying process – deep vacuums. Drying was more efficient and the cracked door technique was really only necessary for gravity-displacement sterilizers, or when using gravity-displacement cycles, which was becoming less and less common in the modern sterile processing department.
Also during this time period, manufacturers became interested in providing good steam quality in steam sterilizers and in designing systems that could work with existing steam. However, the techniques for making improvements were still in the developmental stage, and this led to the increasing occurrence of wet loads. Sterilizer operators were forced to develop their own processes that allowed them to provide acceptable “product” to the operating rooms.

In the 1980s another change occurred that rocked the healthcare sterilization industry: the introduction of non-woven disposable wrap for sterile processing. Although this type of sterilization wrap created serious challenges for sterilizer manufacturers because of its less tolerant drying ability, non-woven sterilization wrap was loved and heartily embraced by sterile processing professionals because it improved the shelf life of sterilized packs, eliminated the need to carefully inspect each reusable muslin wrapper prior to use, and did not require hole mending (there was never a professional consensus to how many patches were allowed before a muslin wrap was considered to have reached the end of its useful life). It was soon evident that drying times that worked successfully with muslin wrapped items were now inadequate for the new non-woven disposable sterilization wrap. Sterilizer manufacturers expended great effort to figure out how to best improve processes and sterilization cycles to compensate for the challenges created by the new sterilization wrap.

One of the phenomena that occurred with the non-woven sterilization wrap was water droplets on the exterior of packs at the end of the cycle. Various methods were used to address exterior droplets (linen shrouds, pack placement, lining sterilizer cart shelves with absorbent materials, etc), and one of them was cracking the door at the end of the cycle. It was discovered that if you left the load in long enough, the exterior droplets would disappear. Although this practice was successful in removing the external water droplets, it was an issue from a sterility maintenance standpoint, and here is why:

We are all taught that a breach in the barrier in any type of sterilization packaging can allow microorganisms to enter a package after it is processed. Any pack that shows evidence of moisture (e.g., visible stains) should be rejected by the sterilizer operator. In the case of a sterilized load we may open the sterilizer door and see external water droplets. This moisture has about the same potential for allowing organisms to penetrate the package barrier as a spilled cup of coffee has on the same package on a sterile storage shelf, with a couple of differences; the moisture-repellent characteristics of a hot sterilization wrapper are different from those of a cold wrapper, and the likelihood of an organism found in the SPD surviving the very hot and humid environment that occurs in the sterilizer while the door is cracked is pretty minimal.

However, there is no guarantee that recontamination will not take place. Until a non-woven sterilization wrap manufacturer makes a formal claim that their products can prevent recontamination when water droplets are present, SPD professionals need to reject any wrapped pack that has external moisture droplets at the end of a cycle. Unfortunately, this also means that personnel must not use the cracked-door technique to help finish the drying process.

**If they can’t crack the door, what should sterile processing personnel do to dry loads?**

In the case of sterilized packs with internal moisture, leaving products in the sterilizer with the door cracked to assist drying may not work as well as pulling the load out of the sterilizer and into the cool-down area. As long as the sterilization wrapper does not have external moisture, the wrapper will protect the inside of the pack from contamination, even if the inside of the pack is still damp. If the load is left in the sterilizer with the door cracked, the inside chamber temperature is still very hot, and the differential between the pack and the outside air temperature is minimal, and probably not much more than 20°. The humidity inside the sterilizer is also not as low as it is outside, so any moisture that is still in the pack doesn’t have much motive force to be driven outside of the pack. Because of the physics involved, leaving a load inside the sterilizer with the door cracked can actually inhibit the drying process.

When a pack is removed from the sterilizer, it remains hot from the sterilization cycle, usually more than 200°F (93°C). If the load is moved into the cool-down area, where the temperature is generally maintained between 68° and 75°F (20° to 24°C), the temperature differential between the inside of the pack and the cool-down area is approximately 130°F (54°C). This differential will help drive off the moisture from the inside of the pack. Once a cart is removed from the sterilizer and packs have reached room temperature, there is no temperature differential, and the drying process will be complete. This is the rationale for allowing packs to cool for at least an hour after processing.

It is also extremely important to avoid placing hot sterilized loads directly under air conditioning vents during the cool-down process. This would be as damaging as placing hot sterilized packs on a cold, solid, metal shelf. The pack would cool far too quickly, resulting in condensation or “sweating” of the packs. The moisture that remains in the pack will...
become condensate instead of being driven off as vapor, causing the load to be considered contaminated and in need of reprocessing.

**Address ongoing wet pack issues**

If a healthcare facility is experiencing problems with external moisture on packages, there is an underlying issue that absolutely must be addressed, whether it is a problem with excessively wet steam, poor loading techniques, or a true sterilizer malfunction. Cracking the sterilizer door is NOT the answer. Sterile processing staff members have historically used a variety of methods to compensate for poor steam quality, but it would be more prudent to perform a thorough wet pack investigation to find the root cause of the moisture, and to work diligently toward resolving the underlying issue.

Over the years, the door-cracking process has been passed down in sterile processing departments as a natural and necessary part of the sterilization process, without any factual basis for the practice. It is time to let go of one more of our sacred cows and reap the benefits of increased productivity by allowing the cooling process to begin as soon as possible after sterilization and freeing the sterilizer for additional loads to be processed.”6

**Summary**

The ability to determine the cause of wet pack situations and to initiate the proper corrective action relies on a careful and reliable diagnosis of the symptoms shown by the wet pack. Once armed with a deeper understanding of wet pack causes and sterilization cycle functions, a sterile processing professional can apply it to the solving of wet pack issues at any facility.
References and Suggested Reading

4. Good Hospital Practice: Steam Sterilization and Sterility Assurance, Arlington, VA: Virginia Association for the Advancement of Medical Instrumentation, 1981.