

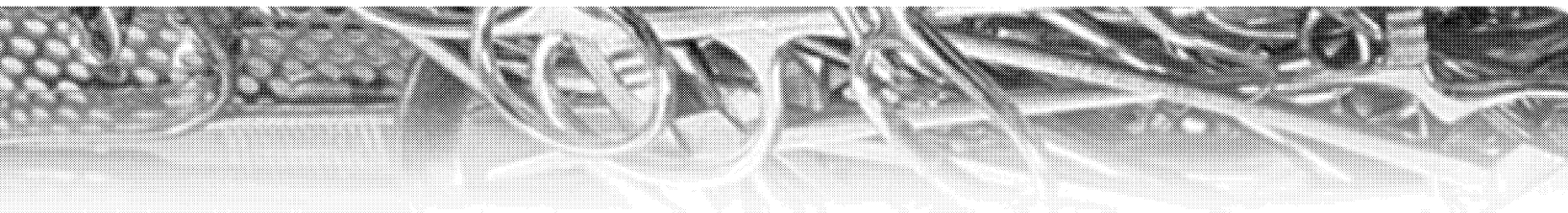


Preparing
Instruments,
Utensils, and
Textiles for
Sterilization
and
Wet Pack
Problem Solving



STERIS®





PREPARING INSTRUMENTS, UTENSILS, & TEXTILES FOR STERILIZATION & WET PACK PROBLEM SOLVING

CONTENT	PAGE
Introduction	2
Steam Sterilization of Instrument Sets	3
17 Pounds	3
Over 17 Pounds; Less Than 25	10
Utensil Sets	11
Textiles	17
Ethylene Oxide Sterilization of Heat and Moisture Sensitive Items	20
Tips for Improving Your Steam Sterilizing Techniques	23
Wet Pack Problem Solving Guide	31
Guideline for Determining Wet Packs	32
Guideline for Solving Wet Pack Problems	40



PREPARING INSTRUMENTS, UTENSILS, AND TEXTILES FOR STERILIZATION & WET PACK PROBLEM SOLVING

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, as well as textile packs. In addition, three important papers on wet pack problem solving are included to assist with troubleshooting the reasons for this common occurrence when using steam sterilization.

Comprehensive information regarding preparation for sterilization is provided by the STERIS video library.* Titles include:

- Decontamination
- Preparation of Instruments and Basin Sets for Sterilization
- Textile Pack Preparation and Sterility Maintenance Concepts
- Steam Sterilization

*These videos can be purchased by calling STERIS Customer Service at 800-548-4873 or 440-354-2600.

Additional resources include the following:

- 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:
 - Steam Sterilization & Sterility Assurance (ST46)
 - Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness (ST41)
- Association of periOperative Room 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.

INSTRUMENT SETS

17 POUNDS OR LESS - There is no magic number that pertains to instrument set weight. 16-17 pounds is desirable, however, only when a tray is 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.
 - c. Use a mesh-bottom tray or equivalent (Figure 2) large enough to equally distribute instruments in a single layer.

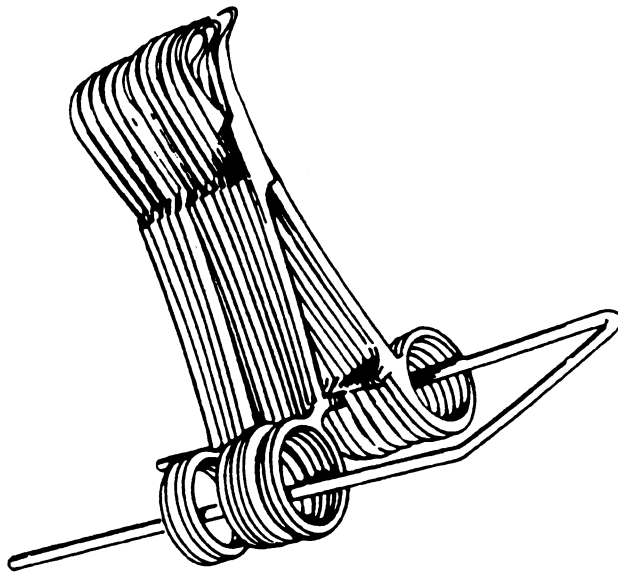


Figure 1. OPEN, UNLOCK, OR DISASSEMBLE INSTRUMENTS.

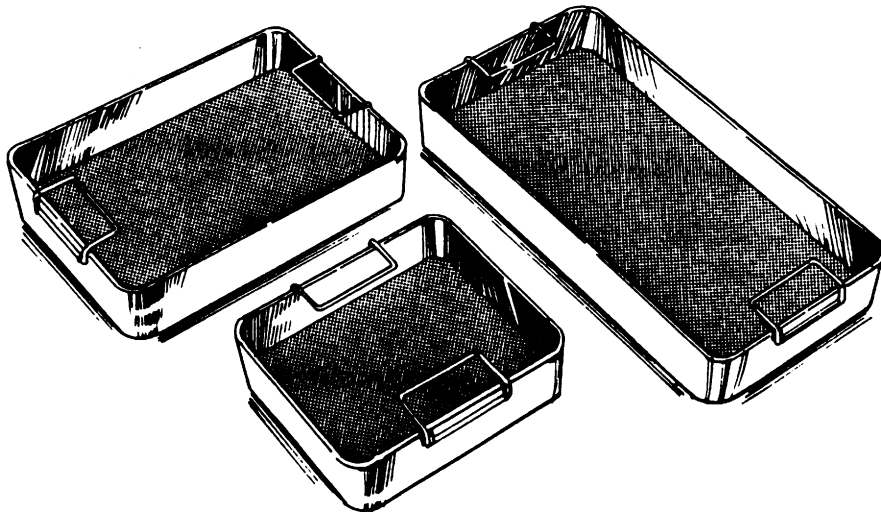


Figure 2. USE MESH-BOTTOM TRAYS.

NOTE: Flush all lumens, such as needles, suctions, and tubing with distilled or sterile water prior to sterilization to facilitate air removal and steam contact within them.

NOTE: Instrument trays must be designed for ease in air removal, sterilant contact, drainage of condensate, and drying.

- d. Place a fully opened (single layer) 100% cotton surgical towel in the bottom of the tray (Figure 3). This will help facilitate drying.

NOTE: Use a towel which covers the bottom of the tray with **minimum excess** overhang.

- e. Place instruments on the towel (Figure 4). Using the proper size tray will enable even distribution of instruments. Concentration of metal mass in one area of the tray can cause formation of localized moisture and a drying problem. 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.
- f. Fold the excess towel over the instruments (Figure 5).
- g. Place an internal chemical indicator on instruments (Figure 6).

Caution: Ink side of indicator should not come in contact with metal surface because it might discolor the instrument.

- h. You may choose to wrap the instrument tray sequentially in two wrappers, 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.

NOTE: Wrapper size should be adequate for the desired method of wrapping but not excessive. Excessive size wrappers may cause drying problems.



Figure 3. PLACE OPENED 100% COTTON SURGICAL TOWEL IN BOTTOM OF TRAY.



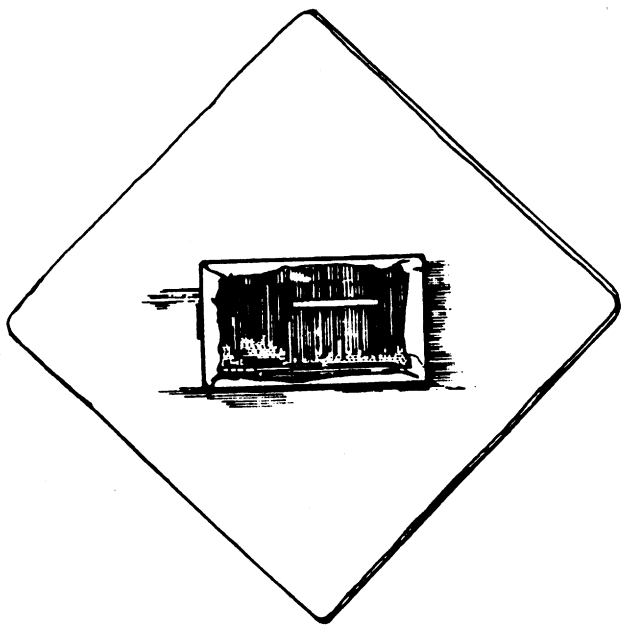
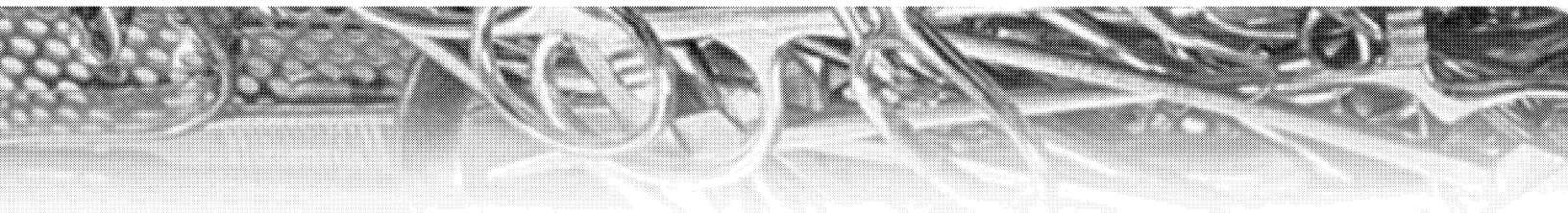
Figure 4. PLACE INSTRUMENTS ON TOWEL.



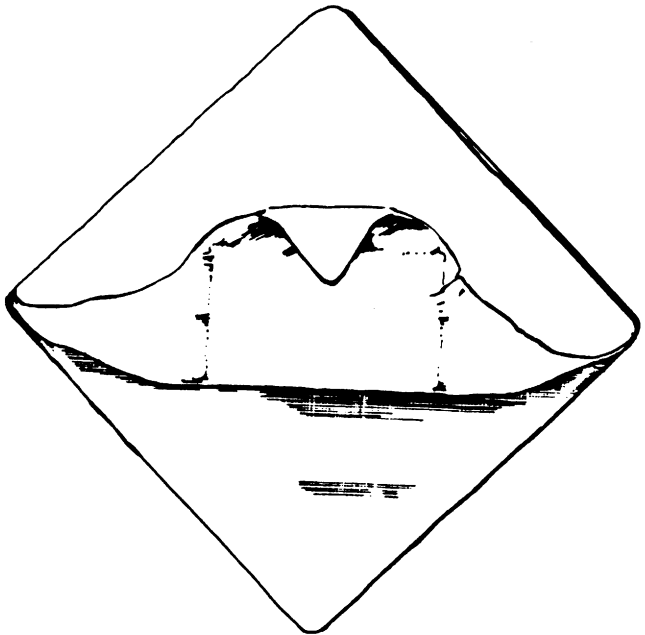
Figure 5. FOLD TOWEL EXCESS OVER INSTRUMENTS.



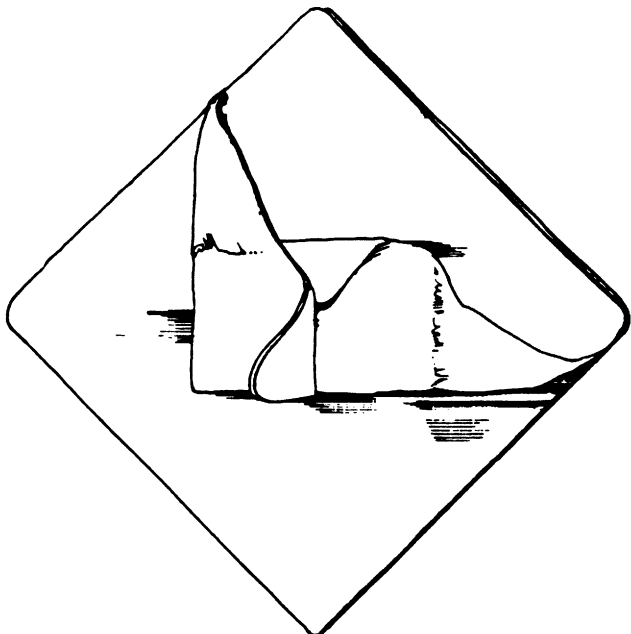
Figure 6. PLACE CHEMICAL INDICATOR ON INSTRUMENTS.



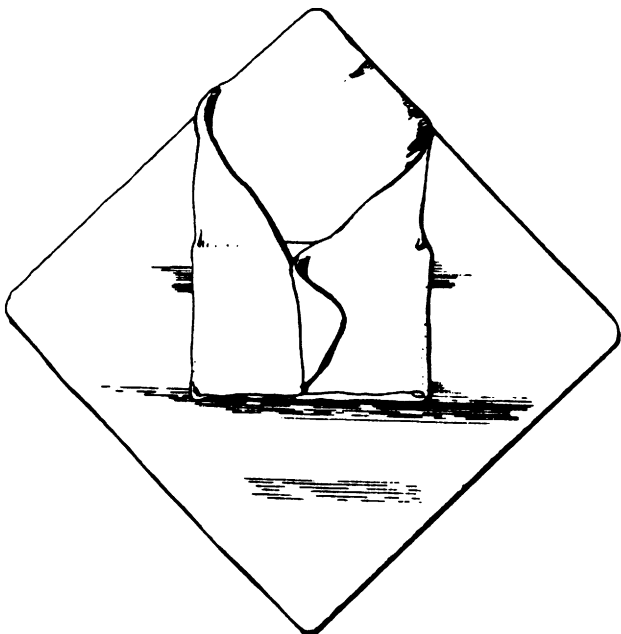
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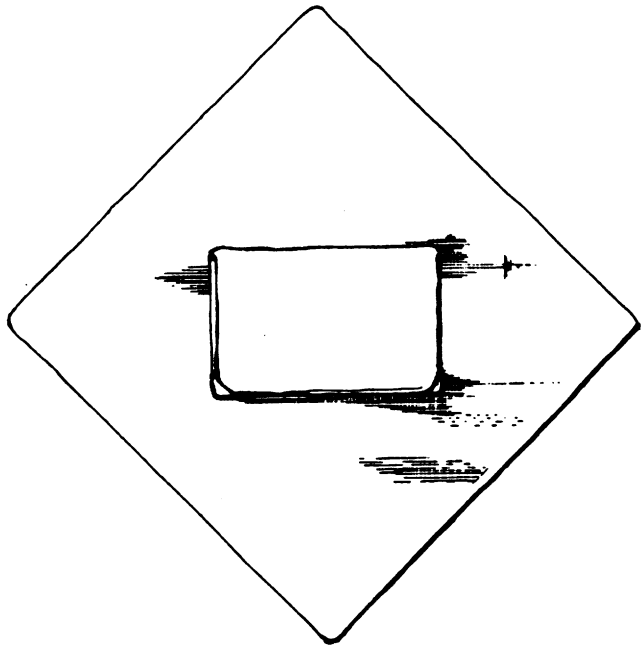
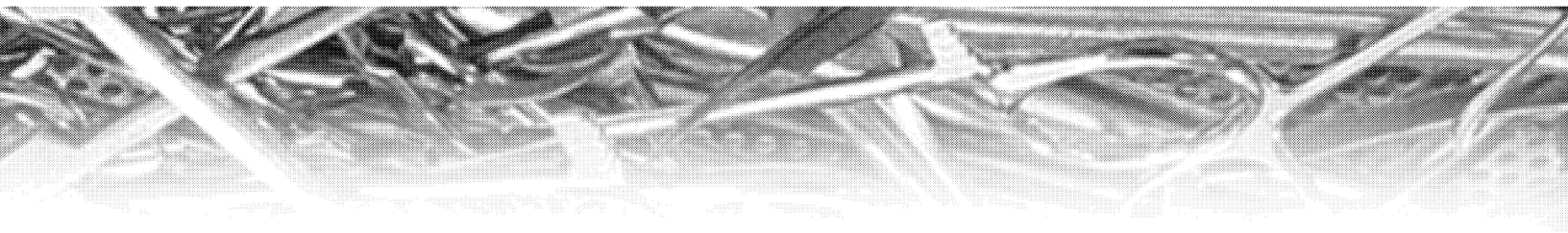


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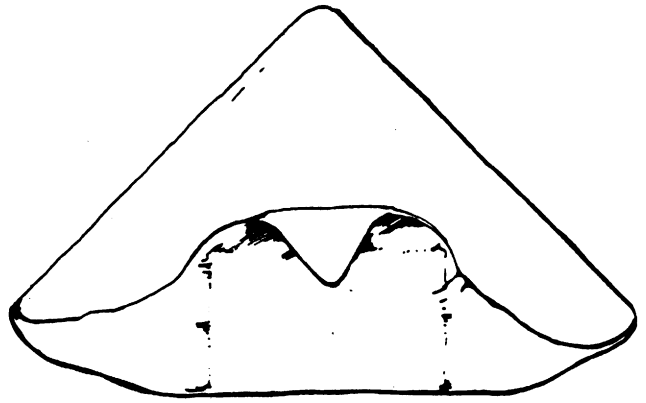


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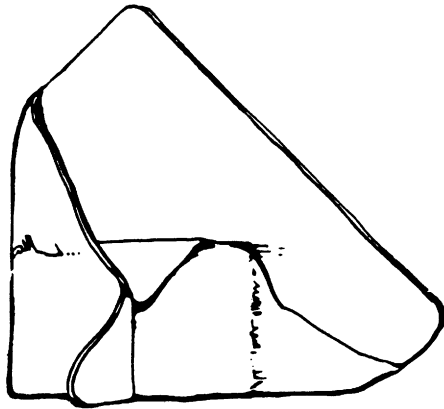
Figure 7. ENVELOPE METHOD – Instruments



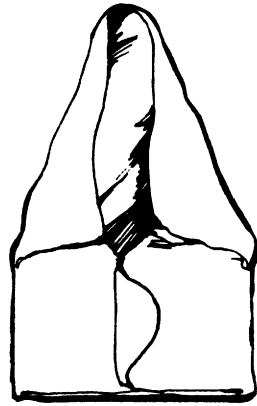
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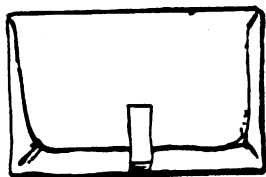
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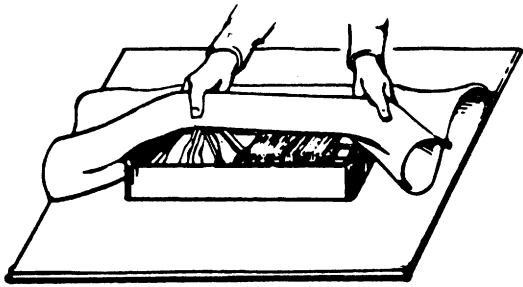
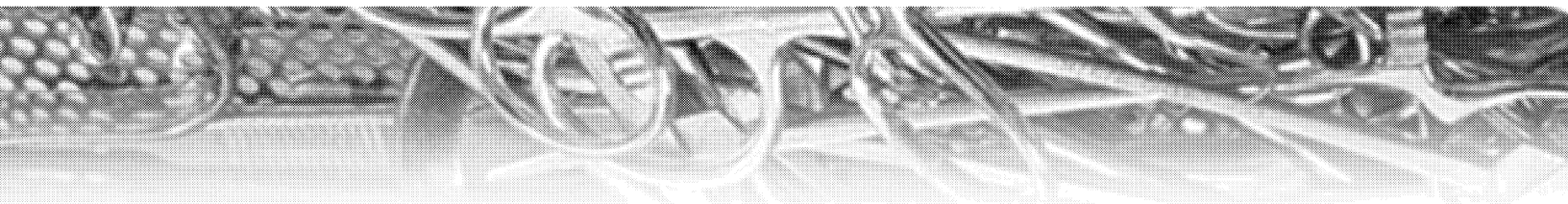
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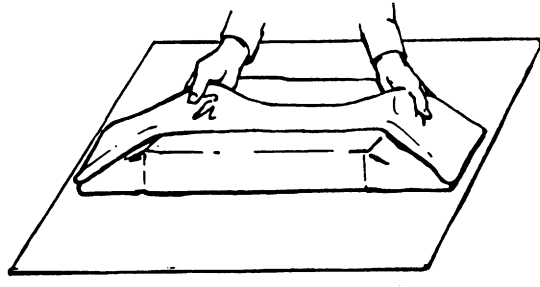
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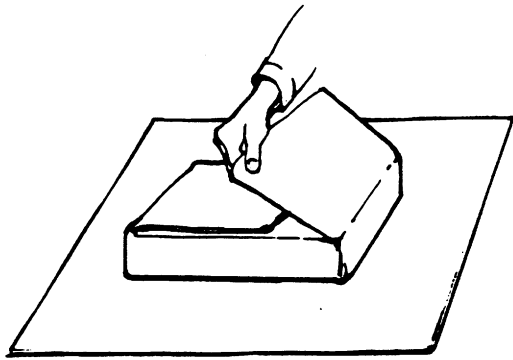
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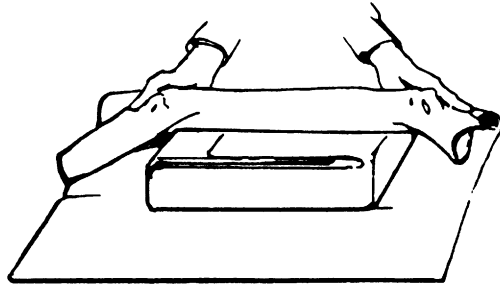
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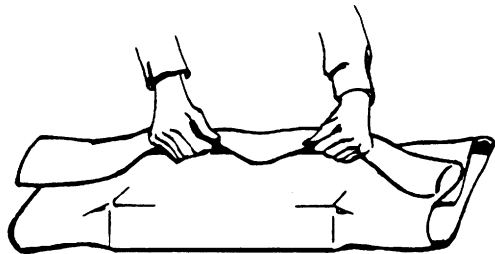
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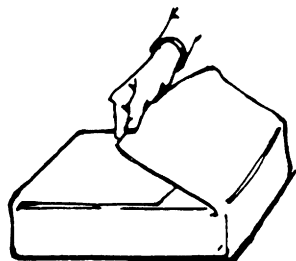
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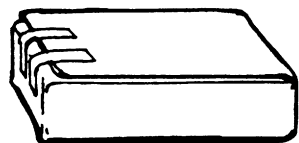
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Figure 8. OBLONG METHOD – Instruments

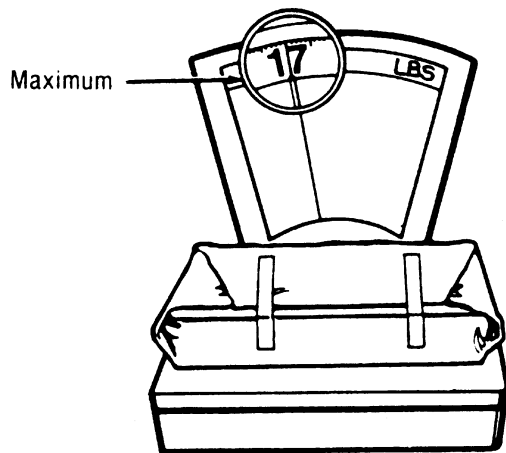


Figure 9. INSTRUMENT SET WRAPPED WEIGHT SHOULD NOT EXCEED 17 POUNDS

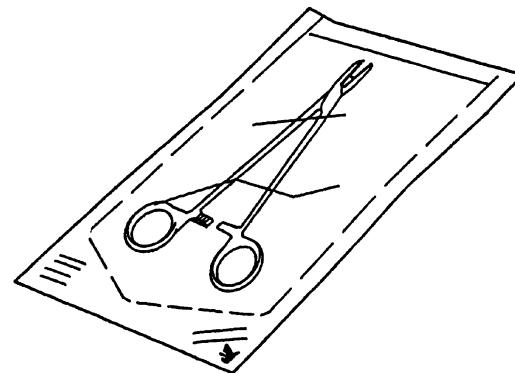


Figure 10. PROVIDE ADEQUATE ROOM FOR THE ITEM, AT LEAST 1 1/2 INCHES FROM THE ITEM TO ALL SEALS

- i. The total weight of a properly prepared wrapped tray of instruments should preferably not exceed **17 pounds** (Figure 9) for a better probability of steam contact and drying.
 - j. Manufacturers of rigid sterilization container systems should provide the user with total container weight and drying information. This 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. Use this type of packaging for lightweight instruments and soft goods only.
 - b. Provide adequate room for the item, at least 1 1/2 inches from the item to all seals (Figure 10).
 - c. Sealing the package may be done using a heat sealer, indicator tape, or self-seal pouches.
 3. Loading the steam sterilizer
 - a. Place wrapped instrument trays flat on the loading car shelf (Figure 11). Never stand heavy instrument trays on edge for sterilization. Proper sterilant contact and drying may not be able to be achieved.

NOTE: If a loading car is not used, it is preferable to loosely place items into sterilizable wire baskets. Otherwise, place packages on sterilizer shelves.

- b. In loads which combine fabrics and hard goods, place instrument tray(s) on the lowest shelf (Figure 12).
- 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, etc. if necessary to hold these 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.

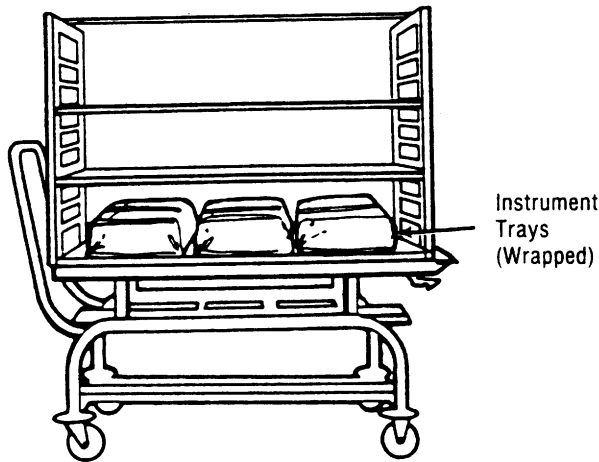


Figure 11. PLACE WRAPPED INSTRUMENT TRAYS FLAT ON SHELF

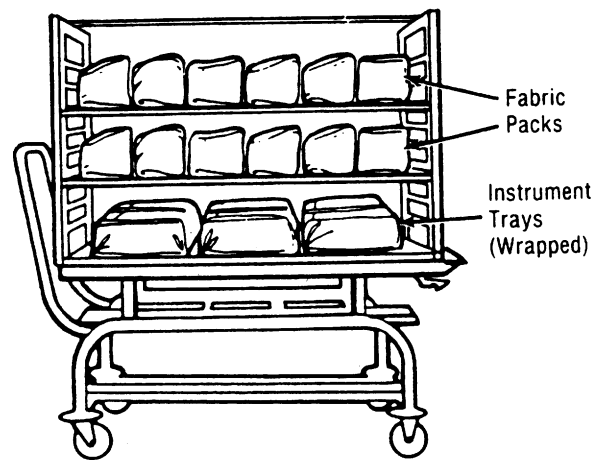


Figure 12. PLACE INSTRUMENT TRAYS ON LOWER SHELF IN COMBINED LOADS.

4. Steam Sterilization Cycles

a. Prevacuum cycle

Temperature	Exposure Time (recommended minimum)	Dry Time (recommended minimum)
270-274° F (132-134° C)	4 Minutes	20 Minutes

b. Gravity cycles*

Temperature	Exposure Time (recommended minimum)	Dry Time (recommended minimum)
270-274° F (132-134° C)	15 Minutes	30 Minutes
250-254° F (121-123° C)	30 Minutes	30 Minutes

5. Unloading the Steam Sterilizer

a. Loading car

- 1) Remove loading car from sterilizer and place it 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 dryness. A wrapped tray of instruments is considered **unacceptable** if there are water droplets or visible moisture on the exterior of the package or on the tape used to secure it.
- 4) Remove instrument tray(s) from the loading car when the load has reached ambient (room) temperature. Depending upon items and environment of the area, this may take a minimum of one (1) hour.

- 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 dryness. A wrapped tray of instruments is considered **unacceptable** if there are water droplets or visible moisture on the exterior 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. Depending upon items and environment of area, this may take a minimum of one (1) hour.

INSTRUMENT SET - OVER 17 POUNDS, LESS THAN 25 POUNDS

NOTE: The recommended combination weight (tray, instruments, and wrappers) is **17 pounds or less**. Although it is not recommended practice, there are occasions when instrument sets do exceed the recommended weight. In such cases, the following guidelines should be observed:

- 1. Preparing and Wrapping for Sterilization - Prepare as for 17 pounds or less instrument tray, with two exceptions:
 - a. Use larger tray in order to distribute the metal more evenly.
 - b. You may make 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. Excess of towel, if any, should be minimal and folded over top instrument layer.
- 2. Loading the Steam Sterilizer - same as for 17 pounds or less tray
- 3. Steam Sterilization Cycles

a. Prevacuum cycle

Temperature	Exposure Time (recommended minimum)	Dry Time (recommended minimum)
270-274° F (132-134° C)	4 Minutes	20 Minutes

b. Gravity cycles

Temperature	Exposure Time (recommended minimum)	Dry Time (recommended minimum)
270-274° F (132-134° C)	15 Minutes	30 Minutes
250-254° F (121-123° C)	30 Minutes	30 Minutes

- 4. Unloading the Steam Sterilizer - same as for 17 pounds or less tray.

NOTE: Information contained herein has been based on routine (basic sets) instrumentation. Specialty surgical instrumentation may require different exposure and drying times. The manufacturer of same should have research to support any special recommendations.

UTENSIL SETS

1. Preparing and Wrapping for Sterilization

- a. When placing utensils in a set, separate each clean, dry basin 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.

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

Caution: Ink side of indicator should not come in contact with metal surface because it might discolor the metal.

- e. You may choose to wrap the utensil set sequentially in two wrappers, 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.

NOTE: Wrapper size should be adequate for the desired method of wrapping but not excessive. Excessive size wrappers may cause drying problems.

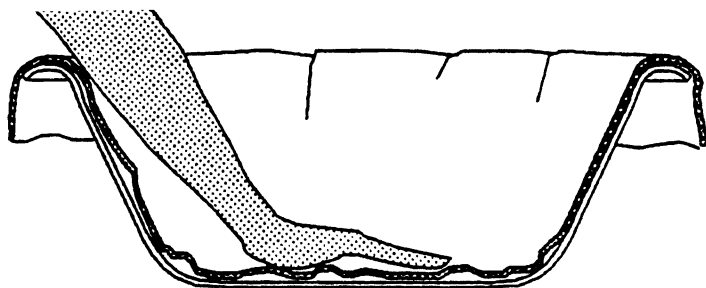


Figure 13. OPEN HUCK TOWEL TO FULLY CONTACT THE BASIN.

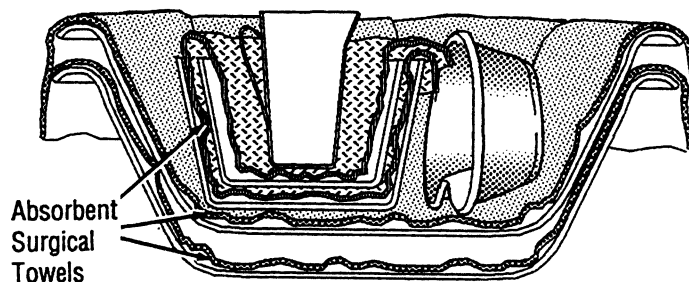
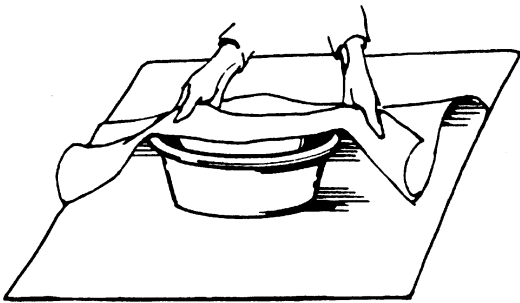
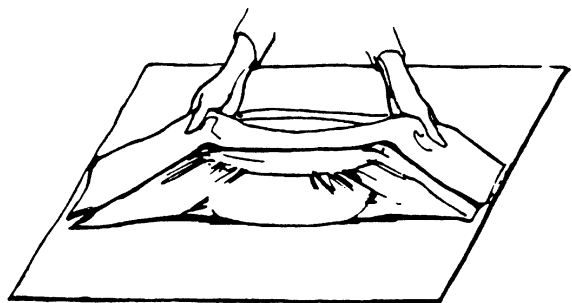


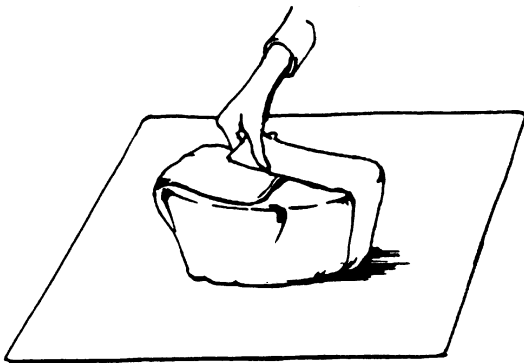
Figure 14. ARRANGE UTENSILS SO THAT BOTTOMS ARE PARALLEL.



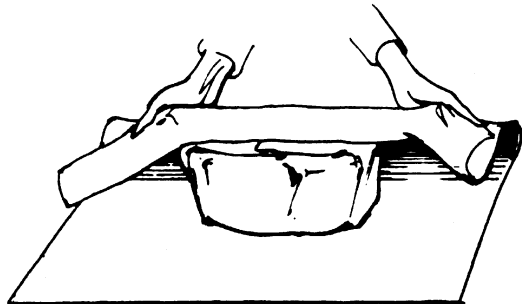
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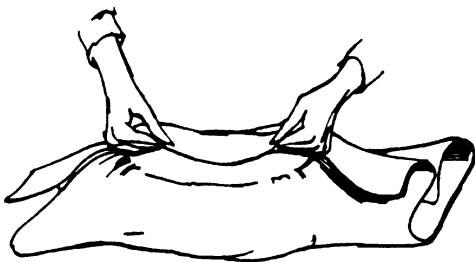
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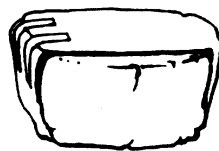
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Figure 15. OBLONG METHOD – Utensils

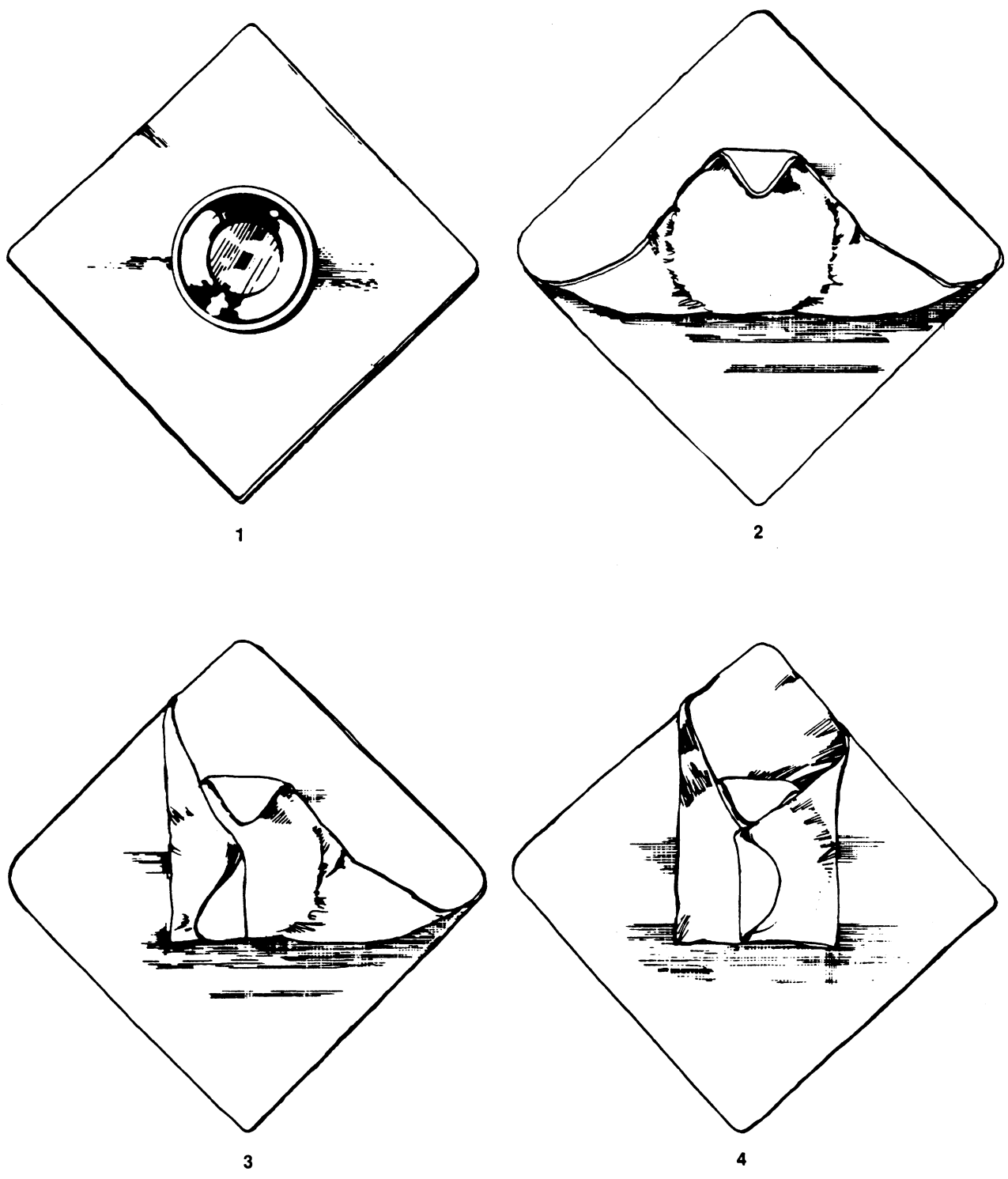
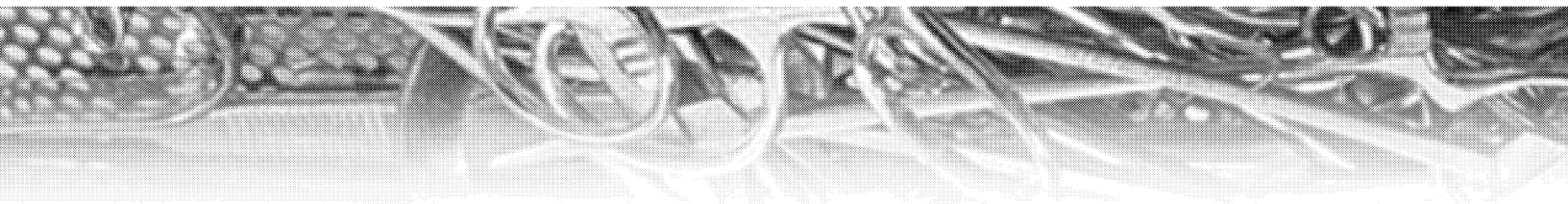
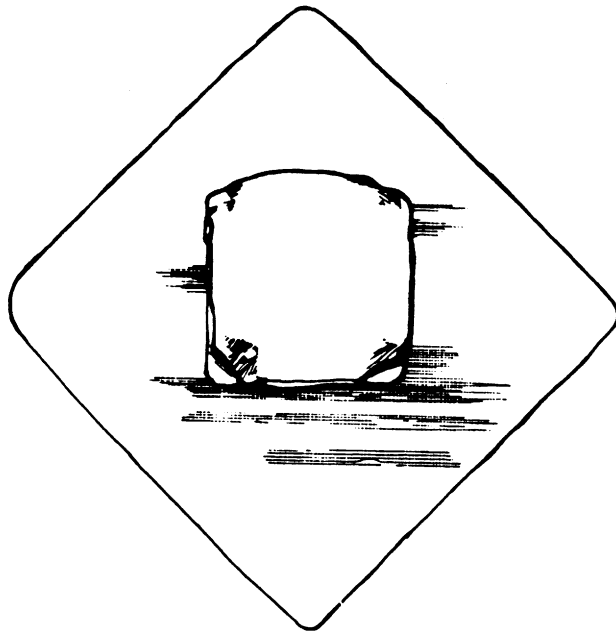
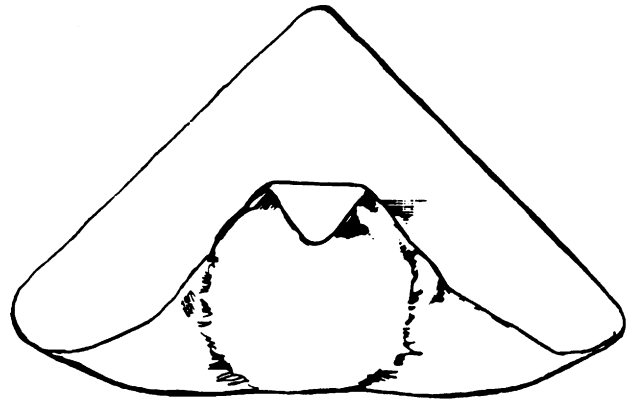


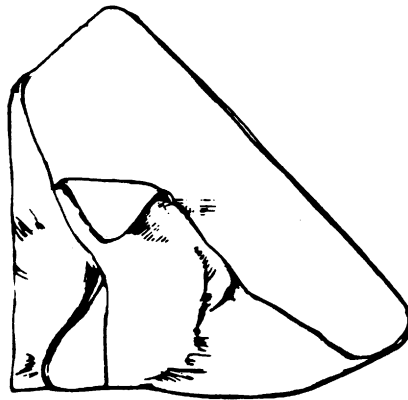
Figure 16. ENVELOPE METHOD – Utensils



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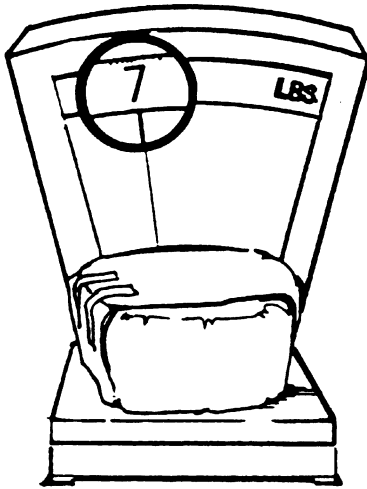


Figure 17. UTENSILS SET WRAPPED WEIGHT SHOULD NOT EXCEED 7 POUNDS.

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).

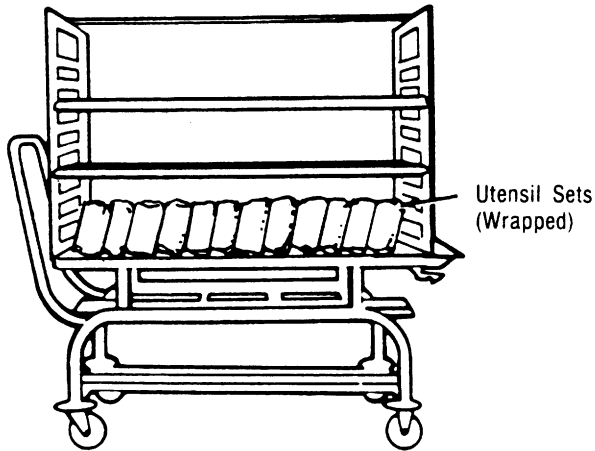


Figure 18. PLACE WRAPPED UTENSIL SETS ON EDGE, TIPPED SLIGHTLY FORWARD.

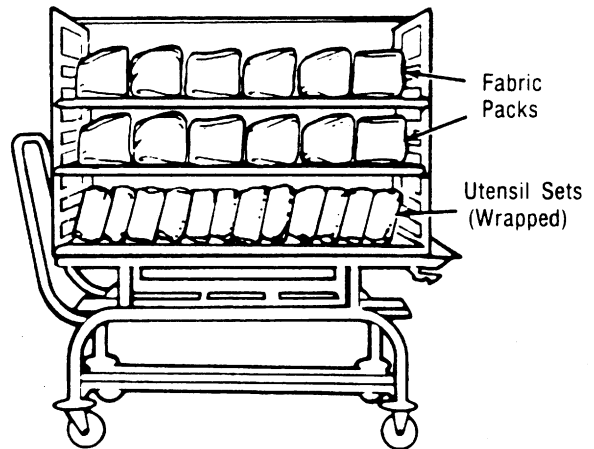


Figure 19. PLACE UTENSIL SETS ON LOWER SHELF IN COMBINED LOADS.

NOTE: When sterilizing any dry solid container, imagine it filled with water. Then position it so the water would drain out freely.

b. Place utensil set(s) on the lower shelf of a loading car in loads which combine fabrics and hard goods (Figure 19).

NOTE: If loading car is not used, it is preferable to loosely place items into sterilizable wire baskets. Otherwise, place packages on sterilizer shelves.

- c. Do not overload shelves. Do not compress packages.
- d. Do not allow wrapped utensil set(s) to contact the sterilizer chamber wall.
- e. Provide **at least 3 inches** between the sterilizer chamber ceiling and the topmost package of the load to facilitate air removal, sterilant circulation, and drying.
- f. Never place utensil set(s), or other packages, on the chamber floor.

3. Steam Sterilization Cycles

a. Prevacuum cycle

Temperature	Exposure Time (recommended minimum)	Dry Time (recommended minimum)
270-274° F (132-134° C)	4 Minutes	20 Minutes

b. Gravity cycles

Temperature	Exposure Time (recommended minimum)	Dry Time (recommended minimum)
270-274° F (132-134° C)	15 Minutes	30 Minutes
250-254° F (121-123° C)	30 Minutes	30 Minutes

4. Unloading the Steam Sterilizer

a. Loading car

- 1) Remove loading car from sterilizer and place it 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 dryness. A wrapped utensil set is considered **unacceptable** if there are water droplets or visible moisture on the exterior of the package, or on the tape used to secure it.
- 4) Remove utensil set(s) from loading car when the load has reached ambient (room) temperature. Depending upon items and environment of area, this may take a minimum of one (1) hour.

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 dryness. A wrapped utensil set is considered **unacceptable** if there are water droplets or visible moisture on the exterior 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 utensil set(s) from the wire cart when set(s) have reached ambient (room) temperature. Depending upon items and environment of area, this may take a minimum of one (1) hour.

TEXTILE PACKS

1. Preparing and Wrapping for Sterilization
 - a. Place two wrappers on work surface.

NOTE: All textiles must be laundered between sterilization cycles.

- b. Place contents on wrappers. Articles should be folded flat, with each succeeding layer placed crosswise to the one below, to promote free circulation of steam.

NOTE: Wrapper size should be adequate for the method of wrapping. Excessive size wrappers may cause drying problems.

- c. Place internal chemical indicator in the center of the pack. (The area hardest to be reached by the steam.)
 - d. You may choose to wrap the contents sequentially in two wrappers using the **oblong method** (Figure 20). Secure with sterilizer (indicator) tape and identify pack contents.

NOTE: Do not wrap too tightly, only enough to hold contents together for a reasonable amount of handling. Pulling the wrap too tight can create a pack that is too dense for proper air removal, sterilant penetration, and drying.

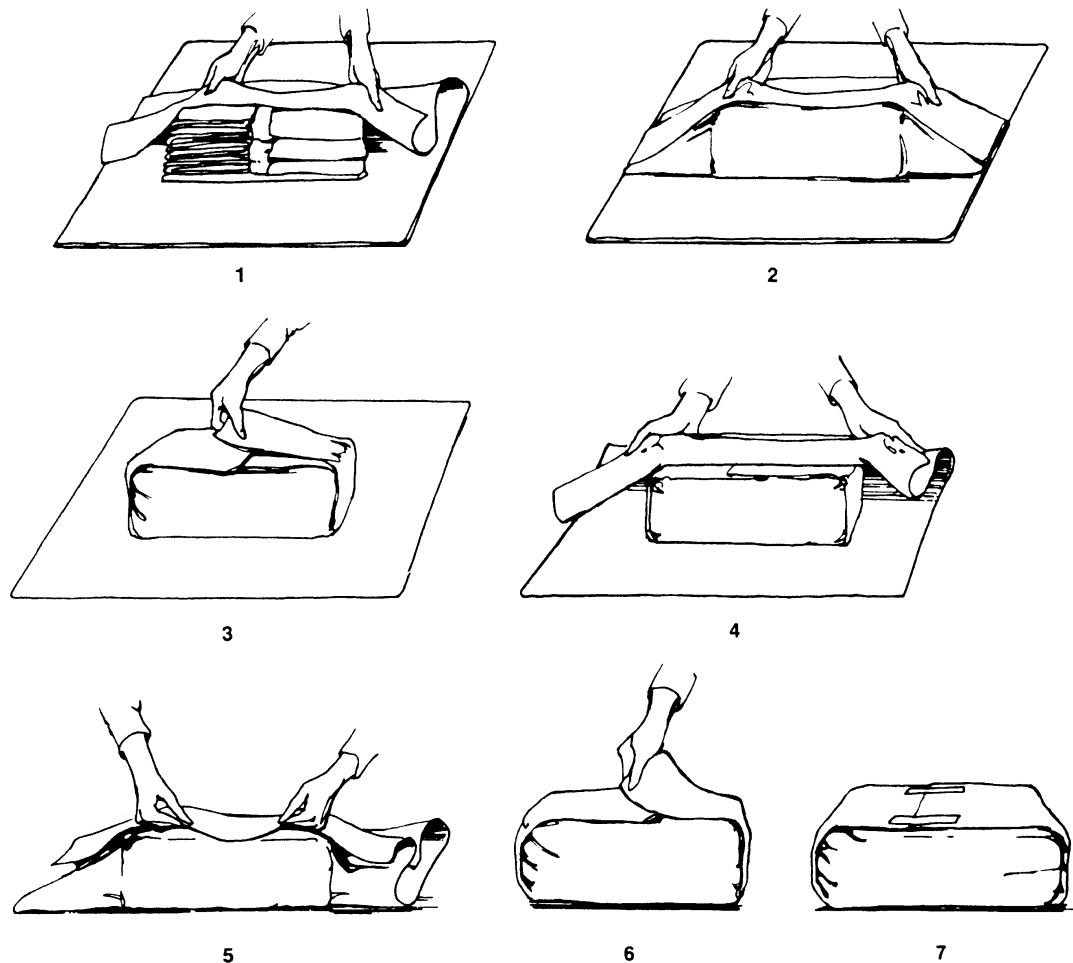


Figure 20. OBLONG METHOD – TEXTILES

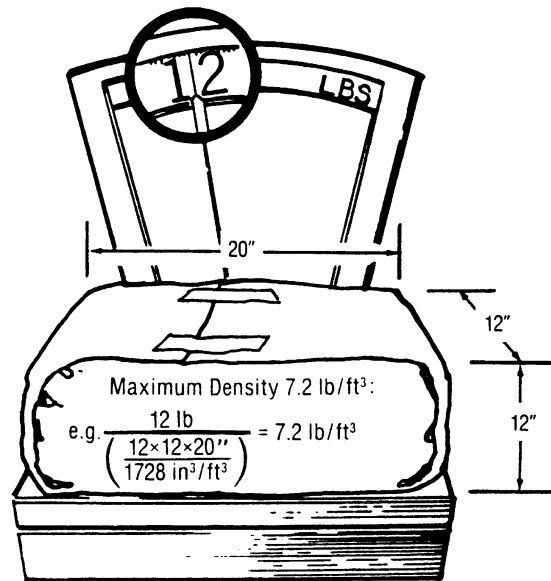


Figure 21. LIMIT THE SIZE, WEIGHT, AND DENSITY OF PACKS

- e. Limit the size, weight, and density of the all-cotton textile pack (**maximum weight: 12 pounds; maximum size: 12" x 12" x 20"; 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.

***NOTE:** 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).
- b. Place textile packs on top shelves of a loading car when combining load with hard goods (Figure 23).

NOTE: If loading car is not used, it is preferable to loosely place textile packs into sterilizable wire baskets. Otherwise, place packages on sterilizer shelf.

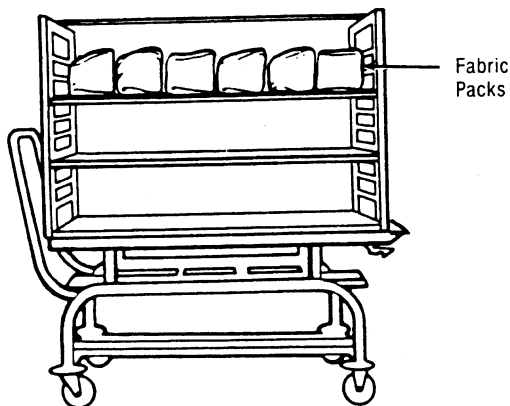


Figure 22. PLACE TEXTILE PACK ON EDGE TO PROMOTE STEAM PASSAGE.

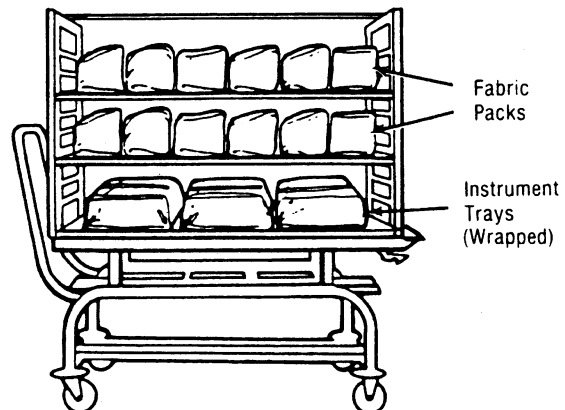
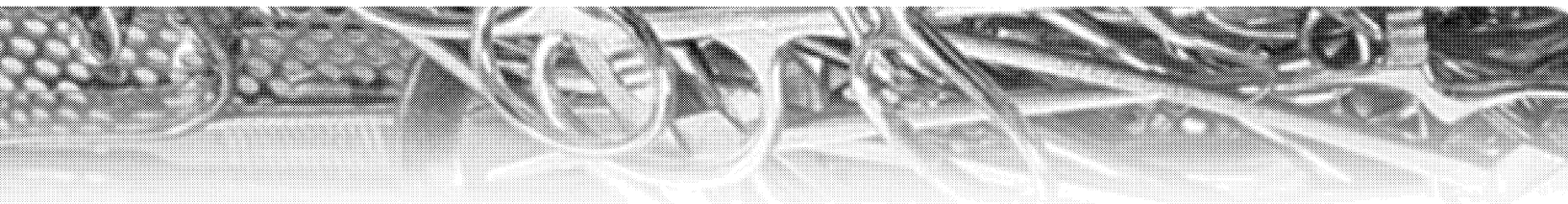


Figure 23. PLACE TEXTILE PACKS ON TOP SHELVES IN COMBINED LOADS.



- c. Do not overload shelves. Do not compress packages.
- d. Do not allow pack(s) to contact the sterilizer chamber wall.
- 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

Temperature	Exposure Time (recommended minimum)	Dry Time (recommended minimum)
270-274° F (132-134° C)	4 Minutes	5 Minutes***

b. Gravity cycle

Temperature	Exposure Time (recommended minimum)	Dry Time (recommended minimum)
270-274° F (132-134° C)	25 Minutes	15 Minutes
250-254° F (121-123° C)	30 Minutes	15 Minutes

***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 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 dryness. A textile pack is considered **unacceptable** if there are water droplets or visible moisture on the exterior 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. Depending upon items and environment of area, this may take a minimum of one (1) hour.

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 dryness. A textile pack is considered **unacceptable** if there are water droplets or visible moisture on the exterior 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 items and environment of area, this may take a minimum of one (1) hour.

HEAT AND MOISTURE SENSITIVE ITEMS

WARNING: THE ETHYLENE OXIDE STERILANT USED IN STERILIZERS HAS TOXIC PROPERTIES. USE CARE IN HANDLING. FOLLOW THE PROCEDURES FOUND IN THE STERILIZER MANUFACTURER'S EQUIPMENT MANUAL.

1. Preparing and Wrapping for Sterilization

- a. Inspect each item to make sure it is clean, dry, and functioning properly.
- b. Open, unlock, or disassemble instruments to allow for penetration of ethylene oxide gas (EtO).
- c. Place item(s) and internal chemical indicator into packaging or wrapping material. Secure and identify contents of package.
 - 1) Paper/plastic pouches
 - Provide adequate room for the item leaving at least 1 1/2 inches from the item to all seals (Figure 24).
 - Sealing the package may be done using a heat sealer, indicator tape, or self-seal pouches.
 - 2) Wrappers
 - a) You may choose to wrap the item(s) sequentially in two wrappers, using either the **envelope method** or **oblong method**.
 - 3) Plastic/Tyvek pouches are prepared the same as paper/plastic pouches.

2. Loading the Ethylene Oxide Gas Sterilizer

- a. Loading car
 - 1) If item is wrapped in a perforated tray or container, it should be placed flat on shelf.
 - 2) Place paper/plastic pouch standing on edge with plastic side of one facing the paper side of the one next to it (Figure 25).

NOTE: Do not stack paper/plastic pouches

- 3) Use wire basket(s) to facilitate handling and loading of small packages.

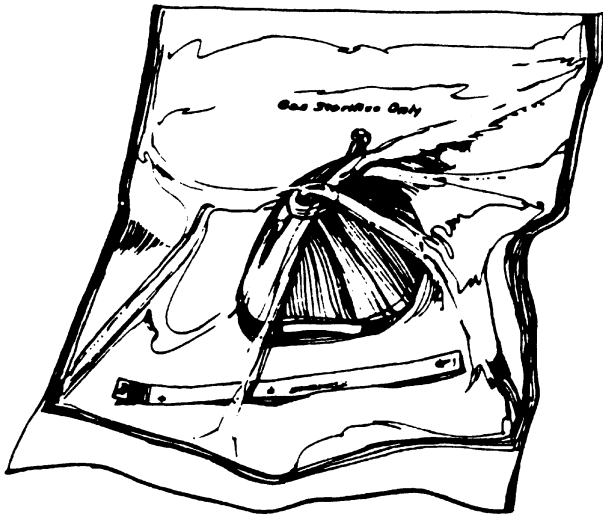


Figure 24. ALLOW 1-1/2 TO 2 INCHES FROM THE ITEM TO ALL SEALS.

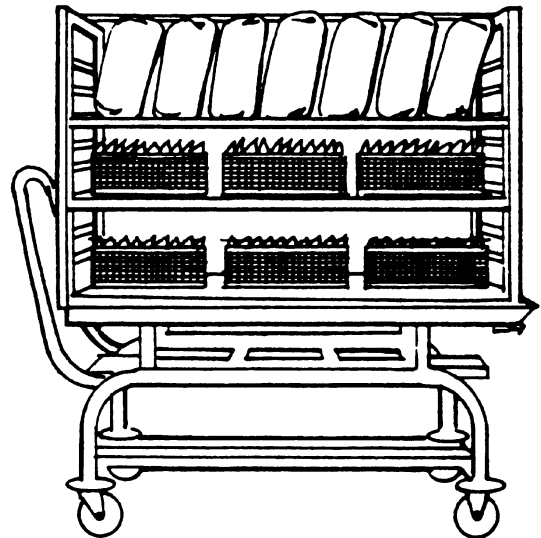


Figure 25. PLACE PACKAGED/WRAPPED ITEMS ON EDGE.

- b. Sterilizer shelves (when loading car is not used)
 - 1) Use wire basket(s) for all items and place on shelf (Figure 26).
 - 2) Refer to guidelines above for "loading car."
- c. Arrange load on shelf and in basket so that gas mixture can circulate freely. **Do not overload shelves or baskets. Do not compress packages.**
- d. Do not allow load components to contact the sterilizer chamber wall.
- e. Provide **at least 3 inches** between sterilizer chamber ceiling and the topmost package of the load to facilitate sterilant circulation and aeration (Figure 27).

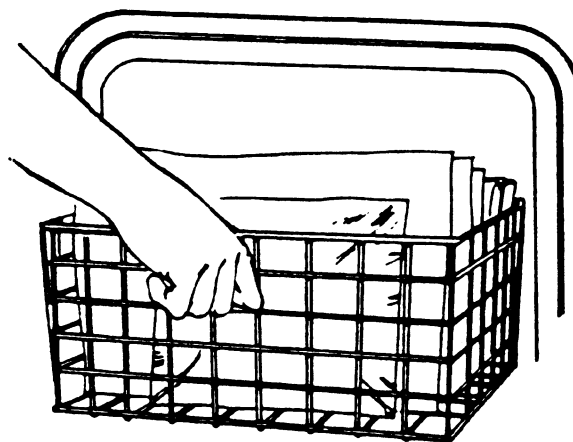


Figure 26. USE WIRE BASKETS FOR ALL ITEMS AND PLACE ON SHELF.

3. Unloading the Ethylene Oxide Sterilizer

a. Loading car

- 1) Open door (approximately two inches) immediately after completion of cycle (Figure 28).
- 2) Leave immediate area for 15 minutes.
- 3) Transfer loading car to aerator immediately following the 15 minute waiting period. **Pull loading car to aerator. Do not push** (Figure 29).
- 4) Put car into aerator as quickly as possible.

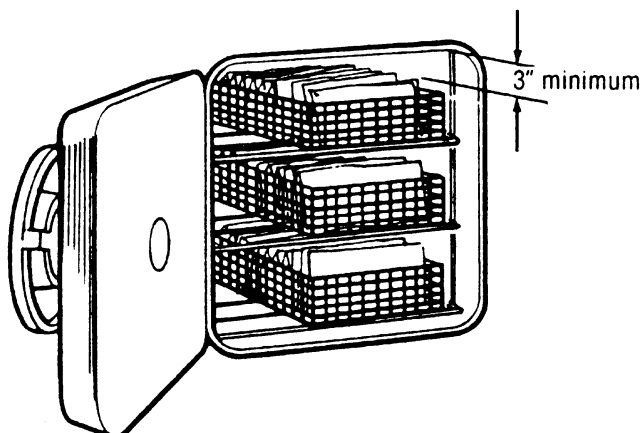


Figure 27. PROVIDE AT LEAST 3 INCHES BETWEEN THE STERILIZER CHAMBER CEILING AND THE TOPMOST PACKAGE.

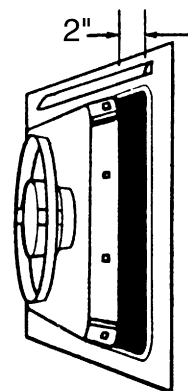


Figure 28. OPEN CHAMBER DOOR APPROXIMATELY 2 INCHES IMMEDIATELY AFTER COMPLETION OF EtO CYCLE

- b. Sterilizer shelves (when loading car is not used)
- 1) Open door (approximately two inches) immediately after completion of cycle.
 - 2) Leave immediate area for 15 minutes.
 - 3) Transfer baskets (with contents) to the aerator immediately following the 15 minute waiting period.
 - a. Carry basket(s) waist high.
 - b. Handle so that hands do not come in contact with packaged items.
 - c. Wear protective gloves if it is necessary to handle or touch an item. Use butyl rubber gloves.
Immediately after use, remove gloves and put them in the aerator, then wash hands.

4. **Aeration**

- a. Aerate ALL items sterilized with EtO gas. (Exception is unwrapped all-metal or all-glass items.)
- b. Follow item manufacturer's recommendations for aeration temperature and time. If no recommendations are available, use the following recommended minimum aeration times:
 - In a sterilizer/aerator:
 - 130° F = 12 hours
 - 100° F = 32 hours
 - In an aeration cabinet:
 - 140° F = 8 hours
 - 120° F = 12 hours
 - 100° F = 20 hours

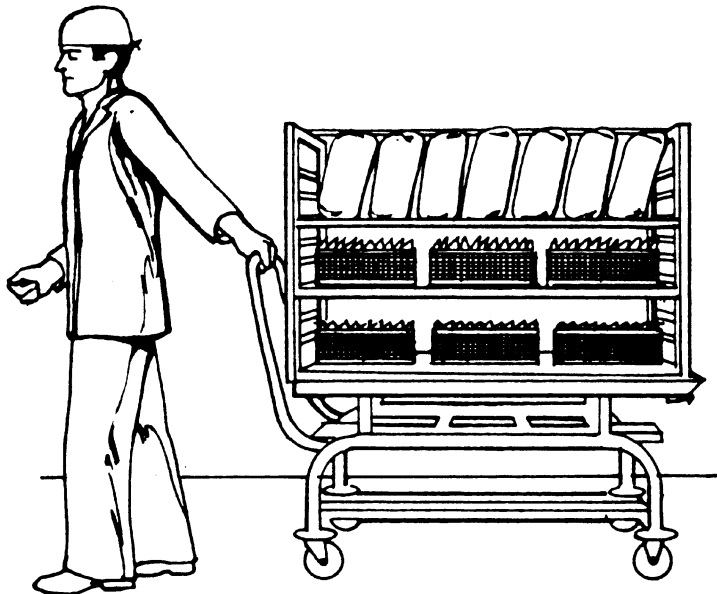


Figure 29. PULL LOADING CAR TO AERATOR – DO NOT PUSH.



TIPS FOR IMPROVING YOUR STEAM STERILIZATION TECHNIQUES

By Sandra A. Lee, R.N.
1992 - Revised 1999

CONTENTS	PAGE
Textiles24
Instruments25
Utensils26
Glass Syringes26
Solutions27
Pack Density28
The Formula29

TIPS FOR IMPROVING YOUR STEAM STERILIZING TECHNIQUES

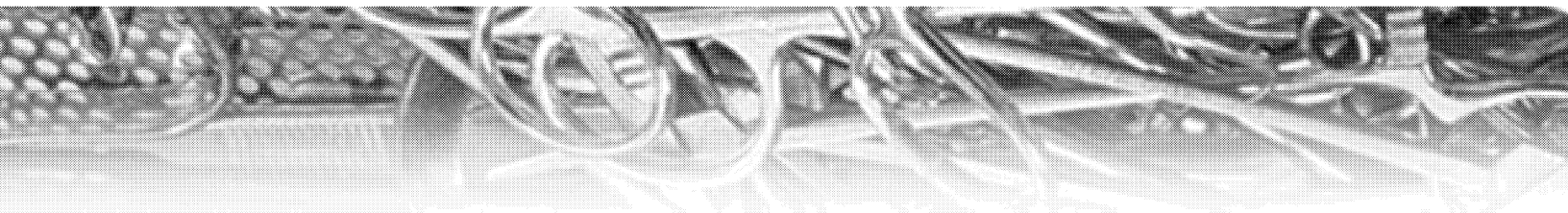
Tips for Improving Your Steam Sterilizing Techniques is provided as a quick reference to suggest probable causes and preliminary suggestions for correction of some problems you may encounter during sterile processing.

Use it along with other resources and references, including your sterilizer operator's manual, to improve your steam sterilizing techniques.

TEXTILES	
1. <u>Damp/Wet Probable Causes</u>	See "Wet Pack Problem Solving Guide."
2. <u>Stained</u>	<u>Correction</u>
<ul style="list-style-type: none"> • Dirty chamber walls and loading shelves, cars, or carts 	Clean (cool) chamber walls, etc. at least weekly, but preferably daily. Never use strong abrasives, steel wool, scouring powders, sharp instruments, etc. to remove stubborn stains. Consult sterilizer manufacturer for specific recommendations.
<ul style="list-style-type: none"> • Chemical reaction between residual laundry compounds in textiles and steam 	Laundry chemicals and steam additives should be appraised by respective management for proper mixtures. Textiles must be thoroughly rinsed.
<ul style="list-style-type: none"> • Boiler compound carryover in steam supply 	Notify hospital maintenance.
<ul style="list-style-type: none"> • Debris in steam lines (most likely after installation of new steam lines) 	Notify hospital maintenance.
3. <u>Torn Wrappers</u>	<u>Correction</u>
<ul style="list-style-type: none"> • Rough surface on loading shelves, cars, or carts 	Repair or replace damaged equipment. Use absorbent shelf covers.
<ul style="list-style-type: none"> • Improper loading and unloading techniques 	Carefully lift, do not PUSH, PULL, or DRAG wrapped packages when positioning or removing them from sterilizer shelves, cars, or carts.

INSTRUMENTS

1. <u>Damp/Wet Packs Probable Causes</u>	See “Wet Pack Problem Solving Guide.”
2. <u>Pitted/Corroded Probable Causes</u>	<u>Correction</u>
<ul style="list-style-type: none"> • Damage to the passivated layer 	Clean instruments carefully and according to manufacturer’s instructions.
<ul style="list-style-type: none"> • Poor cleaning and/or delayed cleaning of blood and body fluids/tissue on instruments 	Do not delay cleaning. Remove gross soil at the point of use by simply using a wet sponge. Promptly transfer to decontamination area for immediate cleaning. Chloride ions in blood and body fluids will attack instruments as does soaking them in saline solution.
<ul style="list-style-type: none"> • Exposure to hard/caustic, highly acidic or highly alkaline solutions or chemicals: acids, iodine, sodium chloride detergents 	If instruments are exposed to hard chemicals, rinse them immediately and thoroughly after contact.
<ul style="list-style-type: none"> • Damage to instrument surface by abrasive scouring compounds, steel wool, sand paper, metal brushes; scraping with scalpel blades; soaking in bleach 	Use only those types of cleaning agents recommended safe and appropriate by instrument manufacturers.
<ul style="list-style-type: none"> • Inferior instruments 	Use only top quality instruments.
<ul style="list-style-type: none"> • Instrument surfaces previously damaged and exposed to moisture 	Avoid soaking instruments for prolonged periods of time and dry them thoroughly.
<ul style="list-style-type: none"> • Metallic deposits resulting from galvanic reaction with sterilizer components/cleaning agents 	Keep sterilizer chamber, accessories, and trays clean using only those cleaning agents recommended by the sterilizer manufacturer.
3. <u>Spotted and/or Stained</u>	<u>Correction</u>
<ul style="list-style-type: none"> • Mineral deposits on instruments 	Wash with appropriate detergent and water quality. Use distilled or demineralized rinse water.
<ul style="list-style-type: none"> • Laundry compound from instrument wrappers 	Inform laundry services management and ask for evaluation of rinsing procedures.
<ul style="list-style-type: none"> • Deposits or stains from strong dyes or chemicals 	Clean and thoroughly rinse instruments immediately after exposure.
4. <u>Stiff Hinges or Joints (Box Locks)</u>	<u>Correction</u>
<ul style="list-style-type: none"> • Corrosion 	Thorough cleaning and lubrication are only a “band aid.” Instrument should be sent for repair or replaced.
<ul style="list-style-type: none"> • Soil 	An enzymatic pre-soak and/or ultrasonic cleaning can be helpful in removing hard to reach soil. Clean and rinse thoroughly.
<ul style="list-style-type: none"> • Jaws or shanks out of alignment 	Realignment by a qualified instrument repair service

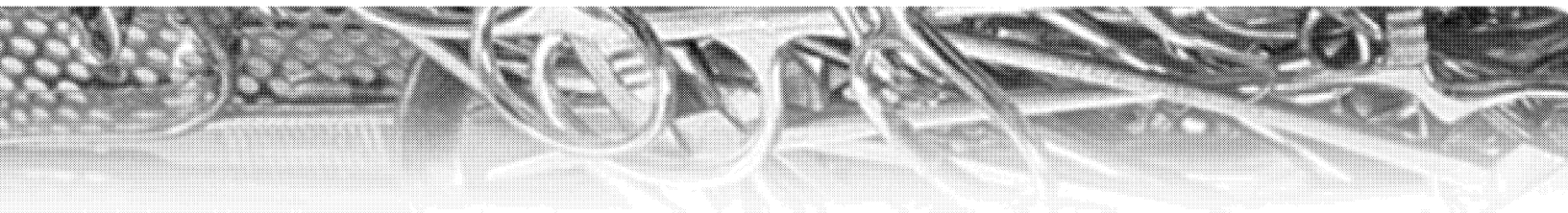


UTENSILS	
1. <u>Damp or Wet Probable Causes</u>	See “Wet Pack Problem Solving Guide.”
2. <u>Misshapen Heat-Resistant Plastic Utensils</u>	<u>Correction</u>
<ul style="list-style-type: none"> • Loaded too tightly 	Load loosely; do not place heavy objects against them.
3. <u>Broken Suction Bottles</u>	<u>Correction</u>
<ul style="list-style-type: none"> • In-rush of cool air when sterilizer door is opened 	Open door a few inches and allow bottles to remain in chamber for 15-20 minutes before handling.
<ul style="list-style-type: none"> • Soft glass 	Use heat-resistant glass bottles; borosilicate (type 1) containers
<ul style="list-style-type: none"> • Chipped or defective bottles 	Inspect bottles for defects before sterilizing.

GLASS SYRINGES	
1. <u>Sticky</u>	<u>Correction</u>
<ul style="list-style-type: none"> • Residual detergent or soil 	Clean and rinse thoroughly; use distilled water for final rinse.
<ul style="list-style-type: none"> • Sterilized while assembled 	Separate barrels and plungers.
2. <u>Excessive Breakage</u>	<u>Correction</u>
<ul style="list-style-type: none"> • Rough handling 	Handle carefully.
<ul style="list-style-type: none"> • Sterilized while assembled 	Separate barrels and plungers.
<ul style="list-style-type: none"> • Poor-quality syringes 	Use good-quality syringes.
<ul style="list-style-type: none"> • Steam erodes glass 	Sterilize by dry heat.
<ul style="list-style-type: none"> • Cracked or chipped 	Inspect for defects prior to sterilization.

SOLUTIONS

<u>SOLUTIONS</u>	
1. <u>Caps “Blow Off”</u>	<u>Correction</u>
• Exhausting sterilizer too rapidly	Use slow exhaust cycle.
• Slow exhaust valve; out of adjustment	Notify sterilizer manufacturer.
• Worn or damaged caps/collars	Inspect before using and replace as necessary, or use appropriate disposable closures.
2. <u>Loss of More Than 5% of Fluid Volume During Sterilization</u>	<u>Correction</u>
• Exhausting sterilizer too rapidly	Use slow exhaust cycle.
• Slow exhaust valve; out of adjustment	Notify sterilizer manufacturer.
• Excessive sterilizing temperature	Sterilize at 250-254° F (121-123° C) using liquid cycle.
3. <u>Cracked Flasks</u>	<u>Correction</u>
• Cracked before sterilization; poor inspection following cleaning	Inspect thoroughly after cleaning; discard chipped or cracked flasks.
• Containers not heat resistant or with screw caps	Use only borosilicate Type 1 containers and automatic sealing and venting closures or appropriate disposable closure.
• Sterilizer exhausting too rapidly	Notify sterilizer manufacturer.
4. <u>No Vacuum</u>	<u>Correction</u>
• Worn or damaged caps and/or collars	Inspect closures thoroughly following cleaning; discard those damaged. Use disposable caps designed specifically for the particular bottle.
• Applying cap and collar to flask separately	Assemble caps and collars prior to placing on flasks.
• Slow exhaust valve; out of adjustment	Notify sterilizer manufacturer.
5. <u>Discoloration</u>	<u>Correction</u>
• Prolonged exposure period	Exposure should be according to size of flasks (fluid volume); do not combine flasks requiring different exposure periods in same load.
• Impure ingredients or dirty flasks	Check purity of ingredients and clean flasks thoroughly.
• Excessive temperature	Sterilize only at 250-254° F (121-123° C) using liquid cycle.



SOLUTIONS

<u>SOLUTIONS</u>	
6. Solutions Boiling When Door Is Opened	<u>Correction</u>
<ul style="list-style-type: none"> • Door opened too quickly or fully opened at the end of the cycle 	Open sterilizer door no more than ONE inch and wait at least ten minutes before unloading sterilizer. Do not touch or move a load of boiling solutions.
<ul style="list-style-type: none"> • Slow exhaust valve; out of adjustment 	Notify manufacturer.
7. Black Particles or “Snowstorm”	<u>Correction</u>
a. Particles	
<ul style="list-style-type: none"> • Deteriorated caps and/or collars 	Replace caps and/or collars. Use appropriate disposable caps.
b. “Snowstorm”	
<ul style="list-style-type: none"> • Clumping of chemicals 	Use only chemically pure ingredients.
<ul style="list-style-type: none"> • Use of “soft glass” containers 	Use only borosilicate (Type I) containers.
<ul style="list-style-type: none"> • Chemicals incompatible with routine sterilizing temperatures 	Obtain specific instructions from chemical manufacturer.

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 repellant/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, steam penetration for sterilization and drying.

It is generally advisable that a cotton/linen textile pack should weigh no more than 12 pounds (5.44 kg) for ease in handling and sterilization.

At this weight, the pack should measure 12" high x 12" wide x 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 (115 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.

The Formula - Using U.S. values

Step #1

$$\frac{\text{Size of pack}}{1728^{(1)}} = \text{Cubic Feet of pack}$$

⁽¹⁾ 1728 is the number of cubic inches in a cubic foot.
This always remains a constant.

Step #2

$$\frac{\text{Weight of pack}}{\text{Cubic meters of pack}} = \text{Density (Kilograms per cubic foot)}$$

Example #1

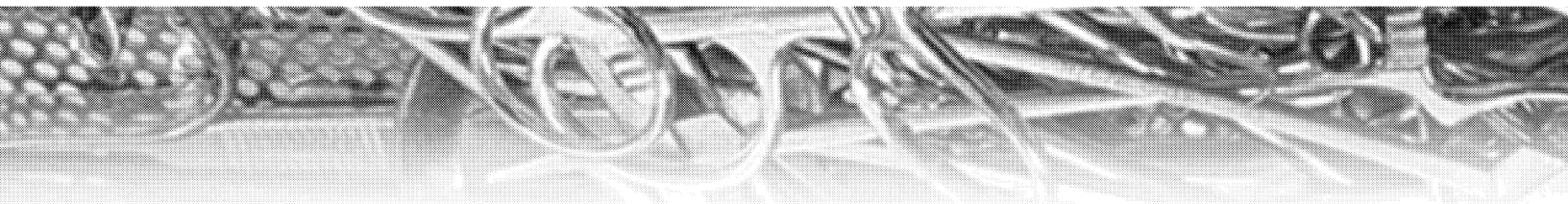
Using a standard 12" x 12" x 20" pack weighing 12 pounds:

Step #1

$$\frac{12 \times 12 \times 20}{1728} = \frac{2880}{1728} = 1.666 \text{ cubic feet}$$

Step #2

$$\frac{12 \text{ pounds}}{1.666 \text{ cu. ft.}} = 7.2 \text{ pounds per cubic foot}$$



The Formula - Using Metric Values

Step #1

$$\frac{\text{Size of pack}}{1,000,000^{(1)}} = \text{Cubic meters of pack}$$

⁽¹⁾ 1,000,000 is the number of cubic centimeters in a cubic meter.
This always remains a constant

Step #2

$$\frac{\text{Weight of pack}}{\text{Cubic meters of pack}} = \text{Density (Kilograms per cubic meter)}$$

Example #1

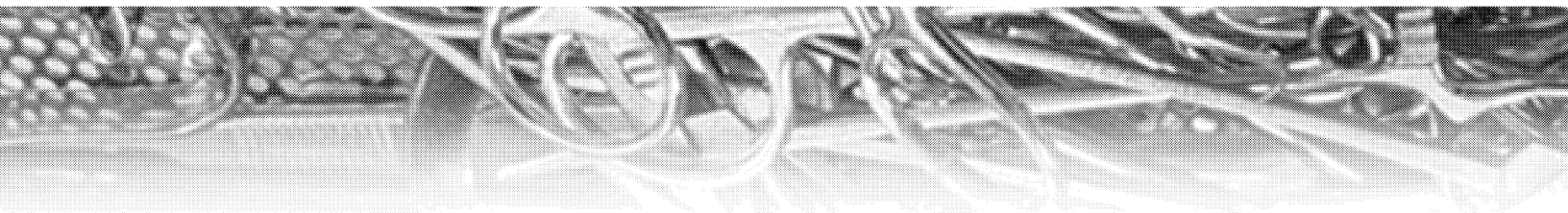
Using a standard 30.5 cm x 30.5 cm x 50.8 cm pack. Weighing 5.44 kilograms:

Step #1

$$\frac{30.5 \text{ cm} \times 30.5 \text{ cm} \times 50.8 \text{ cm}}{1,000,000} = \frac{47257}{1,000,000} = .0473 \text{ cubic meters}$$

Step #2

$$\frac{5.44 \text{ kilograms}}{.0473} = 115 \text{ kilograms per cubic meter}$$

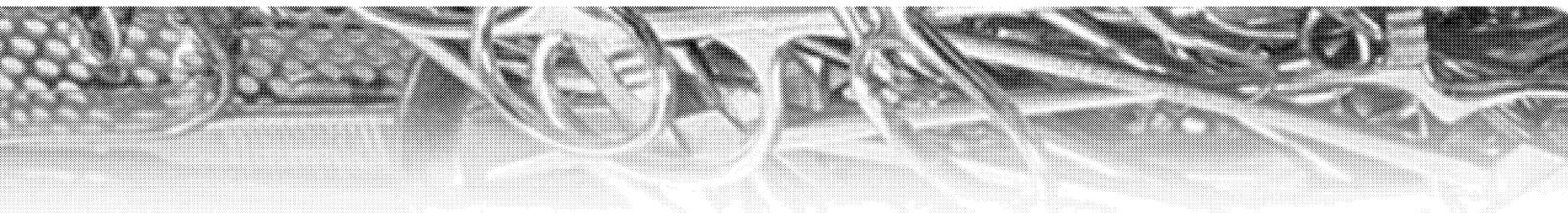


WET PACK PROBLEM SOLVING GUIDE

By Sandra A. Lee, R.N.

1991-Revised 2000

CONTENTS	PAGE
Why Are Wet Packs a Problem	32
Steam Sterilization: Where the Moisture Comes From	32
Looking for Causes and Remedies	33
Finding and Documenting Wet Pack Occurrences	33
Examining Individual Packs	33
Who is Preparing the Packs That You Sterilize? When Did You Last Audit Them?	34
Have You Audited Preparation Practices in Your Own Department Lately?	34
Examining Preparation Techniques	36
Instrument Set Preparation	36
Basin Set Preparation	40
Linen Pack Preparation	42
Appendix A - Equipment, Process, and Environment Audit	46
Appendix B - Wet Pack Log	50
Appendix C - Items Sterilized for Other Departments	51
References and Suggested Reading	52



Perhaps the most frustrating or confounding dilemma that we face using steam sterilization is the occurrence of WET PACKS. Packs are considered wet when moisture in the form of dampness, droplets, or puddles of water is found on or within a textile pack, instrument, or basin set after a completed sterilization cycle and at least a one hour cooling period.

While wet packs can also be seen in ethylene oxide sterilization, they most frequently occur in the mode that is the mainstay of hospital processing throughout the world: steam sterilization. This paper will focus on wet packs that occur with steam sterilization.

WHY ARE WET PACKS A PROBLEM?

Wet Packs are a concern because they 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 nonwoven disposable wrapper's biobarrier may be considered penetrated and the items contaminated.

Moisture found inside a package is often the result of metal items positioned in a way that will enable water to pool or trap steam that 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 too tightly wrapped. All of these items, when properly prepared but improperly loaded for sterilization, can result in moisture forming and remaining within the setup. Internal moisture can "wick" its way to the outside of the pack, providing a pathway for microorganisms to enter.

Some would question why we need to be concerned about internal moisture, perhaps a droplet found well within a set or pack. Certainly that small amount can't contact the outer surface? Could it? The answer: a pack prepared with an absorbent wrapper must always be considered contaminated. The outside of the wrapper may also have been wet, and the moisture found inside the pack could be all that remains due to the outside drying 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. Discuss the likelihood with the manufacturer. Write your policy on moisture within rigid sterilization containers based on the information gained from that manufacturer's testing and documentation.

Now that we've established what a wet pack is and why it's a problem, let's review what happens.

Steam Sterilization: Where The Moisture Comes From

Very simply, 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 reevaporized at the end of the exposure period and 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 reevaporized.

Looking for Causes and Remedies

Once recognized, finding the cause and remedy for wet packs is not always easy. There are many players and factors involved that must be individually considered. This paper will suggest tangible elements to be investigated.

First, we all recognize that this very frustrating problem involves many disciplines, some already mentioned, and that the sterile processing manager has many areas to examine.

Many consultants agree that items improperly prepared and loaded for sterilization are the most common contributing factors in the occurrence of wet packs. However, these are by no means the only probable causes.

A first step at correction, and certainly a good idea for prevention, is a routine review or quality assessment of the basic techniques of preparing and loading items for sterilization. All 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 actually investigating the problem must be to clearly and completely document the occurrences. Using a simple format like this one can be helpful.

WET PACK LOG					
Sterilizer No.	Gravity or Prevac Cycle	Date	Time of Day		Wet Item(s)
			Location in Load	Comments: (Nature of Wetness, Maintenance Dept. Problem, etc)	

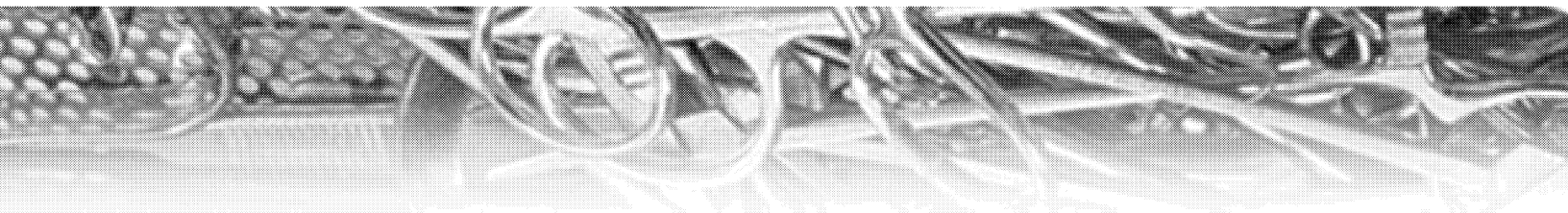
*See full-page log. Appendix B, Page 50.

Wet packs found by the using department can also be documented here. The users can provide information for the comment section while the load documentation system in Central Service provides the rest. The wet packs should be immediately returned to the sterilizing department intact for examination.

As you keep this record, patterns may emerge that give clues to the root cause. Perhaps only the heaviest of instrument sets are involved; only those items coming to you already wrapped from another department; only items prepared by a particular worker; or specialty instruments (multilayered boxes of orthopedic instrumentation.)

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 of course, 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 them before that, realize that warmth goes hand-in-hand with some vapor that will normally revaporize 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 like packs/sets to thoroughly cool before proceeding to examine to see if the wetness remains. If so, you have a legitimate wet pack.

Who is Preparing the Packs That You Sterilize? When Did You Last Audit Them?

ITEMS STERILIZED FOR OTHER DEPARTMENTS*						
Dept. Name	1. Prep. by Dept:		2. Inservice		3. Item Audited	4. Last Audit Date
	In Part	Wholly	Yes	No		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Date	<input type="checkbox"/>	

*See full-page log. Appendix C, Page 51.

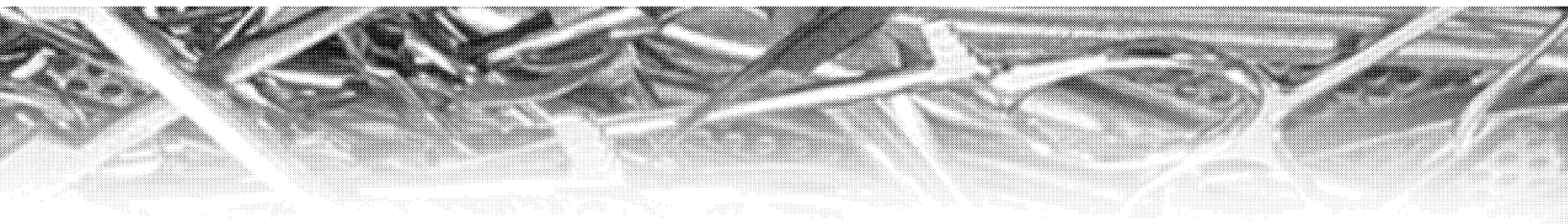
All departments expecting you to sterilize their packs must understand that they are expected to adhere to your requirements if your department is to assume responsibility for successful sterilization and drying.

List where the items that 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. Did you provide them with an in-service program regarding proper cleaning, assembly/disassembly, and wrapping for sterilization?
3. Is each individual item audited?
4. When were their sets last examined or audited by your department for continued compliance and/or updates? Suggest at least every six months.

Have You Audited Preparation Practices in Your Own Department Lately?

Audit all items being prepared by your staff for sterilization. Do they understand that the probability of sterilization and efficient drying is enhanced by everyone following directions carefully? Every detail of preparation should be performed essentially the same way by each individual for a consistent outcome and ease in problem solving.



Survey your department and ask yourself and the personnel a few questions:

1. Are all protocols, policies, and procedures clearly documented, updated, easy to understand, and follow? Consider that photographs and simple diagrams help.
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 return demonstration and description of the process, for example; instrument, basin set or textile pack assembly and loading to assure their understanding?
5. Are the supervisors paying close enough attention to the performance of the workers?
6. Do all workers recognize that items not properly prepared might not be properly sterilized and/or a wet pack could result? Does everyone understand the consequences of a wet pack?
7. Are your workers taking short cuts? A few examples:
 - Not placing an absorbent surgical towel properly within a basin or instrument set.
 - Inappropriately agreeing to a request from the surgical personnel to put all of the instruments into one tray, instead of dividing them among two or more for a better probability of sterilant contact and drying.
 - Overloading the sterilizer shelves with properly prepared packs, squeezing too many packs on a shelf, and creating a tight, dense load that prohibits proper air removal and steam penetration for sterilization and steam evacuation for drying.
 - Improperly positioning items on the sterilizer shelf because you can get more in the load that way.
 - The use of inappropriate trays for the sterilization of heavy instrument sets; for example, those with no holes, too few holes, or holes not in the right places for efficient drainage of condensate.

Only after ascertaining that technique is not the cause of the wet packs should you spend the money to look for poor steam quality, etc.

Examining Preparation Techniques

Now, let's look at guidelines for proper preparation of instruments, basin sets, and textile packs, and some watchouts. Compare your practices to these and see if you can identify a need for improvement; a cause for a wet pack.

Instrument Set Preparation

Choosing The Correct Tray:

1. Always use a "standard" surgical instrument tray that has multiple perforations or a wire mesh-button (or its equivalent used in rigid sterilization container systems) for surgical instrument set assemblies (Figure 1).
2. Always choose a tray that is large enough to distribute the mass of metal instrumentation evenly in a single layer.

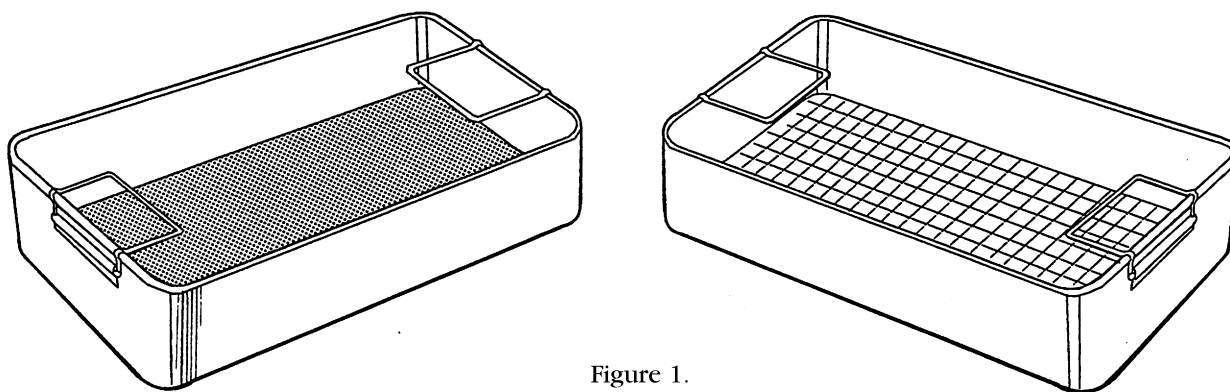


Figure 1.

- 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 for drainage. Note that in the picture, an "X" denotes where additional holes might be drilled for more efficient drainage. These trays are more appropriately used for small "treatment" trays such as cut-down, suture, lumbar puncture, etc. These sets generally contain few metal instruments, so less steam condenses on the instruments, and they are more easily dried (Figure 2).

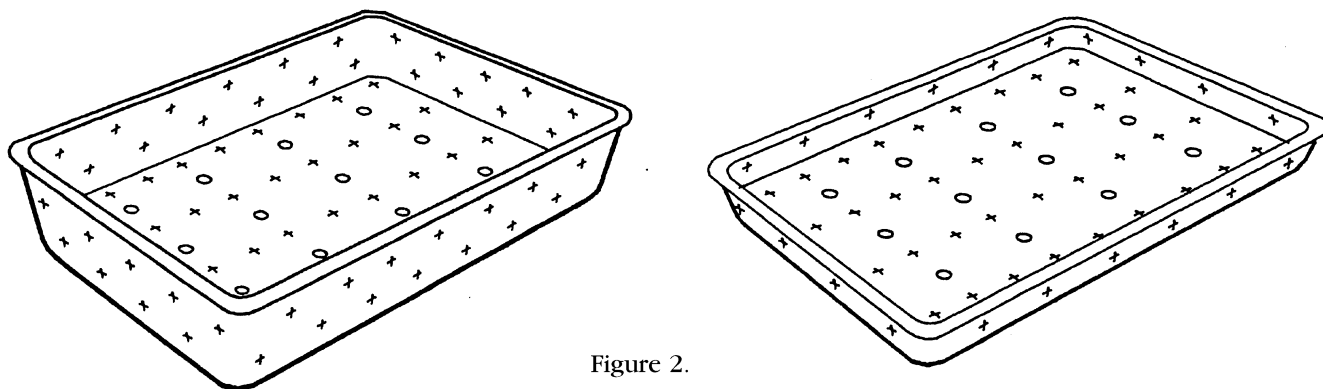


Figure 2.

- Rectangular "cake pan" type or flat trays with no holes are not appropriate for surgical instrument sets. They may allow water to pool in the tray during sterilization. The water cannot drain off, therefore, the set is more difficult to dry.

Assembling The Instrument Set

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

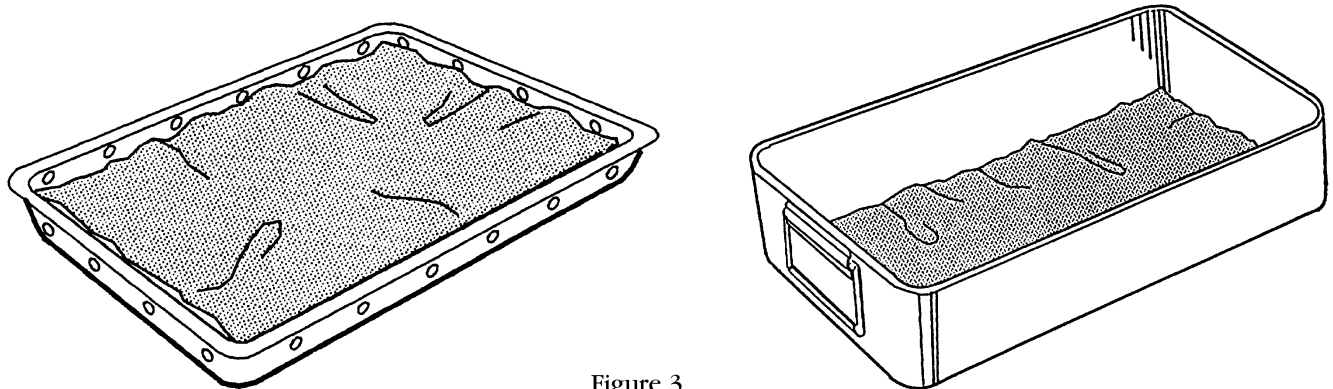


Figure 3.

- a. Do not use a water-repellent textile or nonwoven disposable wrapper or thick super absorbent textile. They may pool or trap moisture making it very difficult, if not impossible, to dry the set. Some foam products can 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 without the advice of the container manufacturer.
2. Besides opening all instruments and evenly distributing them throughout the tray, be certain that all instruments that can be are disassembled for proper steam contact and to avoid trapping steam that can condense and be the source of a wet pack.
 - a. Consider alternating the position of the heavy handles of some instruments like orthopedic chisels and gauges whether setting flat in trays and/or in organizing pouches in an attempt to distribute 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).

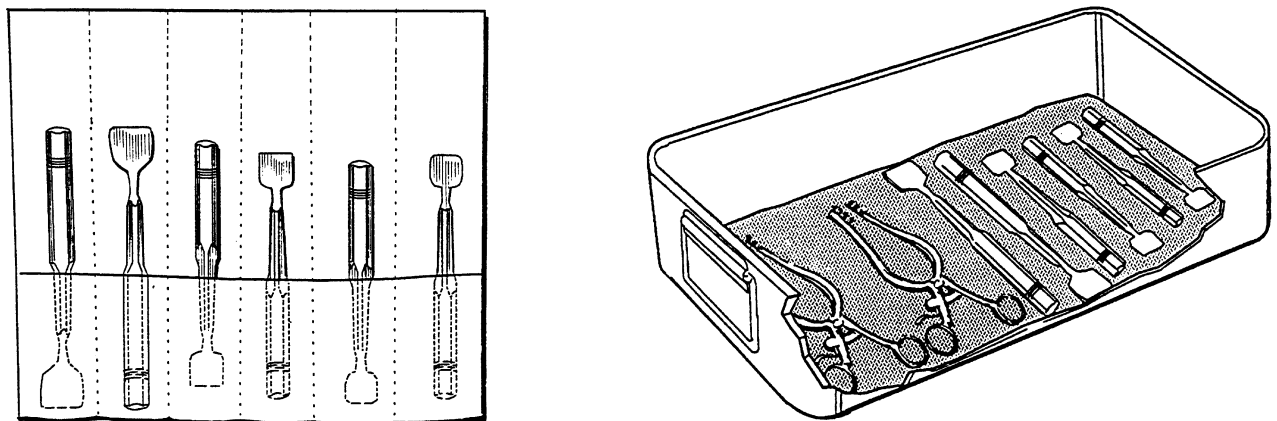
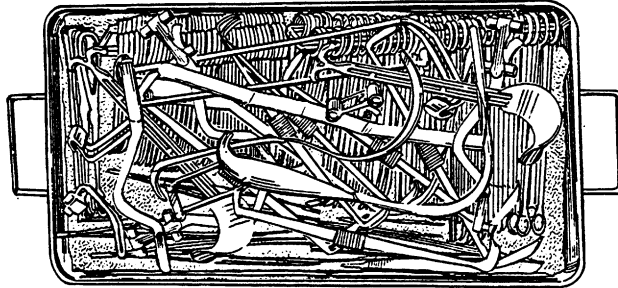


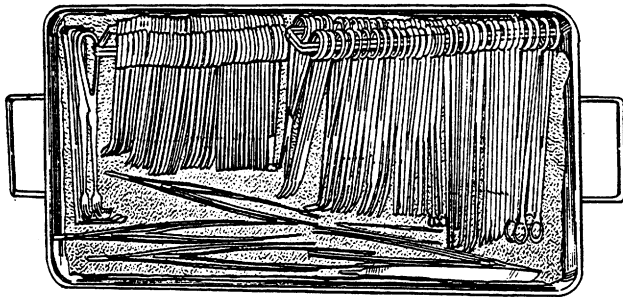
Figure 4.

- b. Avoid piling instruments one upon another. The more metal mass, the more condensation you can expect along with greater difficulty drying (Figure 5).

NO



YES



YES

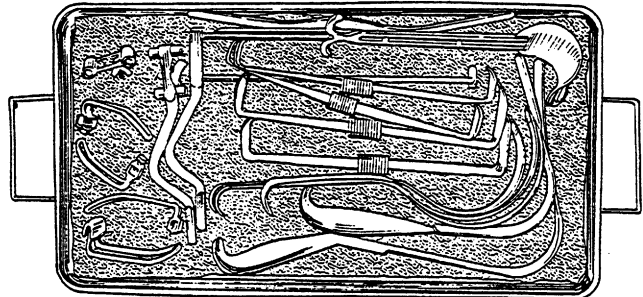


Figure 5.

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

YES

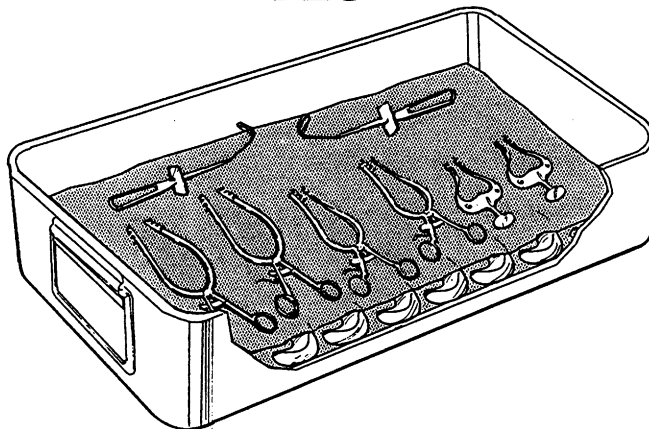


Figure 6.

- d. Do not place handfuls of instruments into paper/plastic peel pouches or water repellent nonwoven disposable wrappers to separate and arrange them within an instrument set. This, too, can be the cause of pooling condensation and can prohibit sterilization (Figure 7).

NO

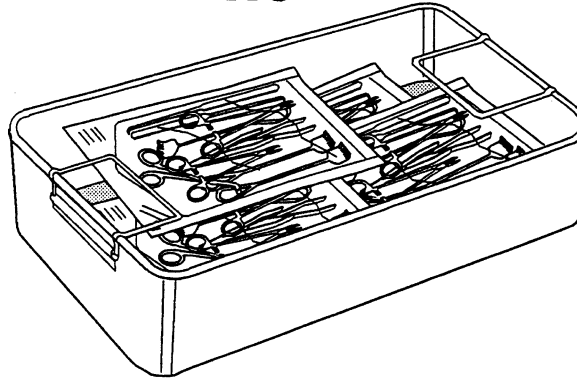


Figure 7.

- 3. Experience has shown that a properly assembled set weighing 16-17 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 a great deal of heat energy will be needed to heat it to sterilizing temperature. Thus, a great deal of condensation will be created. Wet packs often result. Wrapping a heavy device in an absorbent towel before placing it in the tray aids reevaporization 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.

Wrapping the Instrument Set

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

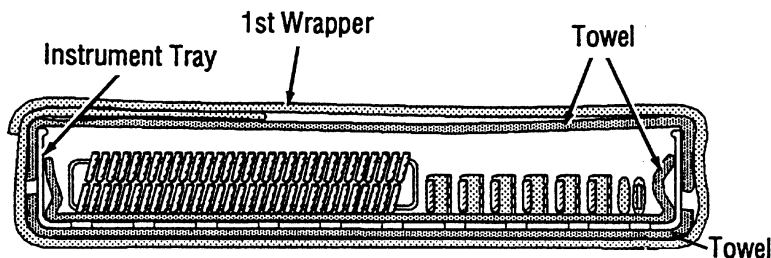


Figure 8.

- a. This is particularly helpful when using nonwoven disposable wrappers, in that excess moisture will usually dry more readily from the textile and prevent pooling inside, on 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 into the other - paper to paper, plastic to plastic. Then you can see the contents, and air and steam can easily pass through the paper during the sterilization process (Figure 9).

Be sure the inner pouch is smaller than the outer. Avoid folding a large inner pouch over and over onto itself to fit into a smaller outer pouch. This can prohibit sterilization and/or trap moisture.

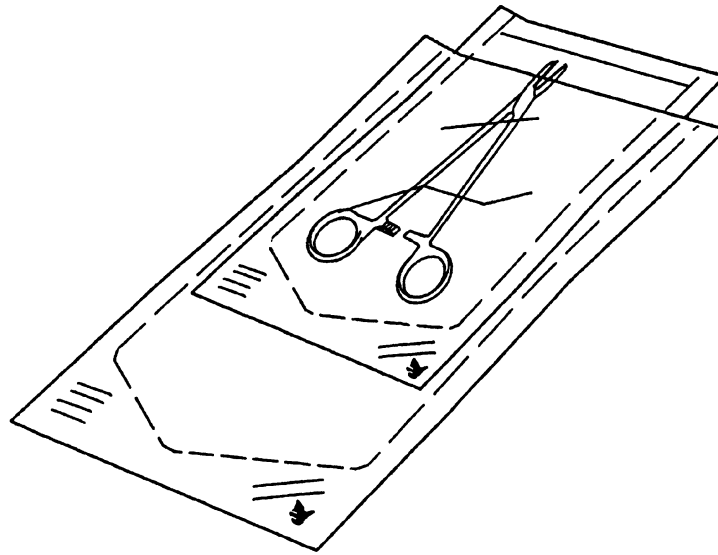


Figure 9.

Basin Set Preparation

Assembling the Basin Set

It is particularly important that all persons who assemble, wrap, and load basin sets for sterilization follow the same plan or guidelines. Then, anyone who picks up a set prepared by someone else will know exactly how to load it properly for sterilization, so that all items within are tilted in a position for drainage. 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 applying a 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).

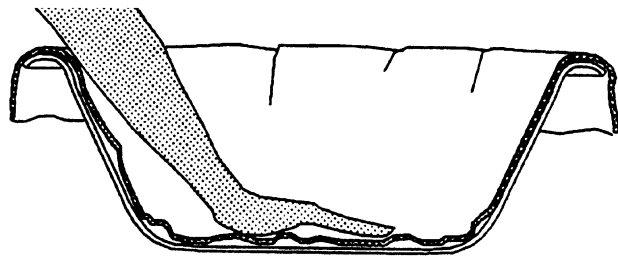


Figure 10.

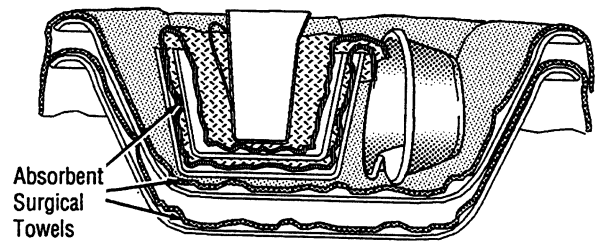


Figure 11.

If the top basin is the same size or only a slightly smaller diameter than the lower one, use a folded absorbent surgical towel to boost it up to prevent a close fit that could trap moisture between them.

- b. Be aware of how you position utensils that have “curled” or turned rims, such as emesis basins, within a set. Stand them on edge because the rim can pool water and be the source of a wet pack.
- 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 drainage position. They often reposition and catch condensate.

Wrapping the Basin Set

1. Consistent assembly and wrapping techniques go hand in hand. That is, sets assembled exactly alike should then be positioned and wrapped exactly alike. That way some external landmark can signal the loader for proper positioning in the sterilizer. One way to do this is to say that the taped side indicates the “standing edge” (Figure 13).
- a. Before applying the wrapper consider the “curled” rim usually found on large solution basins; water can pool there also when it’s tilted for sterilization. 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).

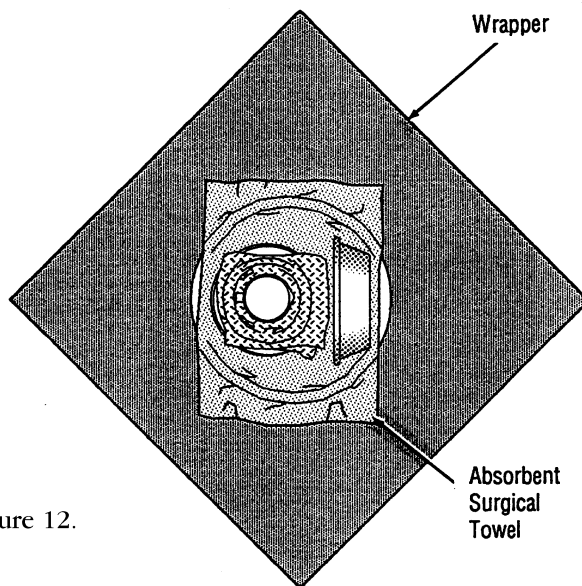


Figure 12.

- a. If moisture is found between the bottom basin and the wrapper, consider placing an absorbent surgical towel between them.

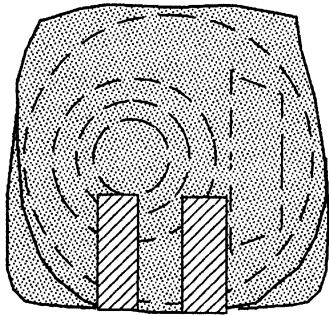


Figure 13.

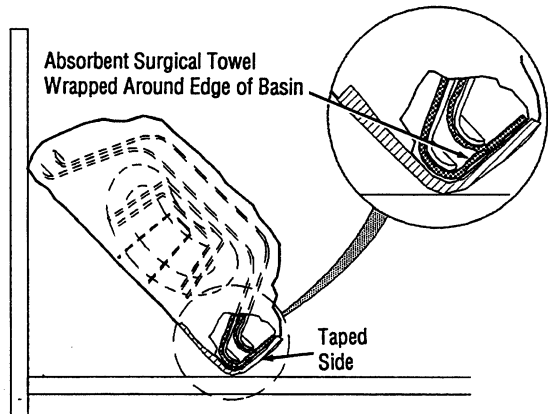


Figure 14.

Linen Pack Preparation

1. For many years we have known that a linen 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 remains important so that there can be proper air removal, steam penetration, and evacuation during the sterilization cycle.

- a. But practically speaking, textiles have changed over the years. The linen 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 prohibited - so consider loosening them up (Figures 15 and 16). Ask the manufacturers of newer textiles for a pack density formula appropriate for their products.
- b. Many layers of tightly woven or water-repellent textiles may need to be rearranged within the pack and/or separated by absorbent, less dense fabrics.
- c. Make certain that you obtain pack preparation instructions from textile manufacturers as well as sterilization parameters. Seek documentation from them that shows that the sterilization testing they performed was done using standard hospital cycles.

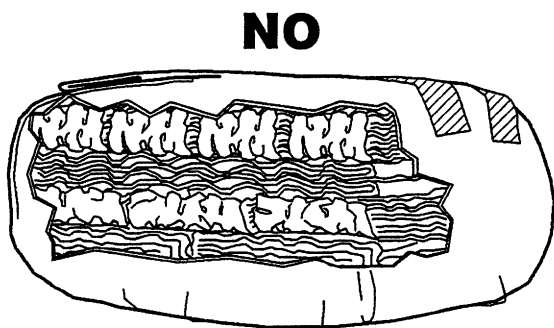


Figure 15.

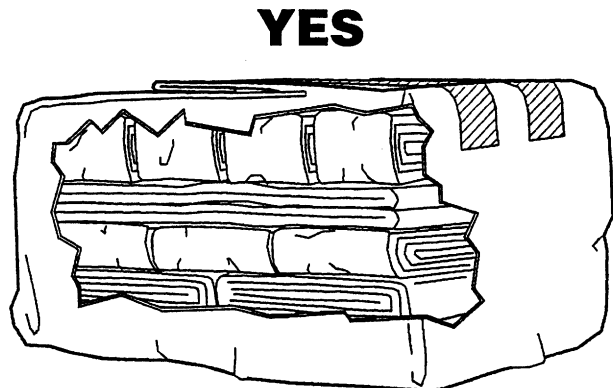


Figure 16.

Containment Methods

We've recognized wet pack difficulties more often since the introduction of nonwoven disposable wraps, new textiles, and rigid sterilization container systems. That is not to say that these products are responsible for them, but that 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.

So now, it's a matter of getting back to basics.

1. Always choose wrappers, etc. that are designed and tested appropriately for the type of sterilization cycle (gravity or pre-vacuum) you intend to use. Always consult wrap, pouch, and rigid container manufacturers for their instructions for proper use.
 - a. Avoid using a wrapper for a dual purpose (e.g., a large table drape). Consider that the excess layers or folds of wrap could prohibit sterilization and/or trap moisture.

Loading The Sterilizer

1. An absorbent shelf cover may be used and can be helpful in drying a load, particularly when disposable wraps and rigid containers are used. The shelf cover will absorb moisture that might otherwise drop onto items on the shelf below.
 - a. Do not use nonwoven disposable wraps as shelf covers. Condensate more readily dries from absorbent materials.
2. It's preferable to sterilize textiles and hard goods in separate loads.
 - a. When that is not practical, remember: textiles on top shelves, hard goods below, and not the reverse, to avoid condensate run-off wetting items below.
 - b. Surgical instrument trays should sit flat on the shelf to maintain even instrument distribution and facilitate proper drainage. Standing 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).

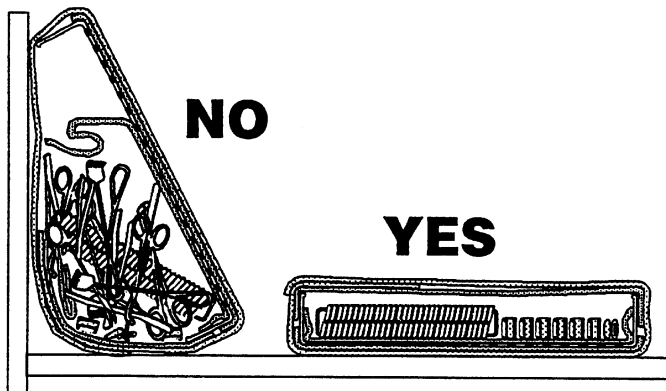


Figure 17.

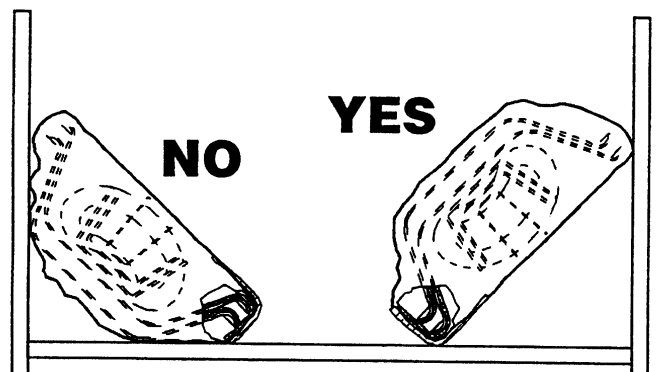


Figure 18.

- 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 cause water to stand on top of the plastic (Figure 20).

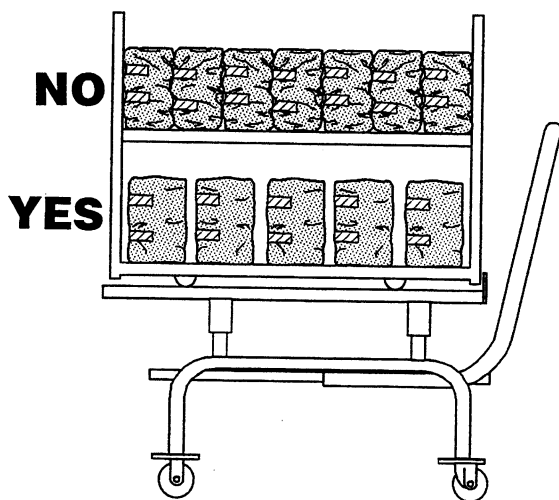


Figure 19.

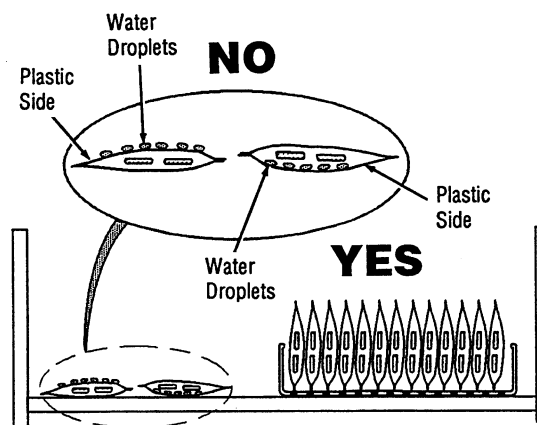
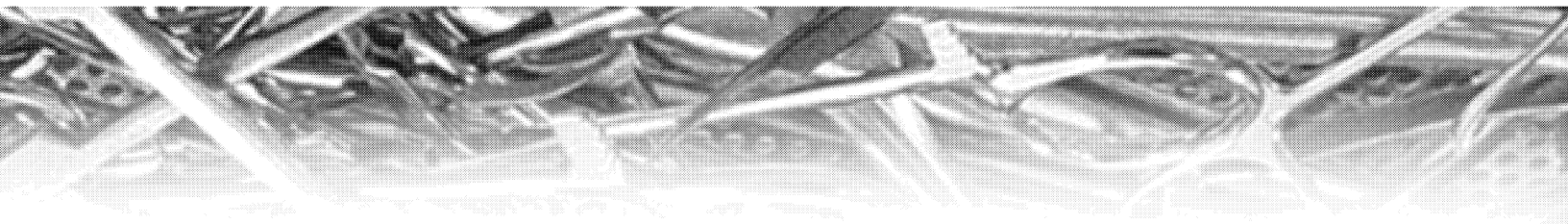


Figure 20.

3. Do not allow items to touch chamber walls where they could contact condensate.
 - a. Use sterilizable baskets to contain small items on sterilizer shelves/carts.
4. Use sterilizer carts whenever possible and have enough so that items can remain on them untouched until thoroughly cooled.
 - a. Consider having one cart cooling, one in the sterilizer, and one that is being prepared (for each sterilizer).
5. Examine how each item is positioned for sterilization and avoid overloading. Always keep the need for efficient air removal, steam penetration, and evacuation in mind; this will not occur properly (even if the items were prepared appropriately) if they were not correctly loaded.
 - a. Consider utilizing “wasted” space by adding another shelf to the sterilizer cart and rearranging the load.

Unloading The Sterilizer

1. Allow items to thoroughly cool on the cart as mentioned earlier.
 - 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.

- 
- e. Likewise, do not place warm packages in plastic dust covers. Condensate will be trapped and remain there until opened and perhaps damage the items within.

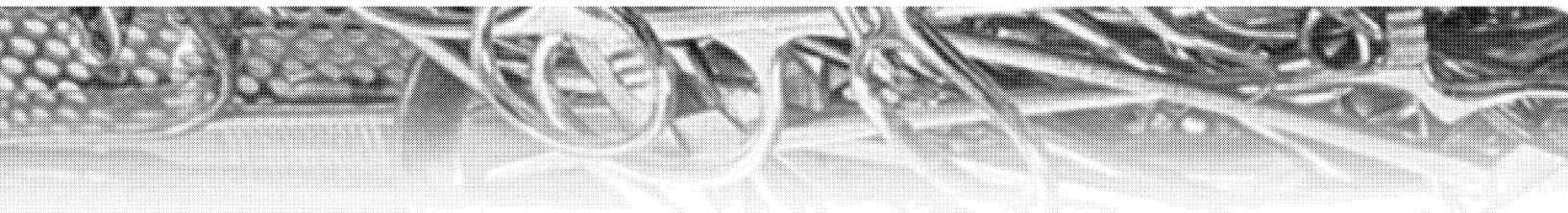
Other Important Considerations

1. Instrument lubricants should be used according to 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 too concentrated may leave instruments slippery and/or give the false impression of wetness.
2. Clean and check the sterilizer chamber drain screen at least every shift. 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 previous information represents some homework that is very important in the wet pack investigative process and provides a logical place to start. Again, you may find that you have a few things to correct and may need to go no farther for a solution.

On the other hand, you may reaffirm that you are preparing items properly, and the investigation needs to stretch to other areas, looking further for the origin of wet pack occurrences - steam quality, plumbing, trapping, etc. The Equipment, Process, and Environment Audit checklist, Appendix A, beginning on page 46, will help you with that assessment.

Wet packs represent an economic loss to the institution because goods must be reprocessed. Unrecognized, they are a hazard to the patient. Resolving the problem takes **PATIENCE** in critical thinking and observation and, most importantly, **COOPERATION** among all concerned.

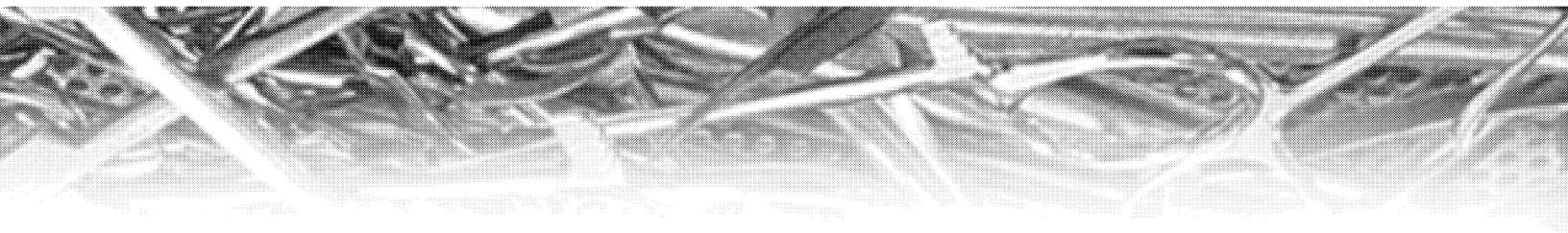


APPENDIX A
EQUIPMENT, PROCESS, AND ENVIRONMENT AUDIT

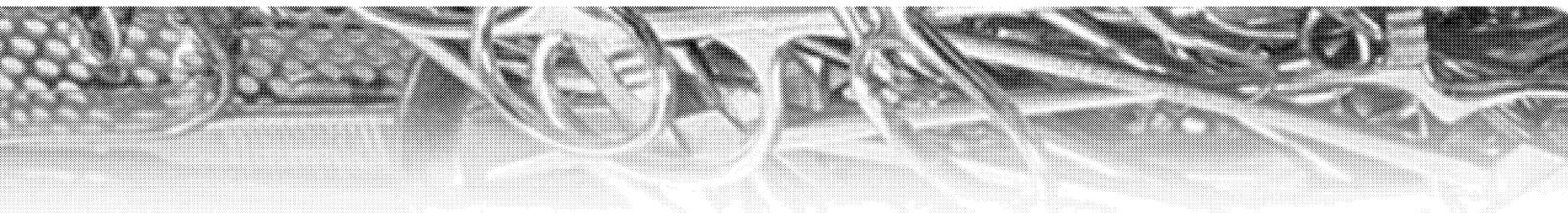
Wet packs are commonly recognized when there have been changes within the overall conduct of the sterilization process or environment.

The following statements are arranged as a checklist. As you read along place a “√” to the right of 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.

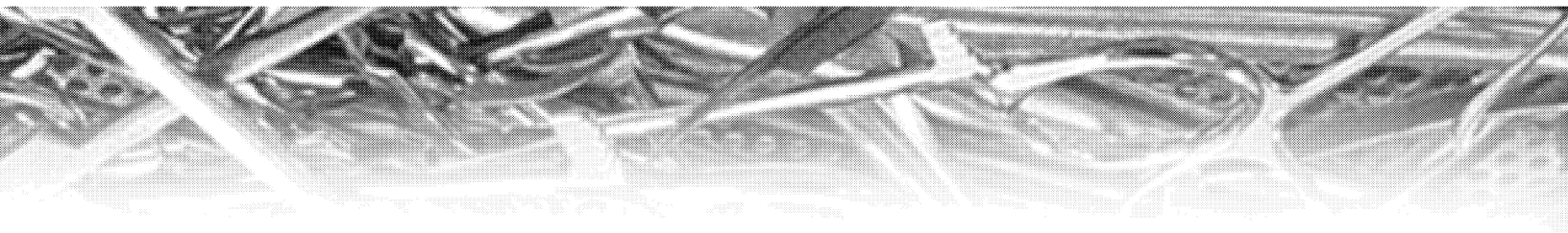
Statement	√	Comments
1. When steam generator (boiler) or plumbing changes have taken place for normal seasonal maintenance or a new construction or renovation project.		
CHECK TO SEE IF:		
- good quality steam is being provided for the steam sterilization process. Remember that steam quality or moisture content of the steam is critical for effective sterilization. A minimum quality of 97% saturated steam with no more than 3% liquid content, or water, is considered best. More liquid content results in steam that is too wet.	<input type="checkbox"/>	
- the steam being provided is being delivered and regulated at the proper dynamic steam pressure from the steam generator to each sterilizer. It should generally be 50-80 psi as read on the steam line gauge.	<input type="checkbox"/>	
- the steam is regulated as it enters the sterilizer to deliver correct steam pressure.	<input type="checkbox"/>	
- the plumbing lines are as direct as possible from the steam generator and/or properly trapped to prevent carry over of condensate in the lines with the flowing steam into the sterilizer chamber.	<input type="checkbox"/>	
- steam lines are covered with insulation.	<input type="checkbox"/>	
- there are any other pieces of equipment or areas requiring steam from the same steam source when the sterilizer is in operation (e.g., washer decontaminators, the kitchen).	<input type="checkbox"/>	
- water conditions and boiler treatment are compatible with the sterilizing process even though the mixtures might vary depending on the season.	<input type="checkbox"/>	
- any maintenance or remodeling was performed on the steam generation and distribution system. Inform the persons responsible of your need to know in the future. Their work could impact sterilization and drying.	<input type="checkbox"/>	
2. New personnel or new managers within the Central Service or user department such as the surgical suite:		
- may be the first to identify wet packs because they may be able to look at the situation more objectively;	<input type="checkbox"/>	
- may cause a problem because they lack experience;	<input type="checkbox"/>	
- have had incomplete or improper employee orientation; or, have had inadequate supervision;	<input type="checkbox"/>	
- misunderstood or misinterpreted instructions;	<input type="checkbox"/>	



Statement	√	Comments
- or don't understand the reasons or principles behind the need for a particular practice;	<input type="checkbox"/>	
- or, may be following inconsistent,	<input type="checkbox"/>	
- unclear,	<input type="checkbox"/>	
- poorly organized, policies, and procedures.	<input type="checkbox"/>	
3. A new or different sterilizer is installed than the staff are used to using. The staff may scrutinize the end product more closely than ever before and with that, find a wet pack.		
BEFORE BLAMING THE NEW STERILIZER:		
- take a good look at the equipment assembly, wrapping, and loading techniques to see if you can find any hints of the origin of the wetness.	<input type="checkbox"/>	
- next, take a closer look at those same items being sterilized in the older sterilizer. They may exhibit the same wetness, but no one has observed it before because they had no particular reason to suspect wet packs.	<input type="checkbox"/>	
- check to see if the sterilizer manufacturer's installation instructions regarding - water temperature (critical to proper function of a vacuum pump or water ejector),	<input type="checkbox"/>	
- water pressure, and	<input type="checkbox"/>	
- size of plumbing connections (both critical to the proper function of a water ejector) have been followed.	<input type="checkbox"/>	
One of these may be the mechanical air removal device for your prevacuum cycle. If it's not functioning properly because of inadequate utilities or connections, there may be difficulty in not only air removal at the beginning of the cycle, but steam removal at the end.	<input type="checkbox"/>	
Steam remaining in the chamber will condense upon cooling and wet the sterile items.		
4. New medical devices are presented for sterilization. Some devices are designed with certain characteristics that are necessary for proper operation and/or effective use. Sometimes these same design factors are directly related to the occurrence of a wet pack.		
For example, some orthopedic instruments with their metal or plastic organizing boxes, weighted vaginal speculums, skin graft devices, power equipment, etc.		
BE SURE THAT:		
- before you purchase a new medical device the C. S. Manager and/or persons responsible for sterilization of the product are a part of the product evaluation process, to ask questions not only about cleaning but proper assembly or disassembly instructions for sterilization and drying. Some might otherwise trap steam that will later condense and be the reason for a wet pack.	<input type="checkbox"/>	



Statement	√	Comments
- manufacturer's instructions regarding preparation for sterilization and drying are complete and easy to understand. If not, reformat them to suit your preparer's level of understanding.	<input type="checkbox"/>	
- inservice education regarding proper preparation and the product idiosyncrasies or "watchouts" were provided for all expected to take part in the sterilization of the device. Document this instruction for future referral.	<input type="checkbox"/>	
- manufacturers are asked about any previous episodes of difficulty drying their medical devices after sterilization, and any suggestions for success if this has been a problem.	<input type="checkbox"/>	
5. Changes in wrap materials or the introduction of rigid sterilization container systems. Wet packs never seen before often have resulted with the change from a textile wrapper to a nonwoven disposable wrapper or rigid sterilization container system. Sometimes simply because the manufacturer's instructions for use were either not clearly provided, with not enough emphasis on important points, or not seriously followed. This transition is a critical one because a porous textile wrapper generally permits revaporization of moisture to occur more easily at the end of the sterilization than does a nonwoven disposable wrap or rigid container.		
CONSIDER THAT:		
- you should verify the sterilization processing compatibility of the new wrap or container by in-house testing prior to purchase to check the efficacy and drying.	<input type="checkbox"/>	
- some rigid containers may require extended sterilization and drying times.	<input type="checkbox"/>	
- some rigid containers and nonwoven disposable wrappers perform best regarding drying when an absorbent surgical towel is included in the instrument tray to absorb moisture. Check with the manufacturer of the wrap or container for proper application.	<input type="checkbox"/>	
- some rigid containers can be stacked one directly upon the other, and other designs require the top container to straddle two below, or cannot be stacked at all.	<input type="checkbox"/>	
- moisture found in a rigid container, with a solid bottom, may have no way of contacting the outside and may not be able to be contaminated; on the other hand,	<input type="checkbox"/>	
- moisture found in a rigid container, with a filtered bottom, is more likely to become contaminated because it may be able to "wick" through the filter and contact the outside.	<input type="checkbox"/>	
- the container manufacturer should present you with written information to back up any claims that internal moisture cannot make contact with the outside of the container.	<input type="checkbox"/>	
- some rigid container manufacturers specify a maximum, tested, overall weight for the set with the container.	<input type="checkbox"/>	
- you should ask the manufacturer of the wrap or container for specific incidences and reasons for wet packs related to their product.	<input type="checkbox"/>	



Statement	√	Comments
-The overuse of fabric softeners can diminish the absorbency of cotton textiles, which could be a contributing cause of wet packs.	<input type="checkbox"/>	
6. Environmental factors such as temperature and relative humidity in the preparation, sterilization, and cool-down areas should be constant. Do they change with the seasons?		
-Consider that all moisture absorbent materials contain some amount of moisture when stored at normal room conditions.		
It is said that textiles normally contain approximately 6% moisture when stored at 70°F and 50% relative humidity (RH) without compromising barrier properties. When the environment is too dry, the pack naturally loses some moisture. This can be a critical consideration when using weight of that measurements before and after sterilization to determine wetness.		
It has been generally accepted that a weight gain of greater than 3% in absorbent materials is indicative of excess moisture in a pack. But, a wrapped pack can exhibit an overall weight loss (if it had been too dry to begin with) after being removed from the sterilizer and still have some localized wet spots within that could be missed.		
This results from the major portion of the wrap having lost some of its initial 6% moisture, prior to sterilization, when in fact a localized area of moisture could contain significantly more moisture than 6% after sterilization.		
- Ambient temperature and relative humidity (RH) should not vary in the processing and storage environments from season to season. They should remain fairly constant at 68°-73° F (20°-23° C) with the RH at 30-60%.	<input type="checkbox"/>	
- Although rarely seen, if the temperature of the air in the access (service) space behind the sterilizer is particularly chilled, that too-cool air, when filtered and drawn into the chamber during the drying phase of the cycle, could condense on the hot items producing moisture on or within the packs.	<input type="checkbox"/>	
- Are the hot processed items placed in a particularly cool area or near air conditioning vents once they are removed from the sterilizer? This too, can cause condensation.	<input type="checkbox"/>	



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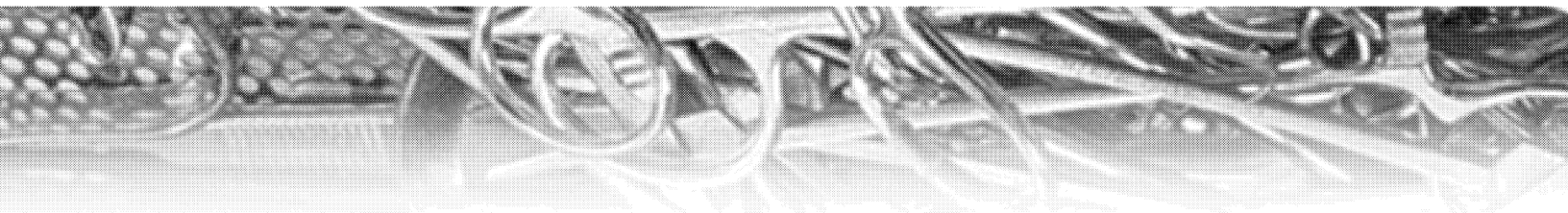
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A GUIDELINE FOR DETERMINING WET PACKS

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Hospital Supply and Central Service
12/83

...identifying and classifying pack conditions and assessing wet pack situations ...

CONTENTS

PAGE

Causes of Wet Packs	54
Evaluation of Wet Packs	55
• Water Droplets on the Exterior of a Pack	55
• Water Droplets Within a Pack	56
• Absorbed Moisture Within a Pack	57
Summary	59

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CAUSES OF WET PACKS

Aseptic techniques for surgical procedures require that all supplies coming in contact with the surgical field be sterile. An inherent, inseparable quality for sterility of supplies is a “state of dryness.” 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. The occurrence of wet packs is a source of frustration for both Central Service and Operating Room personnel. Wet pack problems can result in considerable time and money spent on reprocessing of packs, in serious disruptions in department activities (such as O.R. and Delivery Room), as well as in the fundamental risk of breakdown in the sterility of the product or of a sterile field.

The awareness of wet packs occurring in hospital-sterilized supplies has increased markedly during the last several years. In examining a number of such occurrences, it is noted that there is no single factor which stands out as the primary cause of wet packs, but rather several factors which deserve equal consideration.

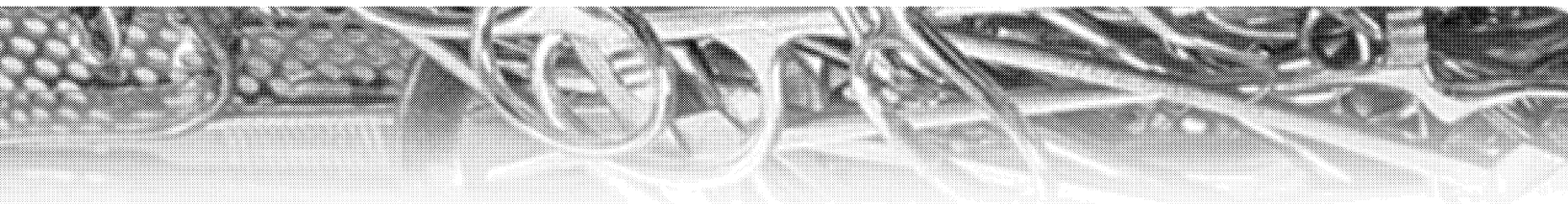
Wet pack conditions occur in various:

- types of loads (i.e., instrument sets, utensil sets, textile packs, and steam or gas sterilized plastic and paper or all plastic peel pouches).
- types and sizes of wrappers (i.e., reusable textiles of all thread counts, disposable cellulose-based, and disposable polypropylene-based).
- types and sizes of sterilizers (i.e., prevacuum steam, gravity steam, and ethylene oxide gas sterilizers)
- 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 wrap manufacturer, and the sterilizer manufacturer to all be involved to some extent in trying to correct a particular incidence of wet packs. Each of these groups has an important role to play in assuring that items are acceptable from a sterility assurance viewpoint.

The *hospital engineering department* has responsibility for maintaining adequate utilities to the sterilizer, including proper steam and water pressures, as well as recommended steam quality and pipe sizes. *Central Service* or *surgical instrument personnel* must establish and ensure that proper pack preparation procedures are carried out and that the recommendations of wrap and sterilizer manufacturers are followed. The *wrap manufacturer* has responsibility for supplying data on the sterilizing and drying characteristics and biobarrier aspects of the wrap. The *sterilizer manufacturer* is responsible for correct equipment design and procedures for proper operation. Responsibility for ensuring that the sterilizer is properly maintained and functioning according to specifications is assumed by the hospital, with assistance from the sterilizer manufacturer if there is a service contract.

Unfortunately, there are some quality assurance responsibilities which are more difficult to assign. For example, specific drying time recommendations for the combination of a particular sterilizer, wrap, and load are not always readily obtainable from either the wrap manufacturer or the sterilizer manufacturer. In general, wrap manufacturers make no reference to drying times, nor do they provide data on the relative drying characteristics of their product with respect to 140 thread count muslin (the reference standard for sterilization cycles). On the other hand, sterilizer manufacturers generally provide generic drying recommendations, which historically have been based on “standard” 140 thread count muslin wraps. General recommended times are frequently given in the directions the sterilizer manufacturer provides for sterilizer operation. Wrap manufacturers do not have access to all varieties of sterilizers for testing their products, and sterilizer manufacturers do not have the resources to test the even wider variety of wraps currently on the market. Each hospital must develop drying times and procedures tailored to their own situation. When problems arise, it is difficult to establish the contributions of hospital technique, the nature of the wrap, the load content, and the sterilizer function to the wet pack problem. Consequently, troubleshooting of wet packs can be as frustrating and time consuming for hospital personnel and for manufacturers of wraps or sterilizers.



A second factor complicating the wet pack situation is the lack of a generally accepted quantitative definition or test method for determining when a pack is considered a wet pack. Whereas standard procedures for evaluating sterilization efficacy have been established and promulgated by such groups as the Association for the Advancement of Medical Instrumentation (AAMI),¹ AORN,² and Center for Disease Control (CDC),³ similar information concerning wet packs and pack drying is not available, nor has it previously been formulated. Consequently, hospital personnel have had to use their own judgment and establish their own criteria for how much moisture constitutes “wet pack.” Probably the most common criteria used in hospitals are visually examining the exterior of the pack and feeling 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 it is possible to formulate such a set of guidelines by which packs can be evaluated for acceptable drying, it is important to review the basic concerns regarding wet packs.

The purpose of a wrap is to provide an effective biobarrier; i.e., the wrap must protect the sterile contents from sources of potential contamination. Most sterilization wraps accomplish this by acting as a tortuous path which inhibits the penetration of microorganisms through the wrap.

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 bacteria or particle of debris. When the muslin becomes wet and a continuous liquid pathway exists through the wrap, bacteria can easily be carried into the pack and tortuous pathway properties are lost. A similar situation exists to a lesser extent for wrappers other than 140 thread count muslin. Therefore, the critical question to be asked when determining if a wet pack condition exists is: *Can, or could, the observed moisture have caused a loss in the biobarrier properties of the wrap?* The answer to this question depends on the type of wrap, its individual biobarrier properties, where the moisture is located, and the quantity of moisture present.

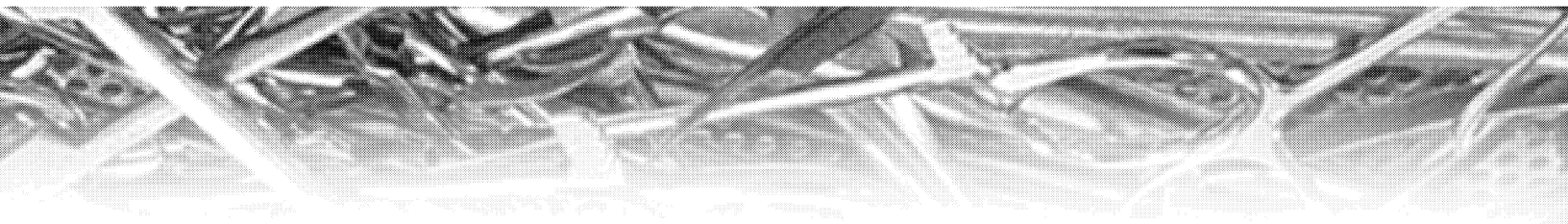
EVALUATION OF PACK CONDITIONS

When evaluating a load for wet packs, the packs should be examined for three conditions which can result in packs which are 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 outer wrap 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, and on water-repellent, nonabsorbent wraps. The occurrence of water droplets has increased significantly with the increased use of water repellent wraps. Although these wraps do not create the droplets (unlike 140 thread count muslin which absorbs and disperses steam condensate that may fall on the wrap surface), they do retain them as 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 both 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, it is necessary to evaluate if such a droplet could result in a loss of biobarrier properties of various wraps by permitting a liquid pathway for bacteria to enter the pack. To this end, several commercially available wraps 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 17 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 upon removal from the sterilizer, an inoculum of 10^8 *Bacillus subtilis* per ml was applied in 1 ml droplets to the surface of the wraps. After periods of 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. The results of the testing are shown in Table 1. Note that, 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 one-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 water-repellent disposable and one water-repellent reusable wraps, of new quality, showed significantly less penetration than the muslin wrap, but did show penetration through the one-thickness outer wrap.

Continuous plastic films provide an effective barrier against bacterial penetration. Therefore, 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 these droplets may be dislodged to fall onto packs with water-permeable wraps, the existence of droplets on even these materials is not desirable.

Although the water-repellent wraps provide significantly better biobarrier characteristics than muslin, they currently cannot be considered to be water-impermeable. Therefore, external water droplets could result in loss of wrap biobarrier properties and are considered unacceptable.

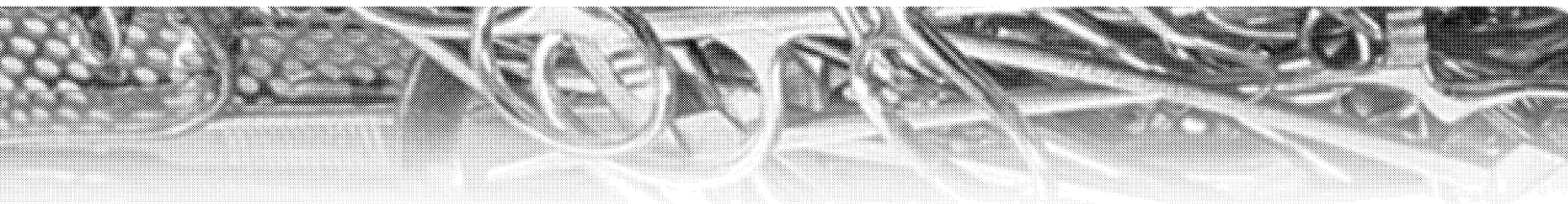
The following guideline applies for water droplets on the exterior of a pack:

Packs wrapped in water-permeable materials and sterilized by ethylene oxide or 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 cannot be displaced onto packs wrapped with water-permeable wraps.

2. Water Droplets Within a Pack

The occurrence of water droplets on the interior surface of wrapped packs is not as frequent a complaint as is external wetting, probably due in part to less visibility and observation of the water droplets. 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 wrapping material used. Moisture, in the form of droplets which occur on the interior surface or between the inner and outer wraps of water-permeable wraps, must be judged with the same criteria as were used for external wetting. The only difference between these two conditions is in the source of the liquid pathway. When water droplets are present on the interior of the pack, although sterile by virtue of the processing, it may result in 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 of ethylene oxide sterilizer into the cooler room environment. 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 should 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 properly filtered aerator.

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 is 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

Up to this point, the discussion has focused on the effect of moisture in the form of liquid droplets. A second form of moisture associated with the wet pack situation is moisture absorbed or entrained within a portion of the pack or its wrapper. It is important to realize 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).

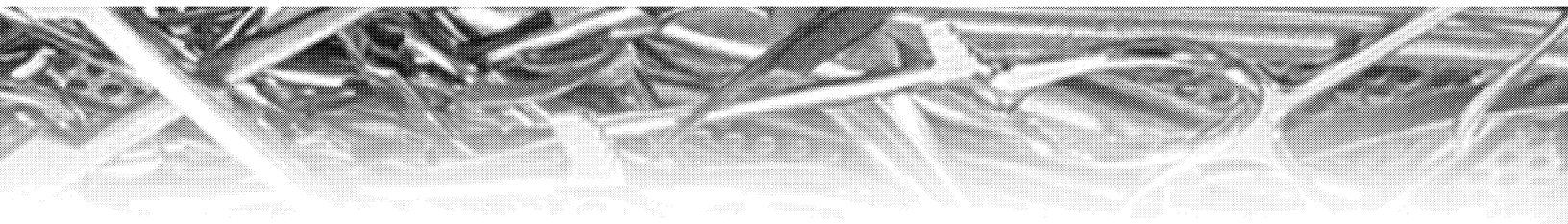
Absorbed moisture becomes a concern for hospital personnel when it occurs as a localized area of dampness in muslin wrappers, huckaback towels, or other moisture-absorptive goods within a pack. The question then becomes one of how much moisture is permissible and should the pack be considered a wet pack.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

As mentioned previously, the criterion for determining whether a wet pack condition exists is to 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. Determining acceptable levels of absorbed moisture in wraps become significantly more complex. One of the major problems is the lack of recognized standardized tests for determining adequate biobarrier properties of wraps. Current shelf life testing methods are inadequate from a methodology point of view and do not provide quantitative guidelines as to what are acceptable contamination levels. If appropriate tests were devised, maximum percent weight gain for various wrappers, following completion of the sterilization cycle, could be established. One problem with using weight gain measurements is that a wrapped pack can exhibit an overall weight loss after being removed from a sterilizer but still have small, localized wet areas. This results from the major portion of the wrap having lost some of its initial 6% moisture, whereas small, localized areas may have significantly more moisture than 6%. Until more data is available, current practices of ensuring that the external wrapper contains 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 are appropriate measures for determining acceptable quality of dryness essential for use of the packs.

Absorbed moisture which results in localized areas of dampness may also occur in pack contents. The most common example of localized dampness occurs in huckaback towels (or their equivalent) used in 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: 1) by dripping, or, 2) by evaporation and recondensation.

A 100% cotton huck towel is an extremely absorbent material which is capable of holding approximately twice its weight, or about 200 g, 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.

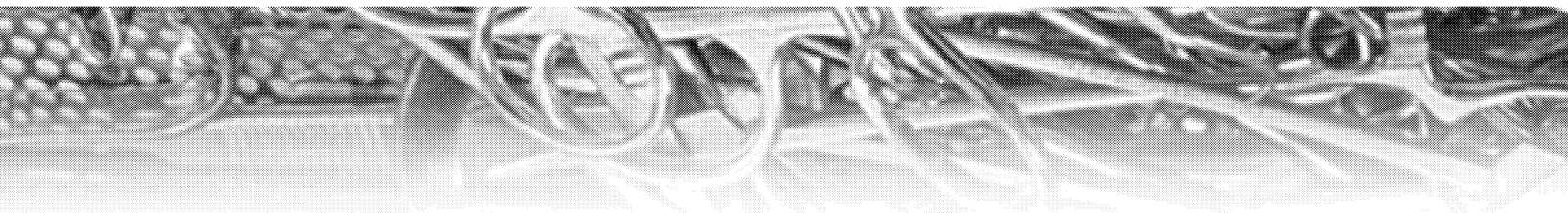
The small amount of moisture held by the huck towel vaporizes until the towel reaches equilibrium with the room environment. For a wet pack to result, the water must vaporize and recondense on the wraps or pass through the wraps and condense on a cold surface external to the pack, thus establishing a 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.

For the case of condensation on cold surfaces outside the pack, standard recommendations are to allow hot packs to cool on the sterilizer loading car or, if it is necessary to transfer them, the shelving used for cooling should be of the wire type which is well padded with absorbent material. These recommendations eliminate the possibility of external recondensation 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 acceptance of 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. Small amounts of moisture in packs are therefore acceptable in this area. However, since no quantification of the acceptable or safe level of moisture has been established, the sterilizer operator must determine a drying time for all loads which provides assured dry packs by the time they are removed from this area for storage or use. A general guideline for this processing responsibility suggests that a drying time be established for each steam sterilizer which produces packs that are completely dry after cooling at room temperature for a minimum of one hour. If a pack contains moisture at the point of use, and is observed as the pack is opened, there is no way of determining if the biobarrier characteristics of the wrap have been compromised because the pack has been subjected to multiple handling operations and storage conditions from the time it leaves the sterilizer until it is opened for use.

The following guideline applies for absorbed moisture within a pack:

A wrapped pack which has been sterilized by ethylene oxide or steam should be considered unacceptable if 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 following removal from the sterilizer.



SUMMARY

The first step in the resolution of hospital wet pack problems is the acceptance by hospital personnel, wrap manufacturers, and sterilizer manufacturers of a set of criteria by which packs are to be evaluated for acceptability. Since no such criteria currently exist, this lack of established quantitative standards for what constitutes a wet pack has resulted in significant confusion, blame, frustration, and expenditures by hospital personnel and wrap and sterilizer manufacturers. This paper has established the following criteria by which hospital personnel might 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 (i.e., 70°F and 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.)

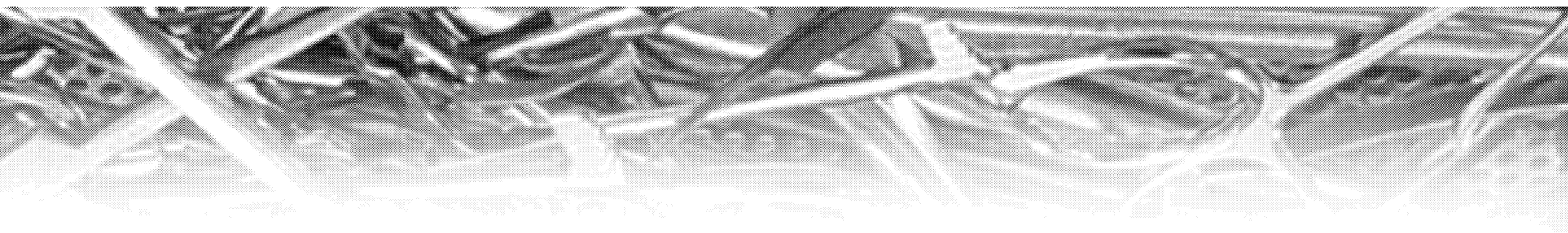
These guidelines are not intended to be the final word in establishment of wet pack criteria but serve as a starting point in development of criteria and test methodology which are scientifically defensible and at the same time practical for implementation within the hospital. This effort requires the cooperation of hospital personnel, wrap manufacturers, and sterilizer manufacturers to address these important issues. 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 wraps, be put into proper perspective.

NOTES

1. **Good Hospital Practice: Steam Sterilization and Sterility Assurance** (Arlington, VA: Virginia Association for the Advancement of Medical Instrumentation, 1981).
2. "Recommended Practices for In-hospital Sterilization," and "Guidelines for Selection and Processing of Aseptic Barrier Material," **AORN Journal**, 32 (August 1980), pp. 222-246.
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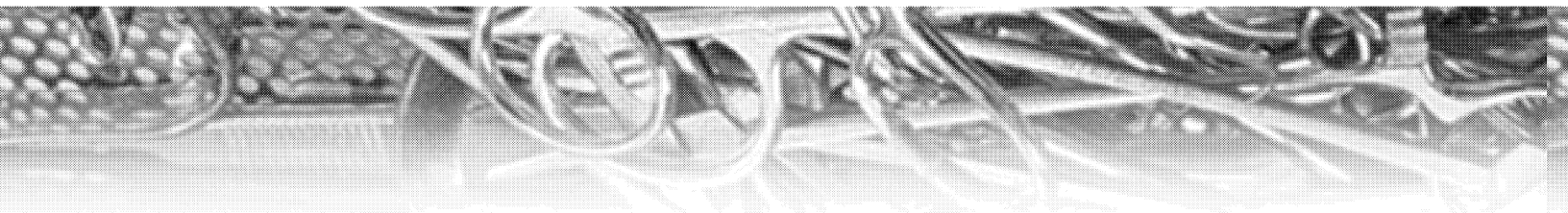


GUIDELINE TO SOLVING WET PACK PROBLEMS

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12/83

...understanding the mechanism of moisture formation and drying in the sterilizer; carefully observing the location and volume of wetness and the forms in which moisture can occur; and initiating the proper corrective actions...

CONTENTS	PAGE
Abstract61
Moisture Formation61
Drying62
Troubleshooting External Moisture63
Troubleshooting Internal Moisture65
Absorbed Moisture66
Summary68



ABSTRACT

A major responsibility of the hospital Central Service is to provide consistently sterile products to the other departments within the facility. To do this, a thorough understanding of proper pack preparation and loading techniques is required. These techniques will give maximum assurance of sterilization and minimal formation of moisture to prevent any possible compromise of sterility later during storage. The successful accomplishment of this task requires the cooperative effort of not only the personnel within Central Service, but also the other departments within the hospital. Failure by one or more departments to perform their required duties could result in the condition commonly referred to as a "wet pack." The manufacturers of sterilization equipment and of hospital products and wraps also have a responsibility to the hospital. They must see to it that their products are reliable, easy to use, and function well with other products commonly used in conjunction with their product.¹

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. The approach to isolation of the cause relies on 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, as well as on the form in which moisture can occur (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's 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 which has formed remains in the chamber during the "sterilize" phase of the steam cycle. It may be either entrapped in the moisture absorbent products or remain as droplets on the surface of nonabsorbent products.

The equation for the amount of moisture formed is:

$$C = .566 W \cdot C_p \cdot \Delta T$$

where:

W = Weight of product (lb.)

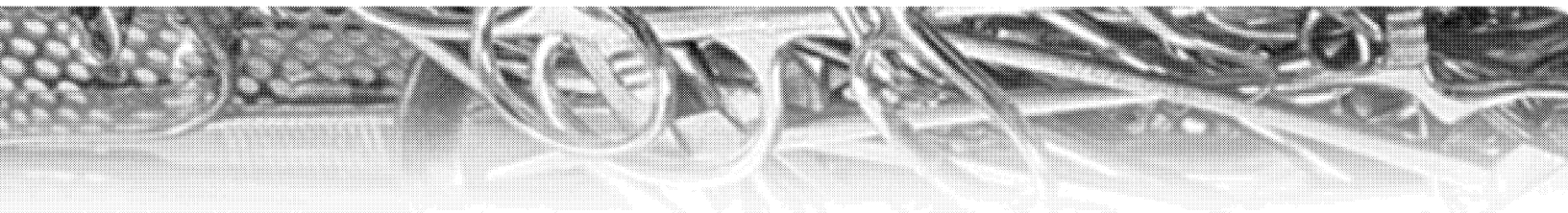
C_p = Specific heat of the product (BTU/lb. F°)

C = Quantity of condensate formed (ml)

ΔT = (Sterilization temperature - initial product temperature) (F°)

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 which is formed totals 240 ml. As the weight of the tray increases, so does the amount of moisture formed. Figure 1 shows a typical relationship between instrument tray weight and the amount of moisture formed.



The nature of the moisture which is formed (i.e., droplets, dampness, etc.) is dependent upon the materials which comprise the product. Absorptive 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 a feeling of wetness or dampness may be evident. 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 products and equipment made of metal or rubber do not absorb any of the moisture which forms during the 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, absorptive products are often placed beneath them to retain the accumulated moisture so it can be dried 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. An effective drying system must be employed to prevent such occurrences.

DRYING

Drying of a product 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.

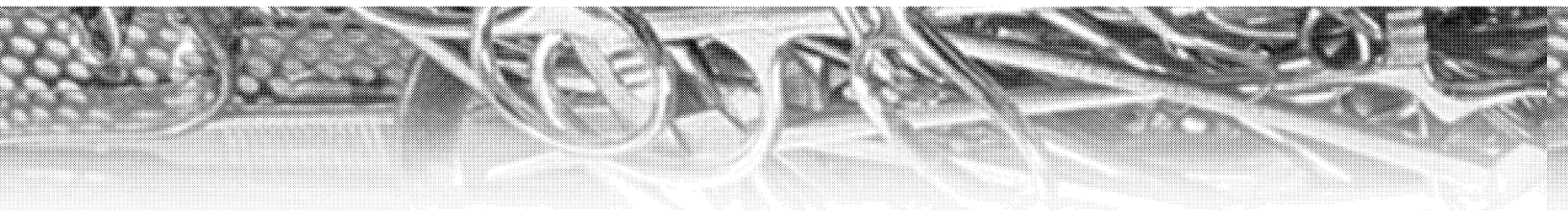
Drying begins immediately after the sterilization phase of the cycle. In the drying phase, the sterilant is exhausted quickly and various techniques such as vacuum, heat from the product, or convective heat from the walls of the sterilizer are utilized to dry the product.

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 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. Figure 2 shows the amount of moisture remaining in a 17 pound instrument tray after drying for various periods of time. 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.

A gravity sterilizer, in contrast to the prevacuum 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. The efficiency of drying 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 product where the moisture remains. The walls are maintained at temperature throughout the processing cycle and continually give off heat. Those products which are closest to the walls benefit the most, while products which 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 between packs at different locations and by as much as 20°F within the same pack from the side facing the wall to the side which is facing another pack.



The products which are 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 which 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.

Let us apply the above principles along with sound methods for pack preparation and loading technique to the resolution of wet pack problems. The process of resolving wet pack problems requires a logical progression of thought from initial discovery of wet packs until dry loads are obtained. The procedure that should be followed, regardless of sterilizer size, type, or model, is to start by evaluating and correcting any deficiencies which result in wetness on the exterior of the load. Then the interior problems can be corrected.

TROUBLESHOOTING EXTERNAL MOISTURE

External moisture is moisture which is observed on the outside of a processed load. It may appear as droplets of water which bead on nonabsorbent materials, beads of water on plastic bags, or as wet areas on muslin wrappers. This type of wet pack is most often the one which is first observed.

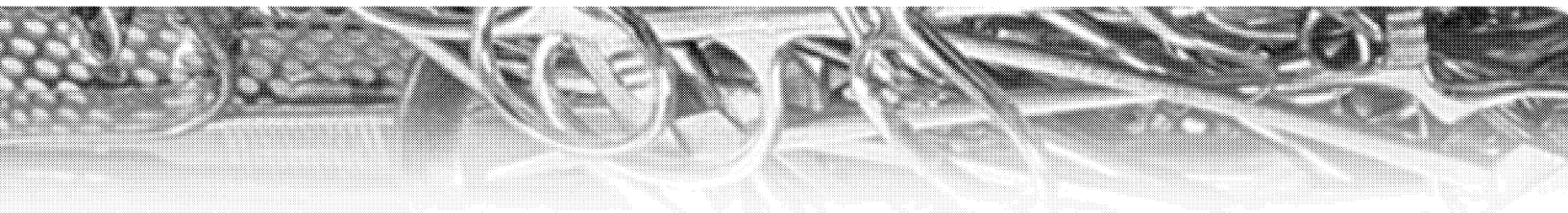
The following general guideline can be applied: *“A pack is unacceptable if there is external or visible moisture on the exterior of the tape, unless that wrap is completely impermeable to water (i.e., plastic films).”*² The concern with water-permeable wraps is that the moisture may transmit bacteria through the wrap to contaminate the inner, sterile layer of wrap. With plastic films, although bacterial penetration cannot occur unless there is a break in the film, one must be aware of the possibility that the exterior droplets may fall onto absorbent parts of the load and compromise them.

There are two ways in which external moisture may be deposited on the sterilizer load. One is localized moisture and the other is dispersed moisture (see Table 1). The location and concentration of external moisture are keys to determining the cause of deposition. Localized moisture is water droplets or wetness which occurs on the exterior of packs in specific locations in the sterilizer chamber. The occurrence of this type of moisture can usually, but not exclusively, be associated with wetting from a source external to 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 uninsulated pipes, or from improperly trapped lines. Wet steam may occur at peak operation periods and, thus, the problem may occur infrequently; or it 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 uninsulated line allows the steam in the line to cool, thus producing excessive moisture. Wet pack causes of this type should be discussed with your hospital engineer, who is responsible for assuring that an adequate volume and quality of steam are supplied to your sterilizer. Give adequate information. Provide a log of the times wet packs occur and how frequently they occur. It will make the job easier in tracking down the demands on the boiler at different periods of the day.

Wetness which is localized on the exterior of the packs at the bottom front of the chamber, especially on the bottom of the packs, is often caused by a failure of a check valve in the drain which then permits water to be drawn into the chamber through the drain port. Alternatively, a faulty jacket trap may also be responsible. A faulty jacket trap may allow water to accumulate in the bottom of the jacket and wet the pack immediately above this location. Explain in detail to your maintenance personnel the location of the wet packs as they have been observed. 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 serviceman; this is a simple and inexpensive repair.



Localized moisture can also result from water droplets which 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 dry time that was employed.

This problem could be solved by draping the product with an absorbent material such as muslin sheet or by replacing the shelving with a lighter shelf designed specifically for nonwoven wraps.

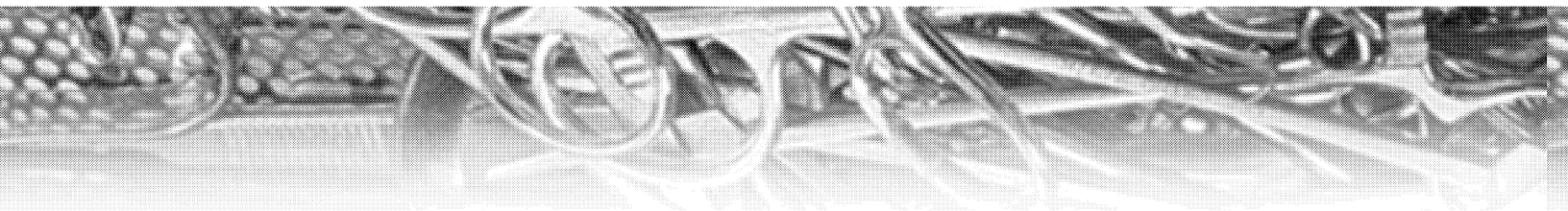
Dispersed moisture is moisture which is distributed over the entire load. It is usually indicated by a feeling of dampness in muslin wrapped items or uniform beads of water on plastic films or nonabsorbent wraps on all or most of the exterior of the products. Dispersed moisture is usually associated with either sterilizer malfunction or technique problems. Examples of these are that the drying phase of the cycle is inadequate for the size or density of the load, that the drying phase of the cycle is malfunctioning, or that the load is packed improperly.

Consider a load, which, when removed from the sterilizer is damp on the exterior. 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 serviceman, using full loads, and have been determined to be operating within specifications. Now examine carefully the size, density, and loading arrangement of the products 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 to efficient sterilization and drying. Specific guidelines have been established by STERIS Corporation,³ AAMI (Association for the Advancement of Medical Instrumentation),⁴ and the AORN (Association of Operating Room Nurses)⁵ for maximum size and density of fabric packs. They recommend 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 16 pounds (STERIS recommends 17 pounds). However, no guidelines for size and density of instrument trays or utensil sets have been established. 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. Table 2 shows the amount of moisture remaining in instrument trays of various load weights after drying times from 0 to 20 minutes. Note that 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, so also does the required drying time. Limit the size and density of trays. Separate products and use adequate size trays to allow ample room for flow of sterilant to the product during sterilization and for removal of moisture during drying. A good rule of thumb is to permit enough space so that a hand, on edge, may be slid between each pack. Remember that 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 which forms during the heating of this product concentrates in one place, namely, at the bottom of the basin. So, place an absorbent liner between basins, limit the weight of the sets (STERIS tests have shown that seven pounds is the maximum weight for utensil sets), and allow ample room between individually wrapped sets for steam penetration and efficient drying.

Improper loading technique or excessive conditioning steam can also cause wet packs in ethylene oxide (EtO) gas sterilizers. If wetness occurs on the exterior of specific items in an EtO sterilizer load; e.g., peel pouch packs or polyethylene bags, examine the way they were placed on the loading cart. These items do not absorb moisture, but they can retain it in droplet form. Proper loading techniques will correct this deficiency. Peel pouches should be placed on edge with the paper side against plastic. Polyethylene bags should be placed on the shelf so that adequate space is available between bags. Avoid creases or depressions in the product where moisture can accumulate.



If a fine, uniform mist occurs on plastic items in an EtO sterilizer, the cause is probably excessive conditioning steam or inadequate sterilizer temperature. Explain to your maintenance personnel the nature and location of the wetness you are experiencing. Again, be specific about the nature and location of the moisture when you discuss it.

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 or polyethylene bag) has moisture on the interior of the wrap or on the product, the causes can be isolated depending on the amount of moisture, the location of the moisture, and its nature.

A general guideline to evaluating the interior is: *“A wrapped pack, sterilized by EtO 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 is acceptable if it is not of sufficient volume to form droplets which 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 earlier during our review of thermodynamics. If a large concentration of metal is placed in a small area, all of the moisture which is 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. The use of an insufficient size 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 in the recommended time.

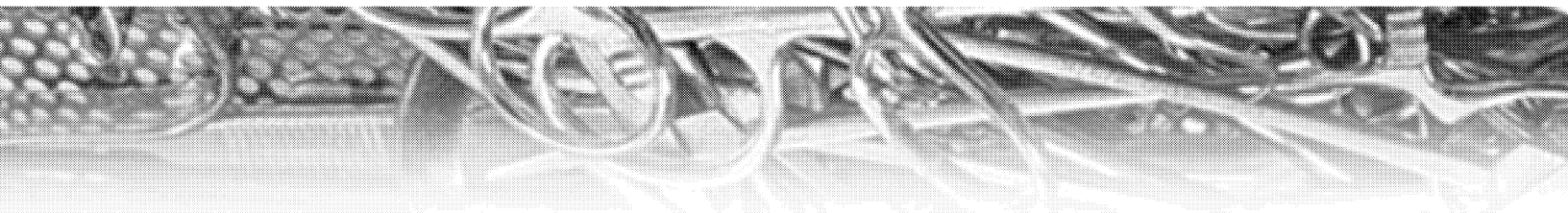
Another very common problem which is encountered when processing utensil sets is entrapment of water in the lip or depression of the utensils. In these instances, the heat from the metal is not sufficient to evaporate the water during drying, and a puddle remains at that site. When the set is removed 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 poor design of basins and pans often results in water entrapment regardless of the orientation of the product.

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 do so to collect the least 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 sterilization processing. If you have purchased a product which cannot be oriented in such a way that water is not retained, consider phasing the product out.

Also consider that if items which are to be sterilized are placed in the sterilizer when wet, they are more likely to be wet at completion 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 which 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, 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 result in excessive moisture on both the interior and the exterior of wrapped products. Some causes of an improperly operating system are constrictions in the drain line or 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. An extensive list of symptoms and probable causes of internal moisture is available in Table 3.

Internal wet packs can also occur in EtO sterilized items. The causes for wetness may be either technique-related or associated with sterilizer malfunction.



Let us say a load is removed from an EtO sterilizer and moisture is observed on the interior of bags of respiratory therapy tubing or on peel pouches. We know that the moisture in the bag is sterile by virtue of the processing it has just completed. But is it acceptable? Reference 1 indicates that droplets, depending on size and volume, are undesirable but acceptable from a sterility point of view since the moisture cannot provide a path for bacteriological penetration. Excess interior moisture is probably due to an excess of product in the bag or pouch, the sterilizer producing too much conditioning steam, the product being wet when pouched, or the temperature of the product being dropped. EDITOR'S NOTE: If moisture in EtO sterilized peel pouches is due to items that were not thoroughly dry before packaging and processing, the moisture may be ethylene glycol, an undesirable by-product of combining EtO and water. The sterile product must be aerated and reprocessed before use.

First, try reducing the amount of product in the bag or pouch or preheating the load. Large, dense items, especially plastic or metal, retain moisture on their surfaces in droplet form. These drops are extremely difficult to remove during the post-vac phase of an EtO cycle. Heating the product before sterilization so that steam will not collapse on the product or reducing the mass to reduce condensation are two approaches to this problem.

If the small, light products in the pouches are also wet, then the sterilizer may be producing too much conditioning steam or the product was wet when pouched. First, be sure the product is clean and dry before it is packaged. A wet product will not be dried by processing. Additional steam is required to heat the extra moisture. If the product is clean and dry when packaged, the sterilizer may be putting in excessive steam during conditioning. Large water droplets on the product or on the packaging material are indicative of this malfunction. Request that the serviceman check the conditioning steam adjustments on your sterilizer.

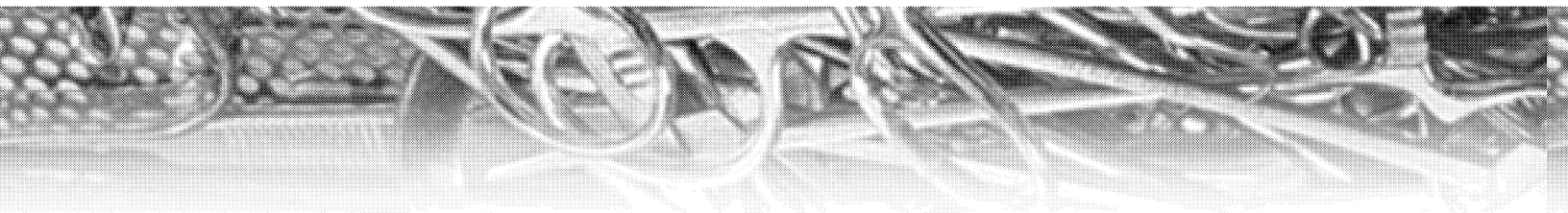
If an EtO load is permitted to cool quickly to room temperature, internal wetness may result. Do not permit a loaded sterilizer cart which has been processed with EtO to remain in the chamber with the door fully open or in a cool room for any period of time. In addition to allowing undesirable outgassing of EtO into the room, it permits the product to cool. In doing so, the warm moist air surrounding the product can no longer retain as much moisture and, thus, water condenses on the cool surfaces of the product. Transfer EtO processed items to a properly operating, heated, and well-vented aerator immediately upon removal from 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 suggests that packs which are EtO or steam sterilized be considered unacceptable if 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.² 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 which were conducted on full loads of 17 pound instrument trays which were wrapped in double wraps of nonabsorbent, disposable wrap or in 140 thread count muslin. They were processed, 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. As shown in Table 4, the moisture remaining 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 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 which is free from direct drafts from air conditioning. During this period, handling should be minimized and care should be taken not to place them on cold surfaces. If a sterilizer loading cart is used, it is best to allow the packs to remain on the warm loading cart during this period of time.



Perceptual Evaluation of Huck Towels is Either Muslin or Nonwoven Wrapped Trays

D - Dry

L - Localized perception of dampness

F - Definite feel of dampness in localized area

T - Damp to touch, not visibly wet

V - Visibly wet area

W - Overall extremely wet

If visible moisture is evident after the packs are cooled, first review the drying time you have selected. If 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 which 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 which are confined to a small tray may require preheating if processed in a gas sterilizer; or they may be placed in a larger tray if steam sterilization is preferred.

Sterilizer malfunction can be tested by a qualified serviceman. An analysis of the vacuum level should be done with both an empty chamber and full load of products in the chamber. The serviceman 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 continues. A more extensive list of the symptoms and probable causes of internal moisture are outlined in Table 3.



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. This article, although not exhaustive, discusses the more common wet pack problems that are experienced in hospitals and suggests methods for corrective action.

Notes

1. Ryan, P. "Wet Pack Syndrome: Causes and Cures," **Particulate and Microbial Control**, 1 (September/October 1982) p. 73.
2. Karle, D. and Ryan, P. "Guidelines for Evaluating Wet Packs," **AORN Journal**, p. 38 (August 1983).
3. Perkins, J. **Principles and Methods of Sterilization in Health Sciences**, 2nd ed. (Springfield, IL: Charles C. Thomas, 1969), p. 205.
4. **Good Hospital Practice: Steam Sterilization and Sterility Assurance** (Arlington, VA: Virginia Association for the Advancement of Medical Instrumentation, 1981).
5. "Guidelines for Selection and Processing of Aseptic Barrier Material," **AORN Journal**, 32 (August 1980), pp. 222-246.

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