CE ONLINE

Proper Handling Techniques for Sterilization Wrap and Wrapped OR Trays

A Continuing Education Activity
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Proper Handling Techniques for Sterilization Wrap and Wrapped OR Trays

(An Online Continuing Education Activity)

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OVERVIEW

An expected outcome for all surgical patients is that they are free from the signs and symptoms of infection.

Today, surgical site infections (SSIs) represent an important health care concern, because they are a source of patient morbidity and mortality and a contributing factor to increased health care costs. A key strategy for reducing the risk of SSIs is the provision of surgical instruments and other devices that are free from contamination at the time of use; an important aspect in implementing this strategy is appropriate packaging of the items for sterilization. As a barrier material used in the perioperative practice setting, sterilization wrap must provide an effective barrier to microbial penetration, protect the packaged items from contamination during handling, and allow aseptic delivery of the contents to the sterile field. Because the materials used for sterilization wraps continue to evolve, all members of the perioperative team should be aware of the various products available today in order to select and use them properly. Personnel should also understand proper handling techniques for sterilization wrap and wrapped operating room (OR) trays to protect patients from developing SSIs. This continuing education activity will provide a brief overview of the clinical impact and economic burden of SSIs today. The key characteristics of sterilization wrap materials that help reduce the risk for SSIs, with a focus on nonwoven double layer sterilization wrap, including test data that should be obtained from the manufacturer, will be reviewed. Clinical considerations related to proper care and handling techniques for sterilization wrap and wrapped OR trays, based on professional standards and recommended practices, will be discussed.

OBJECTIVES

After completing this continuing education activity, the participant should be able to:

1. Describe the clinical and economic implications of SSIs in today's health care environment.
2. Identify the important characteristics of sterilization wrap products that reduce the risk for SSIs.
3. Identify manufacturer test data used to evaluate the effectiveness of sterilization wrap products.
4. Describe general guidelines for proper handling of sterilization wrap.
5. Discuss key clinical considerations related to the proper use, care, and handling of wrapped OR trays.

INTENDED AUDIENCE

This continuing education activity has been designed for sterile processing department technicians, perioperative nurses, and other health care professionals involved in the preparation of surgical instruments and equipment for sterilization and who are interested in learning more about proper handling techniques for sterilization wrap and wrapped OR trays.

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INTRODUCTION

Today, the development of a surgical site infection (SSI) remains a common complication of care and represents one of the leading causes of postoperative morbidity and mortality; in addition, SSIs are also associated with significant additional costs for both hospitals and health care systems.[1] An expected outcome for every surgical patient is that he/she is free from the signs and symptoms of infection.[2] In this regard, sterility assurance is a critical cornerstone of effective surgical patient care. The ongoing challenge of upholding the integrity of the sterilization process is further affected by leaner budgets and shrinking staff sizes. As sterilization wrap products continue to evolve, perioperative personnel should have an understanding of how these products, as well as techniques for proper handling of wrapped trays in the operating room (OR), can increase efficiency while maintaining the same high standards of infection control in order to achieve positive patient outcomes.

THE CLINICAL AND ECONOMIC IMPACT OF SSIs TODAY

In the United States, approximately 200,000 SSIs occur every year, accounting for 20% of all health care-associated infections (HAIs), second only to urinary tract infections.

In a study done in 2009, SSIs occurred in 2% of all surgical procedures and overall were responsible for 20% of all HAIs. SSIs extended hospital stays by 9.7 days and increased costs/admission by $20,842. In the aggregate, SSIs resulted in an additional annual increase of 406,730 hospital days at a cost exceeding $900 million. In addition SSIs resulted in 9,161 readmissions that cost over $700 million in care delivered.[3]

Reducing the incidence of surgical site infections (SSIs) is a major initiative for all health care organizations as this contributes to complications that increase cost to the facility and the patient, increase the length of stay in the hospital and have a negative impact on patient satisfaction and the reputation of the health care facility.

The clinical impact of SSIs directly affects their economic impact. While the costs associated with an SSI vary depending on the type of procedure as well as the type of pathogen, estimates range from $3,000 to $29,000 per infection; furthermore, SSIs account for significant costs that could potentially account for up to $10 billion annually in total health care expenditures.[4] As a result, the following initiatives are currently in place to improve the quality of care by incentivizing health care facilities to reduce preventable medical errors, including HAIs and SSIs.

- Reimbursement from the Centers for Medicare and Medicaid Services (CMS). Since 2009, hospitals are no longer reimbursed by CMS for the additional costs of care associated with HAIs.[5] The acute-care Inpatient Prospective Payment System final rule, which updated Medicare payments to hospitals for fiscal year 2009, provided additional incentives for health care facilities to improve the quality of care provided to Medicare patients by the inclusion of payment provisions to reduce preventable medical errors. In particular, if a condition is not present upon admission, but is acquired during the course of the patient's hospital stay, Medicare no longer pays the additional costs of the hospitalization and care;

in addition, the patient is not responsible for these costs and cannot be billed. Since this time, hospitals have been encouraged to prevent adverse events and improve the reliability of care provided to Medicare patients.

CMS issued a final rule that updated fiscal year 2012 payment policies and rates for hospitals on August 1, 2011.[6] This final rule implemented statutory provisions of the 2010 Affordable Care Act, as well as other federal legislation; it continues a payment approach that incentivizes hospitals to adopt practices that reduce errors and prevent patients from acquiring new illnesses or injuries during a hospital stay. This approach is part of a comprehensive strategy that is being implemented across the Medicare payment system, intended to decrease overall costs by improving how care is delivered and places greater emphasis on the prevention of HAIs in general acute care hospitals.

- The Joint Commission.[7] Preventing HAIs continues to be a focus of The Joint Commission. Goal 7 of the 2013 Joint Commission National Patient Safety Goals (NPSGs) is to reduce the risk of HAIs and SSIs by compliance with current hand hygiene guidelines and implementing evidence-based prevention practices.

KEY CONSIDERATIONS RELATED TO STERILIZATION WRAP IN PREVENTING SSIs

Overview

Microbial contamination of the surgical site is a prerequisite for the development of an SSI.[8] During a surgical or other invasive procedure, the wound is at risk for contamination from both endogenous and exogenous microorganisms, some of which have become resistant to current treatment modalities; furthermore, the risk of an SSI increases with the dose of bacterial contamination and the virulence of the bacteria. Inadequate sterilization of instruments is recognized as a factor that may lead to an SSI.[9] While there are other patient factors (eg, altered immune response, remote site infections, colonization with microorganisms, poor nutritional status, cigarette smoking) that increase the patient's risk for development of an SSI that perioperative personnel cannot control, proper instrument sterilization is a factor that can be addressed in the practice setting and also has the potential for a significant impact on the prevention of surgical site infections.

As noted, one important measure for preventing wound contamination and subsequently reducing the risk of SSIs is to provide surgical instruments and other devices that are free from contamination at the time of use.[10] The appropriate selection and use of sterilization wrap and proper handling of wrapped OR trays are key components in providing sterile surgical instruments and supplies, as an effective barrier fabric provides a means of protecting patients from disease transmission.

Critical Characteristics of Sterilization Wrap

The United States Food and Drug Administration (FDA) regulates sterilization packaging systems intended for use in health care facilities as Class II medical devices.[11] The FDA uses the term "medical sterilization packaging systems" to refer to sterilization wraps,

sterilization packs, sterilization pouches, sterilization containers, sterilization trays, and sterilization cassettes, including related components such as trays, holders or mats, used by health care facilities to package and sterilize medical devices intended for either single use or reuse. Manufacturers of sterilization packaging systems intended for the terminal sterilization of medical devices in health care facilities must submit and have cleared a premarket notification in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act before introduction of the product to the market. The performance data that need to be provided in the 510(k) submission include the following:

- Sterilant penetration;
- Package integrity;
- Maintenance of package integrity;
- Drying and aeration;
- Material compatibility; and
- Biocompatibility.

Sterilization wrap should ensure the integrity of the sterilized contents until the package is opened for use; it should also permit aseptic delivery of the contents to the sterile field.[12] Materials selected for use as a sterilization wrap should be safe; meet the identified needs of the facility; and be appropriate for the items to be sterilized. Therefore, key characteristics of an effective sterilization wrap include that it should:[13]

- Provide an adequate barrier to microorganisms or their vehicles, particulates, and fluids;
- Be suitable for the items being sterilized;
- Maintain the sterility of the contents until the package is opened;
- Allow the sterilant to penetrate, ie, to come into direct contact with the item and surfaces, and also permit removal of the sterilant;
- Be free of toxic ingredients and nonfast dyes;
- Permit aseptic delivery of the contents to the sterile field (eg, minimal wrap memory);
- Allow for complete and secure enclosure of the item(s);
- Protect the contents of the package from physical damage (eg, stacking, compression);
- Allow a method of sealing that results in a complete seal and provide adequate seal integrity;
- Be resistant to tears, abrasions and punctures; prevent the transfer of microorganisms;
- The seal is tamper-proof and able to seal only once;
- Permit adequate air removal;

- Be low-linting;
- Allow the contents of the package to be identified;
- Be large enough to evenly distribute the mass;
- Allow ease of use by personnel preparing and/or opening the package;
- Be shown by value analysis to be cost-effective; and
- Include manufacturer's instructions for use.

The characteristics of sterilization wrap and their clinical goals are outlined in Table 1.

Table 1 – Characteristics and Clinical Goals of Sterilization Wrap[14]

Characteristics	Clinical Goal(s)
Barrier effectiveness	Ability to prevent microbial penetration and maintain sterility of surgical pack and prevent penetration of liquids (ie, repellent)
Penetrability (steam)	Allows steam to penetrate
Penetrability (eg, ethylene oxide; low temperature gas plasma)	Allows sterilizing gases or plasmas to penetrate
Aeration	Permits aeration post-sterilization (ie, allows ethylene oxide to dissipate)
Non-toxic	Promotes patient and personnel safety
Minimal wrap memory	Permits aseptic delivery of the contents to the sterile field
Drapeability	Conforms to equipment pack; contours smoothly and closely
Flexibility	Adequate sizes to accommodate any sized or shaped item
Puncture resistance	Resists puncture
Tear strength	Resists tears
Toxicity	Non-Toxic
Odor	Odorless
Low linting	Minimal linting during use
Cost	Low cost during use
Waste disposal	Adheres to local and state solid waste disposal regulation

Types of Sterilization Wraps[15,16]

Barrier fabrics used for sterilization wraps are divided into two general categories: woven and nonwoven.

- Woven wrap. Originally, 140-thread count muslin cloth was used for sterilization wraps. The advantages of this material included that they were soft, reusable, inexpensive, absorbent, and drapeable; a significant disadvantage was that the cloth was woven and therefore, did not provide complete protection against microbial penetration. In order to reduce the risk of microbial contamination of the contents inside a wrapped package, hospitals initiated double sequential wrapping.

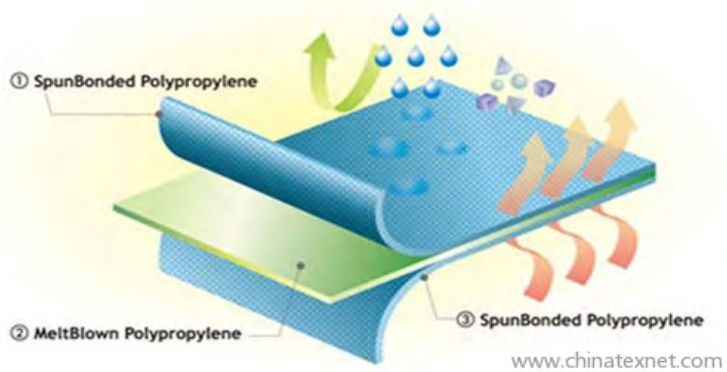
  Tightly woven polyester-cotton blends, which are chemically treated, were developed to improve the barrier properties of the material. Fabrics constructed of polyester microfibers are durable, cool, breathable, and water-repellant. In general, the barrier effectiveness of waterproof reusable fabrics deteriorates with multiple processing; repeated laundering and sterilization gradually disrupt the

integrity of the fabrics. As the fabrics experience wear through repeated swelling and shrinking during laundering, the threads begin to loosen, which permanently alters their ability to protect the patient and members of the surgical team. Tests have shown that treated materials lose their barrier quality after being laundered and sterilized 75 times.

- Nonwoven wrap. In the 1960s, nonwoven materials were introduced; these products provided an effective tortuous path that protected against microbial contamination and, when treated, also provided liquid resistance capability. However, the material used for these products was derived from cellulose and did not have adequate strength; as a result, sequential wrapping was still necessary.

  The introduction of polypropylene allowed the development of wraps that possess strength, barrier, and repellent properties. Sterilization wraps composed of a trilaminate nonwoven spunbond/meltblown/spunbond (SMS) fabric are available today (see Figure 1). This fabric consists of meltblown polypropylene between two layers of spunbonded polypropylene; the "spunbond" provides the strength and the "meltblown" provides the barrier. Double wrapping – sequentially with two nonwoven, disposable wrappers or simultaneously with a single fused, nonwoven disposable wrapper - provide excellent protection from microbial contamination and therefore a reduced risk of compromising the sterilization process. Both wrapping techniques provide a tortuous pathway to impede microbial migration and permit a sterilized pack to be opened aseptically on the sterile field. The simultaneous double-wrapping technique with a fused or double bonded wrapper also saves time because wrapping is performed only once.

Figure 1 – SMS Sterilization Wrap

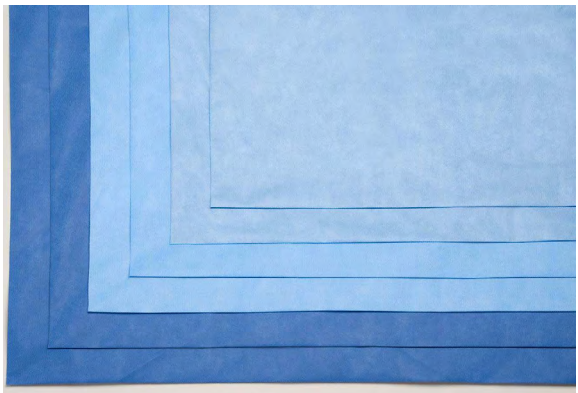


In a study conducted to test a double layer sterilization wrap product before introducing it to the hospital's sterile processing unit, 400 packs containing 1,199 items were prepared; half of the packs were wrapped in multi-use linen and a single use sterile wrap; half were wrapped in a single use, nonwoven double layer sterilization wrap.[17] The time of wrapping was measured on a series of 50 packs (25 using each product), wrapped by one experienced person; the packs were unwrapped by an operating room nurse, which again was timed. The results

showed that the average time taken to wrap the test tray with the double wrap (the linen and sterile wraps) was 56.4 seconds compared with 32.4 seconds with the single use, double layer wrap. Unwrapping of the packs wrapped with the single use, double layer wrap was also faster than unwrapping the double- wrapped packs (5.02 seconds versus 6.92 seconds, respectively). The authors concluded that wrapping sterile items using a double layer nonwoven sterile wrap may lead to significant cost savings in both labor (ie, time to wrap) and consumables (ie, linen and recycling costs).

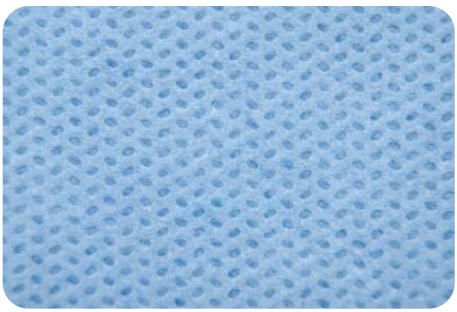
Today, SMS sterilization wrap is available in various weights and sizes; in many systems, the basis-weight selection process is streamlined through a color-coding system and identification printing on each individual wrap (see Figure 2). The distinguishable color differences between various weight wraps allows for quicker wrap selection and less misidentification, which result in reduced product waste and improvements in staff efficiency.

Figure 2 – Sample Color-Coding System for Basis-Weight Selection Process



SMS sterilization wraps are also available with different bond patterns. The bond pattern, specifically uniformity in a pattern, is key to providing a good, clear view of any potential tears or holes. Figure 3 shows the differences in bond patterns between two nonwoven double layer SMS sterilization wraps.

Figure 3 – Sample Bond Patterns of Nonwoven, Double layer Sterilization Wraps



This is an important point, as routine detection methods to inspect and evaluate surgical fabrics for breaches before using the contained instruments may not always be effective. Because the sensitivity of the inspection process for detecting defects in sterilization wrap has not been established, a study was conducted in which 90 sterilization wraps were divided into two groups: one with no defect and one with six sizes of defects ranging from 1.1 to 10.0 mm in diameter; the puncture-type defects were created using nails of a known diameter.[18] All of the wraps were evaluated by personnel for evidence of a breach. The detection rates ranged from 6.7% to 96.7% from the smallest to largest defects, respectively. The potential for bacterial transmission through the defects in the wrap was also evaluated. The results demonstrated that contaminated nails of the smallest size transmitted bacterial contaminants through the wrap during the creation of the puncture defects. The authors concluded that substantial perforations in sterilization wraps are frequently missed when evaluated with commonly used screening techniques. Defects with a diameter approximately that of a pencil (6.7 mm) were missed 18% of the time, although contamination can be transmitted by a nail with the diameter of a pin (1.1 mm). Furthermore, these results demonstrate that commonly used procedures to evaluate breaches in sterilization wrap, ie, direct visual inspection, have low sensitivity in detecting puncture-type wrap breaches and therefore raise questions about the effectiveness of these methods.

Compatibility with Specific Sterilization Processes[19]

As noted, one of the important characteristics of sterilization wrap is that it should be compatible with the specific sterilization process(es) for which it is designed, ie, ensure that the items to be packaged can be sterilized by specific sterilization methods. The criteria for sterilization wrap related to specific sterilization modalities are outlined below.

- Steam Sterilization
  - Packaging systems for steam sterilization should allow adequate drying.
  - The efficacy of steam sterilization can be affected by several factors, such as humidity; altitude; packaging materials and contents; load; position of items within the sterilizer; the size, weight, and density of the pack or container; and the parameters of the sterilization cycle. Perioperative personnel should follow the manufacturer's written instructions for each packaging system used for steam sterilization.
- Ethylene Oxide (EO)
  - Packaging systems for EO sterilization should:
    - Be permeable to EO gas, air, and moisture;
    - Permit aeration;
    - Be constructed of a material that is recommended by sterilizer and sterilant manufacturer; and
    - Maintain material compatibility with sterilization process (ie, are non-biodegradable).

- Woven and nonwoven sterilization wrap are permeable to EO and do not impede rapid aeration of the contents. However, woven materials may absorb a large amount of the relative humidity that is required for EO sterilization; this may prevent adequate hydration of microorganisms for penetration of EO gas to all surfaces of the package contents.

- Low-Temperature Gas Plasma
  - Packaging systems for low-temperature gas plasma should:
    - Permit sterilizing plasmas to penetrate the packaging materials;
    - Be compatible with the sterilization process (ie, are nondegradable; nonabsorbable);
    - Be constructed of a material that is recommended by the sterilizer manufacturer; and
    - Be used according to the packaging manufacturer's written instructions.
  - Because low-temperature gas plasma sterilization is affected by absorbable packaging materials (eg, textile wrappers or porous wrap), both the packaging and sterilizer manufacturer's written instruction should be followed. The absorption of the hydrogen peroxide (ie, the plasma sterilant) by porous wrap could have an adverse effect on the efficacy of the sterilization process.

- Ozone
  - Packaging systems for ozone sterilization should comply with the sterilizer manufacturer's written recommendations. Packaging materials that are not intended for use in ozone sterilizers may compromise the sterilization process. Uncoated nonwoven material is a suitable wrap material for ozone sterilization.

Industry Test Data

In order to select and use sterilization wrap appropriately, perioperative personnel should request and review important test data from the manufacturer, as briefly described below.

- Grab Tensile Strength.[20] Grab tensile strength represents a fabric's resistance to breaking when pulled apart. In the test, force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile strength – is measured in pounds of force (lbf). Higher numbers indicate that the fabric will resist breaking when being pulled apart or stressed in opposing directions. Sample test result data are outlined in Table 2.

Table 2 – Sample Test Result Data: Grab Tensile Strength

Sterilization Wrap Weight	Average Grab Tensile Strength (lbf)
Very heavy weight	110.8
Heavy weight	81.8
Moderate to heavy weight	81.7
Light to moderate weight	65.2
Light weight	45.2
Very light weight	42.1

- Bursting Strength (Mullen Burst Test).[21] Bursting strength represents a fabric's ability to resist puncture by a blunt object and is measured in pounds per square inch (psi). The higher the bursting strength, the less likely a blunt object will cause a hole or tear in the wrap. Sample test result data are outlined in Table 3.

Table 3 – Sample Test Result Data: Burst Strength

Sterilization Wrap Weight	Average Bursting Strength (psi)
Very heavy weight	109
Heavy weight	82.4
Moderate to heavy weight	89.1
Light to moderate weight	96.9
Light weight	51.2
Very light weight	55.3

- Trapezoidal Tear Strength.[22] Trapezoidal tear strength represents a fabric's resistance to tearing when an initial tear exists; it is also measured in pounds of force (lbf). The higher the tear strength, the more the wrap will resist tearing. Sample test result data are outlined in Table 4.

Table 4 – Sample Test Result Data: Trapezoidal Tear Strength (lbf)

Sterilization Wrap Weight	Average Trapezoidal Tear Strength (lbf)
Very heavy weight	34.7
Heavy weight	27.5
Moderate to heavy weight	29.8
Light to moderate weight	22.4
Light weight	14
Very light weight	13.9

- Sterilization Validation Studies.[23,24] As outlined above, sterilization wrap should be compatible with, and also designed and approved for use with, the specific sterilization technologies used; it should also be able to withstand the physical conditions of the various sterilization processes.

Perioperative personnel involved in the selection and use of sterilization wrap should request, review, and be familiar with the manufacturer's written sterilization validation studies for the various types of sterilization methods (eg, steam, EO, and low temperature gas plasma).

An example of sterilization validation studies for various low temperature hydrogen peroxide gas plasma sterilization systems are outlined in Table 5. (Note: always refer to the manufacturer's data for specific sterilization wrap systems.)

Table 5 – Sample Validation Studies with Low Temperature Hydrogen Peroxide Gas Plasma Sterilization Systems

Cycle	Intended Load	Maximum Recommended Chamber Load
Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: – An inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens – An inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens	10.7 pounds
Advanced Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: – An inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens *– OR –* – One single-channel flexible endoscope with or without a silicone mat and no additional load; the flexible endoscope may contain a single- channel Teflon®/polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter	10.7 pounds
Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: – An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens (a maximum of 5 lumens per tray per sterilization cycle)	21.4 pounds
Flex Cycle	One or two single-channel flexible endoscope(s) with or without a silicon mat and not additional load; the flexible endoscope may contain a single-channel Teflon®/ polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter (a maximum of 2 flexible endoscopes, one per tray per sterilization cycle)	12.2 pounds

Express Cycle	Non-lumened reusable metal and no-metal medical devices that require surface sterilization, or sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens	10.7 pounds
Duo Cycle	One or two single-channel flexible endoscope(s) with or without a silicone mat and no additional load; the flexible endoscope may contain a single-channel Teflon®/ polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter	13.2 pounds
Lumen Cycle	Reusable metal and non-metal medical devices, including up to 20 lumens of the following dimensions per chamber load: – An inside diameter of 1 mm or larger and a length of 125 mm or shorter – An inside diameter of 2 mm or larger and a length of 250 mm or shorter – An inside diameter of 3 mm or larger and a length of 400 mm or shorter	19.65 pounds
Non Lumen Cycle	Non-lumened reusable metal and non-metal medical devices	19.65 pounds
Flexible Cycle	Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of the two following configurations: 1. Two trays, each containing a flexible endoscope with a light cord (if not integral to the endoscope) and mat with no additional load 2. One tray containing a flexible endoscope with a light cord (if not integral to the endoscope), mat, and an additional tray containing non-lumened medical devices The flexible endoscope(s) may contain either: – A single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter – Two lumens, with one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter	24 pounds

- Sterility Maintenance Data. Perioperative personnel should also evaluate and test the performance data of each packaging system and use this information to determine that conditions for shelf life, transport, storage, and handling can be met.[25] The packaging system compatibility with the intended sterilization process(es) and existing equipment should be verified prior to purchase.

The manufacturer should provide data demonstrating the product's microbial barrier effectiveness, specifically, current event-related sterility maintenance information as well as time-related sterility maintenance information on the sterilization wrap (eg, 30 days, 180 days).[26] These sterility maintenance studies should be conducted by an independent laboratory.

CLINICAL CONSIDERATIONS IN HANDLING TECHNIQUES FOR STERILIZATION WRAP AND WRAPPED OR TRAYS

In order to protect the integrity of all wrapped, sterilized items and improve patient safety, perioperative personnel should handle sterilization wrap as well as wrapped OR trays and other items properly. Most manufacturers of sterilization wrap specify that their specific wrap products should be used in accordance with the preparation, wrapping, and sterilization chamber loading guidelines and recommendations outlined in:

- American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.*[27]
- ANSI/AAMI ST41: *Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness.*[28]
- The current Guidelines for Perioperative Practice (AORN) guideline for:
    - Instrument Cleaning;[29]
    - Selection and Use of Packaging Systems for Sterilization;[30] and
    - Sterilization.[31]

Perioperative personnel should always follow the manufacturer's written instructions for use for the specific wrap used in their facility. Some general guidelines regarding the use of sterilization wrap and handling wrapped OR trays are outlined below.

General Guidelines for the Use of Sterilization Wrap and Wrapped OR Trays

- Indications for Use/Warnings
    - Sterilization wraps should be used only for the sterilization modalities as indicated by the manufacturer. For example, some sterilization wraps may be indicated for use with pre-vacuum steam, EO, or low-temperature gas plasma sterilization modalities and may not be intended for use with dry heat, gravity steam, or radiation sterilization methods.
- Precautions
    - The package containing sterilization wrap should not be opened with a knife, as this can easily damage the wrap. As noted, personnel should confirm that all medical/surgical devices intended to be enclosed with any sterilization wrap are compatible with and indicated for sterilization via the modality and parameters described in the wrap's specified instructions for use. The written instructions from the manufacturer of the device to be sterilized

should also be consulted, as some devices may require special packing configurations or other sterilization considerations.

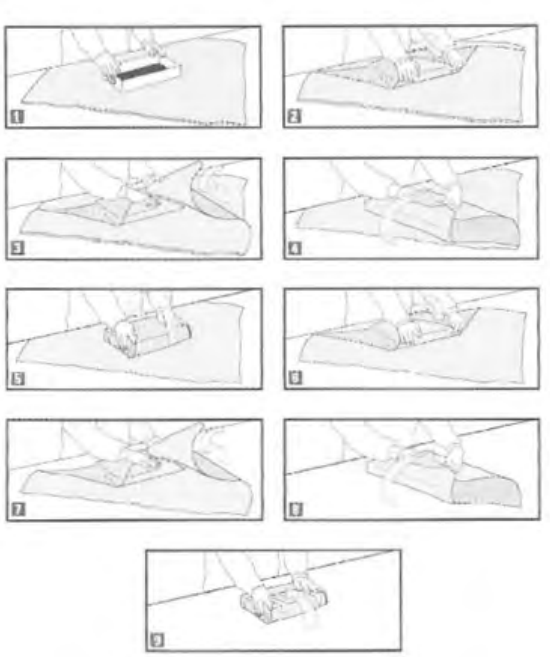
- Sterilization wrap should not be used in the presence of flammable anesthetics.
- If wrapped devices are to be transferred between facilities for sterilization and/or storage, check with the wrap manufacture for recommendations regarding the use of an additional covering to protect wrapped devices from contamination.

- Storage and Processing Prior to Use
  - The storage location for sterilization wraps should be clean, dust free, and away from fluorescent or ultraviolet light.
  - The first in, first out (FIFO) stock rotation method should be used.
  - The wrap should always be inspected closely for damage or any extraneous matter prior to use; if any type of damage or defect is detected, the wrap should be discarded.
  - The item(s) to be wrapped should be thoroughly clean and dry items to be wrapped.
  - Additional considerations related to storing and processing packing materials so that they maintain the qualities required for sterilization include:[32]
    - Reusable woven textile materials should be laundered between every use for rehydration. Resterilization without relaundering can lead to super heating and could be a limitation in achieving sterilization. Superheating and sterilization failure may also be caused by over-drying, heat-pressing, and storage in areas of low humidity.
    - Packaging materials should be stored at 20° C to 23° C (68° F to 73° F) and at a relative humidity of 20% to 60% for a at least two hours prior to use. Maintaining room temperature and moisture content of packaging materials facilitates steam penetration and prevents superheating during the sterilization process. The temperature and humidity levels in the packaging room/area should therefore be monitored.
    - Single-use packaging material should be used for one sterilization cycle; disposable packaging material should be discarded after opening.
- Assembly, Handling, and Wrapping Techniques
  - The contents of a package to be sterilized should be assembled, handled, and wrapped in a manner that provides for an aseptic presentation of the package contents to the sterile field.[33]
    - The appropriate sized wrapping material should be selected in order to adequately cover the items being packaged. The items should then

be wrapped securely to prevent gapping, billowing, or air pockets from forming, all of which may lead to compromised sterilization.[34]

- The method of packaging should be performed in a manner that facilitates the aseptic presentation of the package contents.[35]
    - There are a number of wrapping techniques that may be indicated in the manufacturer's instructions for use and are also explained in detail in the current sterilization guidelines.
    - Sequential wrapping using two barrier-type wrappers provides a tortuous pathway to impede microbial migration and also permits ease of presentation to the sterile field without compromising the contents' sterility.
    - An example of Sequential wrapping: envelope fold from the ANSI/AAMI ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* is seen below (Figure 4). Sequential wrapping refers to when two layers of wrap material are wrapped individually using a fold technique that begins by applying a single envelope fold warp to the item and then sequentially following with a second sheet of wrap material and repeating the wrap sequence to form a package within a package.

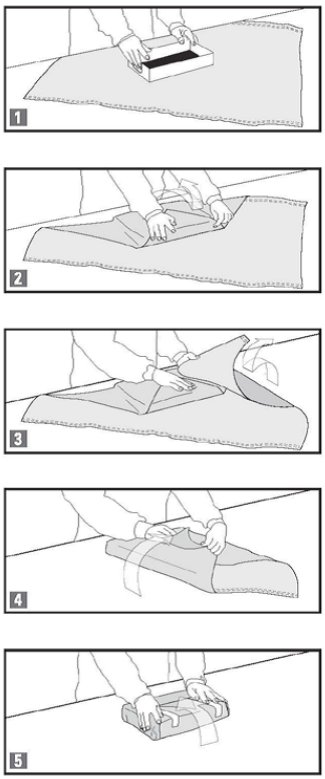
Figure 4 – Sequential Wrapping Technique



Use only wrappers validated for use in double simultaneous wrapping. Two single-layer wrappers or one bonded double-layer wrapper can be used. Simultaneous double wrapping refers to when two layers of wrap material are wrapped together simultaneously using the fold technique described below.

1. Place the wrap sheets on the table to form a diamond shape. Place the device(s) to be wrapped in the center of the wrap, parallel with the edge of the table.
2. Bring the lower corner up to completely cover the contents and fold the tip back on itself to form a tab or flap (which is used later to assist in opening the pack aseptically).
3. Fold the left corner over the contents and fold the tip back to form a tab.
4. Fold the right corner over the left fold and fold the tip back on itself to form a tab.
5. Bring the top corner down over the contents and tuck the corner under the right and left folds. A small tab should be left out for easy opening. Secure with two pieces of chemical indicator tape as shown in Figure 5 (one piece of tape may be sufficient for smaller packages).[37]

Figure 5 – Simultaneous double-wrapping: envelope fold technique



Two single-layer wrappers or
One bonded double-layer wrapper

- Sterilization
    - As previously discussed, personnel should consult the sterilization wrap's indications for use regarding the intended sterilization parameters and content recommendations for which the wrap may be used. In addition, the sterilizer manufacturer should be consulted for the appropriate sterilizer loading configurations.
    - In the event of a sterilizer malfunction or if the full cycle is not completed for any reason, all packages should be rewrapped with an unprocessed wrap and then re-sterilized.
    - Sterilizers vary widely in their design and performance characteristics. Because several factors can affect drying time other than the sterilization wrap (eg, the pack configuration that is used, sterilizer loading, cycle variations, the performance of the sterilizer, temperature and steam distribution, altitude, and ambient environmental conditions), perioperative personnel should consult the sterilizer manufacturer's operator manual for specific drying times, as recommended in the ANSI/AAMI ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*.[38]
- Post-Sterilization Cooling and Unloading the Sterilizer
    - After steam sterilization, the contents of the sterilizer should be removed from the chamber and left untouched until they are cool enough to handle without concern that retained moisture may act as a wick for bacteria that is on the hands of personnel who touch the package. This is usually accomplished in 30 to 60 minutes, depending on the load contents, but up to two hours may be necessary for the cooldown, and there is a lack of scientific evidence to support an exact amount of time needed for cooling. Cooling times will vary according to how hot items are at the end of the cycle, the density and composition of the materials contained within the load, packaging material, and the temperature and humidity of the ambient environment.[39] If freshly sterilized packages are placed on cool surfaces (eg, metal tabletops), vapor that is still inside the essentially dry package may condense to water, which may dampen the package from the inside to the outside. When the outside of the package is wet, bacteria may follow the moist track into the contents of the package. Any package that is wet following sterilization must be considered unsterile because bacteria are capable of passing through layers of wet materials; the contents of a wet pack should not be used.
    - Items should be cooled down in an area free of traffic and without strong air currents.
    - All of the wrapped items should be visually inspected as they are removed from the cart; if the wrap is damaged in any way, the items should not be used and then sent for reprocessing.

- Sterility Maintenance
    - Health care facilities may use acceptable standards of practice to monitor sterility maintenance of wrapped packages. While maintenance of package sterility is validated by the manufacturer with real-time testing for a specific time period for each indicated modality (eg, 30 days; 180 days), this time parameter does not prevent facilities from continuing to use established health care facility protocols and following industry guidelines.
    - Key considerations related to maintenance of package integrity are outlined below:[40, 41]
        - The shelf life of a packaged sterile item should be considered event-related. All sterilized packages should be considered sterile until an event occurs to compromise the package barrier integrity.
            - Health care facilities should determine the best methods and materials for packaging sterile items, based upon several factors such as the anticipated storage, handling, and environmental events that may be encountered. The loss of sterility of a packaged sterile item is event related; ie, an event must occur to compromise the package content sterility. Examples of events that may affect the sterility of a package include, but are not limited to, the following:
                - Multiple handling that results in seal breakage or loss of package integrity;
                - Compression during storage;
                - Moisture penetration;
                - Exposure to airborne and other environmental contaminants;
                - Storage conditions (ie, type of shelving, cleanliness, temperature, humidity, traffic control);
                - Type and configuration of packaging materials used; and
                - The use of sterility maintenance covers and the method of sealing.
            - Sterile wrapped packages should be stored under environmentally controlled conditions in order to reduce the risk of contamination.[42,43]
                - Room temperature, humidity, and ventilation should be controlled in accordance with local, state, and federal policies and regulations. Regulatory agencies may enforce the recommendations outlined by the American Society for Healthcare Engineering (ASHE) or AAMI or they may enforce other guidelines.
                    - Recommendations from AAMI include that the temperature in sterile storage areas not exceed 75° F (24°C); that there be a minimum of 4 air

exchanges per hour; and that the relative humidity is maintained between 20% and 60%, and never higher than 70%.

- Recommendations from ASHE are that temperatures in the sterile storage area range from 72°F to 78°F (22°C to 26°C) and that humidity not exceed 60%.

- Access to the sterile supply areas should be limited to those personnel who are trained in handling sterile supplies.
- Sterile storage areas (including shelving, racks, bins, and containers) should be kept clean and dry.
- Sterile supplies should be stored in a manner that allows adequate air circulation and facilitates cleaning in compliance with local fire codes and in a manner that decreases the risk of contamination. Recommendations for supply storage are generally 8 to 10 inches from the floor and 2 inches from outside walls. The minimum ceiling clearance between sprinkler heads and stored items is typically 18 inches to allow the sprinkler system to be effective.
- Heavy wrapped instrument trays should be stored on middle shelves and not stacked on shelves or ring stands for ease of handling by staff; stacking packs can result in damage to the wrap caused by undue pressure from the weight.
- Sterile items should not be stored underneath a sink or any other location where they can become wet.
- Sterile items should be stored in closed cabinets or covered carts; they may be stored on open shelving if it is located in a clean, secure, and environmentally controlled area.

- The end user should visually inspect the package or other container before opening for package integrity (ie, that it is free of holes in the fabric).

- Other general considerations related to sterility maintenance include:

  - Staff members should always carry a wrapped sterile tray in front of themselves, parallel to the floor.
    - A wrapped tray should never be dragged across any surface or stacked.
    - A wrapped tray should not be stored on its side.
    - A wrapped tray should always be lifted off a shelf; it should not be slid or dragged off the shelf.

- When opening a sterile tray, the sterilization tape should be broken at the seam; it should not be torn or ripped.

- Transport [44, 45] Transportation of sterile items should also be controlled. Because sterility of a packaged item is event-related, it is dependent upon the amount of handling, conditions during transportation and storage, and the quality of the packaging materials.
  - Sterile items should be transported in covered or enclosed carts with solid-bottom shelves to protect the items from exposure to environmental contaminants during transportation.
    - If the doors to the cart are damaged and do not close securely, air may enter the cart as it moves; this "wind effect" can force dirty air under pressure against the packs to potentially contaminate them.
  - Sterile items should not be crushed, stacked, bent, or compressed during transport:
    - If air inside package is forced out, it can rupture the closures and/or seams of the package; subsequently, a void is created which could potentially allow contaminated air to enter the package.
    - If an item is dropped, the jarring and compression on landing can force dust as well as airborne microorganisms into the package.
  - Sterility maintenance covers (ie, dust covers) may be used to protect and extend the shelf life of properly packaged and sterilized items that could be subjected to environmental contaminants or multiple handling prior to use. Only products that are specifically labeled as sterility maintenance covers should be used for this purpose. A sterility maintenance cover or dust cover should be clearly designated as such, so that it is not mistaken for a sterilization wrap. Sterility maintenance covers are designed to provide protection against outside elements, such as dust, and are not designed to provide a microbiological barrier. If sterility maintenance covers are to be used, they should be applied to a packaged item as soon as possible after sterilization and after the items are thoroughly cooled and dry. If a sterility maintenance cover is placed on a package that is not cool and dry, condensation could form inside the sterility maintenance cover; because this cover is not sterile, the package contents will become contaminated.

    In order to be an effective barrier, a sterility maintenance cover must be sealed; it should be sealed using either a heat sealer designed to seal plastic to plastic or with an alternative method that is similarly effective; a self-sealing cover also may be used. The lot or load control number and expiration date should be visible through the sterility maintenance cover; if not, an additional label should be used on the sterility maintenance cover.
  - Carts and reusable covers should be cleaned after each use.

- Use of Transport Tray. Transport trays are available with some sterilization wrap systems. This type of tray is intended to be used to support wrapped instrument trays during movement, sterilization and storage. A typical protocol is as follows:
    - Sterilization. After an instrument set is wrapped for sterilization, the appropriate size transport tray is selected and the wrapped instrument set is placed on the tray. The wrapped instrument set should rest on both of the two raised ridges on the inner surface of the tray (see Figure 6). Consult the manufacturer's written instructions to verify the tray's indications for use, ie, the sterilization modalities and parameters; in addition, some trays may not be intended for use with sets wrapped with woven wrappers or instruments that are wrapped without an instrument sterilization tray. The entire tray is lifted and then moved to the sterilizer.

Figure 6 – Wrapped Instrument Set on Transport Tray

    - Transport to Sterile Storage Area. After the sterilization cycle and appropriate cooling time (as specified in the manufacturer's written instructions) are completed, the wrapped instrument set on the transport tray can be transported to the sterile storage area. As the instruments are needed in the OR, the wrapped instrument set and transport tray are either placed on the case cart or transported as a unit according to facility policy.
    - In the OR. In the OR, the wrapped instrument set is removed from the transport tray before the set is unwrapped. The transport tray is returned to the sterile processing area and reprocessed (ie, cleaned and decontaminated) in the same manner as instruments, according to the manufacturer's instructions. Transport trays should not be reused if they are found to be damaged or defective; this includes the formation of cracks, splinters, or sharp edges which could abrade the sterilization wrap or if the tray becomes warped so that it can no longer support a wrapped instrument set on the raised ridges.

- Opening and Presentation to the Sterile Field. Items introduced to the sterile field should be opened, dispensed, and transferred by methods that maintain the sterility and integrity of the item and the sterile field.[46]
    - All sterile packages should be inspected for proper packaging, processing, and package integrity immediately prior to presentation to the sterile field. Since sterility is event-related, it is dependent upon maintenance of the integrity of the package. The sterility of an item does not change with the passage of time; however, it may be affected by certain events or environmental conditions, as outlined above.
    - If an expiration date is provided, perioperative personnel should check the date before the package is opened and the contents are delivered to the sterile field. Items should not be used after the labeled expiration date.
    - Heavy items should be opened on a separate clean, dry surface.
    - Wrapped sterile items should be opened starting with:
        - The farthest wrapper flap (this prevents contamination that might occur from passing an unsterile arm over the sterile item);
        - Each side of the flaps; and
        - The nearest wrapper flap.

      The wrapper edges are considered contaminated and should be secured when supplies are opened and presented to the scrubbed team member or sterile field; securing the loose wrapper edges helps to prevent them from contaminating sterile areas or other sterile items.

      Instrument tray wrappers should be visually inspected for moisture and integrity before the contents are placed on the sterile field. If there is any sign of damage, moisture, or potential contamination either before or after opening the package, the contents of the package should not be used, as the sterility could be compromised; in addition, if any of these conditions are noted, the package contents should be reprocessed using an unprocessed wrap.
- Disposal. Nonwoven sterilization wraps are designed for single use and may not be resterilized unless the manufacturer provides written instruction for reprocessing.[47] Therefore, perioperative personnel should consult with the wrap manufacture regarding the reuse and/or resterilization of its sterilization wrap; in general, manufacturers will not warrant the product's performance if it is reused.
    - Used sterilization wrap should be recycled, sent to a landfill, or incinerated according to state and local regulations. Since nonwoven wrap is composed of polypropylene plastic, it has a plastics recycling code of "5."[48]
- Loading and unloading case carts. Case cart systems are used by most facilities to gather and deliver supplies for every surgical procedure (see Figure 7).[49] Both sterile and nonsterile supplies are selected according to procedural routines or as listed on the surgeon's preference card. Personnel in the sterile processing

department prepare the case carts with the required instruments and supplies, using the OR schedule, preference cards, and case cart pull sheets.

Figure 7 – Case Cart

The surfaces of a case cart should be smooth and free from crevices, sharp edges, burrs or other projections that could potentially damage wrapped sterile trays or packs. The welds, as well as the shelving, should also be smooth to reduce the potential for tearing sterile packages. The cart should also be designed to contain or control small packaged items from getting dropped, torn, or crushed.

Care should be taken when loading and unloading sterile wrapped OR trays and other packages into or out of case carts to prevent compromise of the items. For example, tears or other compromises may occur if the trays are dragged across the wire racks in case carts when being unloaded for the procedure in the OR.[50]

- Policies and Procedures.[51] Policies and procedures regarding the selection and use of packaging systems should be written, periodically reviewed, and readily available in the practice setting. The maximum weight and tray configurations should be identified in the policy. Policies and procedures also establish guidelines for performance improvement activities to be used to monitor the efficacy of packaging systems.
- Competency Assessment.[52] Personnel involved in the selection and use of all sterilization packaging systems should demonstrate competence prior to use. They should also be knowledgeable about the principles of sterilization, the manufacturers' written instructions, risk, strategies to minimize these risks, and corrective actions to use in the event of a failure of a packaging system.
    - Education should be provided during orientation and periodically to reinforce safe use and provide new information on changes in technology, its application, and compatibility of sterilization equipment and processes as well as potential hazards.

- An introduction to the related policies and procedures should be included in the orientation and ongoing education of personnel to assist in the development of the knowledge, skills, and behaviors that affect patient outcomes.
- The competency of staff members in the use of packaging systems, according to facility and departmental policy, should be periodically assessed and documented in order to minimize the risks of misuse and thus provide a safe environment of care. Competency assurance verifies that personnel have a basic understanding of packaging systems, the associated risks, and appropriate corrective measures that should be taken in the event of a product or process failure.

Troubleshooting Wet Pack Problems

All sterilization modalities in which humidity (usually steam) is a parameter of the process present the potential hazard of producing wet packs.[53] As previously noted, microorganisms can easily migrate through moisture when a pathway is provided from the outside to the inside of the package. Water droplets may be visible on the outside or inside, or the absorbed moisture may be seen or felt. A stain on a wrapper may be indicative that moisture was present, but has dried. Should be considered unsterile and should be discarded. Any pack that is wet should be considered unsterile and therefore unacceptable for use. The cause of a wet pack should be investigated and promptly corrected.

Solving a wet-pack problem can be complex, as it may involve more than one contributing factor. Some factors and corrective actions that may help resolve wet-pack issues are outlined below.

- Most wet pack problems relate to the steam supply; other factors that can contribute to wet loads include poor or improperly maintained condensation return systems; low steam pressure; and seasonal changes in heating and cooling in the building. Appropriate actions include:
  - Verify that there is at least 97% saturated steam.
  - Check that the sterilizer has good steam quality, which can be improved by the use of filters and separators. Long steam runs, end-of-line connections, boiler maintenance, and chemical treatments can contribute to poor steam quality.
  - Verify that the dynamic steam pressure is within the specified range and is properly trapped.

- If the steam supply is ruled out, the problem could be related to preparation and loading techniques.
    - Trays should be adequately sized to distribute mass. Overloaded trays cause slower heat transfer and inefficient drying.
    - Disassemble complex instruments to avoid trapping steam.
    - During the sterilization process, condensation is created. Drainage, or the ability to drain condensate, is crucial.
        - Follow the ANSI/AAMI ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*[54] and the sterilizer manufacturer's recommendations for load configurations.
        - Containers and heavy sets should be loaded on the bottom shelf with wrapped instruments above.
    - Steam must have the ability to make contact with the load. Overloading the chamber inhibits steam contact.
    - Loads must not be touching the chamber walls, ceiling or baffles.
    - Plastic containers are difficult to dry, especially large orthopedic containers with multiple layers.
    - As noted, it is good practice to let the load sit on the load cart out of the chamber for 30 minutes to 60 minutes(or up to 2 hours as needed) to allow the load to cool and the heated steam vapor to dissipate. Opening an instrument tray or basin set immediately after the cycle may create condensate which would have normally dissipated during cool time.
        - Keep the load away from air conditioning vents during the cooling process.
        - If utilizing transport trays, cooling time needs to increase to 60 minutes.
    - Adding time in the sterilizer with the door cracked open, after the cycle is complete, may be more effective than adding more dry time.
- In rare cases, mechanical or design issues may be contributing to wet packs.
    - If the solutions outlined above do not solve the wet-pack issues, the sterilizer manufacturer should be contacted for further guidance.

SUMMARY

A major responsibility for every member of the perioperative team across all surgical practice settings is to minimize the patient's risk for the development of a surgical site infection; a key strategy for reducing this risk is to provide surgical instruments and other devices that are free of contamination at the time of use. To achieve this goal, it is essential that sterilization wrap used for items to be sterilized provides an adequate barrier to microorganisms, particulates, and fluids; ensures the integrity of the sterilized contents until opened for use; and permits aseptic delivery of the contents to the

sterile field. The appropriate selection and use of sterilization wraps in any health care facility today remain key responsibilities, as these products impact not only surgical instrumentation and medical devices, but also infection prevention practices, patient safety, and the facility's bottom line, especially in the face of today's challenges related to decreased budgets and staffing levels.

In order to be effective, sterilization wrap materials must possess certain characteristics, including but not limited to the ability to allow for sterilant penetration and air removal; allow for complete and secure enclosure of the item(s); protect the package contents form physical damage; and resist tears, punctures, and abrasion. Today, single-use, nonwoven, double layer sterilization wrap is strong, fluid resistant, breathable and provides durable protection. This type of a double layer wrap is securely bonded seal on three sides and thus provides excellent protection from microbial contamination and therefore a reduced risk of compromising the sterilization process. It also allows for use of the simultaneous double-wrapping technique, which saves time in both resources and consumables, and allow permits a sterilized package to be opened aseptically on the sterile field.

Specific data for sterilization wraps should be obtained from the manufacturer when comparing and evaluating sterilization wrap; this includes the results of various performance tests as well as the written instructions for use. Perioperative personnel should also remain aware of the current professional standards and guidelines that provide guidelines for the proper use and handling of sterilization wraps and wrapped OR trays. Through this knowledge and these skills, all members of the perioperative team who are involved in the sterilization of surgical instruments and devices will be able to select the appropriate sterilization wrap material and properly handle wrapped OR trays in order to reduce the risk of SSIs, thereby promoting positive patient outcomes.

GLOSSARY

Aeration	The method by which absorbed EO is removed or reduced in EO-sterilized items that uses warm air circulating in an enclosed cabinet specifically designed for this purpose.
Barrier	A physical or mechanical obstacle between a person and a hazardous substance or microorganism.
Barrier Material	Material that minimizes or retards the penetration of microorganisms, particulates, and fluids.
Barrier Effectiveness	The ability of a protective product to resist the penetration of liquids and liquid-borne microorganisms.
Case Cart	A system of gathering and delivering sterile instruments and supplies to the perioperative environment. Some models include a provision for return of instruments and contaminated items to the appropriate decontamination area after completion of the procedure.
Drying Time	The time required to dry steam-sterilized items before they can be handled.
Endogenous	Growing from or on the inside; caused by factors within the body or arising from internal structural or functional causes.
Event-Related Sterility	The shelf life of a packaged sterile item depends on the quality of the wrapper material, the storage conditions, the conditions during transport, and the amount of handling.
Exogenous	Growing from or on the outside; caused by factors or an agent (as a disease-producing organism) from outside the organism or system; introduced from or produced outside the body.
Health Care-Associated Infection (HAI)	An infection caused by a wide variety of common or unusual bacteria, fungi, or viruses during the course of receiving medical care; the infections may not become apparent until the patient has been discharged from the hospital.

Linting	The release of fiber fragments and other particles from a fabric during handling and use.
Medical Sterilization Packaging Systems	Sterilization wraps, packs, pouches, containers, trays, or cassettes, including related components such as trays, holders or mats, used by health care facilities to package and sterilize medical devices intended for either single use or reuse.
Meltblown	A material that is similar to spunbonded material in that it is formed from a polymer by in-line melt spinning, but the fibers are finer and may not be continuous.
Nonwoven Material	A manufactured sheet, web, or batt of directionally or randomly oriented fibers or filaments, natural or man-made, excluding paper and paper products, which are woven, knotted, tufted, or stitch-bonded and have not been converted into yarns. Nonwoven materials are bonded to each other by friction and/or adhesion and/or cohesion. Nonwovens are designed as single-use materials.
Package Integrity	Unimpaired physical condition of a final package.
Particulates	Very small solids that are suspended in air or liquid and can vary in size, shape, and density.
Penetration	The movement of matter, on a nonmolecular level, through porous materials, closures, seams, or imperfections (eg, pinholes) in a protective product.
Sequential Wrapping	A double-wrapping procedure that creates a package within a package. The item is wrapped once, completely, and then a second time, completely, each within a single sheet of wrap.
Seal	The result of joining of the layers, eg, by use of adhesives or thermal fusion.
Seal Integrity	Condition of the seal, which ensures that it presents a microbial barrier to at least the same extent as the rest of the packaging.
Shelf Life	The length of time an item is considered sterile and safe to use.

Simultaneous Wrapping	Wrapping with two layers of wrap at the same time using typical wrapping methods; also known as nonsequential wrapping.
Spunbond/Meltblown/ Spunbond (SMS)	A fabric consisting of three thermally or adhesively bonded layers. Spunbonded materials are made up of continuous filaments, which are formed by in-line melt spinning. Meltblown materials are similar in that they are formed from a polymer by in line melt spinning, but the fibers are finer and may not be continuous.
Spunbonded	A material made up of continuous filaments, which are formed by in-line melt spinning.
Steam quality	The steam characteristic reflecting the weight of dry steam present in a mixture of dry, saturated steam and entrained water; the dryness fraction (ie, the proportion of completely dry steam in the steam being considered) should not fall below 97%. Steam of poor quality can contribute to suboptimal steam sterilization cycles that may not be identified by biological monitoring.
Sterile	The state of being free from all living microorganisms. In practice, usually described as a probability function, eg, as the probability of a microorganism surviving sterilization being 1 in 1,000,000.
Sterilization	Processes by which all microbial life, including pathogenic and nonpathogenic microorganisms and spores, are removed or destroyed.
Sterility Maintenance Cover	A protective plastic bag used to protect sterile items from environmental contamination such as moisture, dust, and lint; also known as a dust cover.
Sterilization validation Studies	Tests performed by the device manufacturer that demonstrate that a sterilization process will consistently yield sterile container contents under defined parameters.
Superheating	A condition in which dehydrated textiles are

	subjected to steam sterilization; a superheated package or product becomes too dry, which causes destructive effects on the strength of the cloth fibers.
Surgical Site Infection (SSI)	An infection that occurs within 30 days after an operative procedure; defined as superficial incisional, deep incisional, and organ/space.
Tortuous Pathway	The impediment to microbial movement through a barrier material, based on the design of the material. In nonwoven materials, it is created by the configuration of the layers.
Wet Pack	Defined as the internal aspects of a sterile package that remain moist or damp after being subjected to a sterilization process. Packs are considered wet when there is moisture in the form of dampness, droplets, or puddles of water found on or within a textile pack, instrument, basin set, or containment system after a completed sterilization cycle and at least one hour after cooling. Wet packs indicate that the items inside the package are nonsterile.
Woven Material	A reusable fabric constructed from yarns made of natural or synthetic fibers or filaments that are woven together to form a web in a repeated interlocking pattern.

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