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Document Type:	Policy
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Department/Section:	Sterilization and Reprocessing Unit
Document Title:	**POLICY ON THE PACKAGING OF SURGICAL INSTRUMENTS, EQUIPMENT AND DEVICES**

PURPOSE:

1. To reinforce best practices related to the selection and use of packaging material for *the sterilization of items, including evaluation of the characteristics that are* important to the selection of the packaging material.
2. To discuss general recommendations regarding the preparation of items for sterilization.

LEVEL:

Sterilization and Reprocessing Unit (SRU)

DEFINITION OF TERMS:

Sterilization- a validated process use to render an object free from viable microorganisms, including viruses and bacterial spores, but not prions.

Inspection- checking of instruments using a magnifying lens to see if there are residues, corrosion, cracks and breakage in the surface and test for functionality.

Chemical indicator- test systems that reveal a change in one or more predefined variables based on a chemical or physical change resulting from exposure to the process.

POLICY:

1. Packaging materials shall be evaluated before adoption and purchase. This is to ensure it will meet the performance standards of the unit.[1]
   1.1. Packaging materials and seals should have the following general characteristics:

a) Allow the sterilizing agent to penetrate and reach all surface areas of the item(s) to be sterilized.
b) Maintain the sterility of the item up until its use; perform as a reliable barrier to microorganisms.
c) Permit the package to be opened in an aseptic manner that allows for sterile items to be easily removed or transferred to the sterile field without contamination.
d) Conform to the size and shape of the item(s).
e) Cover the contents in their entirety.
f) Provide for the maximum amount of use.
g) Allow air to be completely removed during the sterilization process.
h) Withstand the physical conditions produced by the autoclave, including moisture, pressure, and high temperatures.
i) Be permeable to the sterilizing agent and moisture.
j) Allow the escape and removal of the sterilizing agent at the end of the sterilization process.
k) Allow the contents to be dried after sterilization with no presence of moisture.
l) The packaging material must also have the characteristic of being able to be dried to avoid wet packages upon removal from the sterilizer. This is particularly important when using ethylene oxide sterilization since water combined with EtO can produce toxic byproducts.
m) Allow ethylene oxide gas and moisture to escape during the aeration cycle when using ethylene oxide sterilization.
n) Resist tears and punctures, during sterilization and normal handling.
o) Should not quckly degrade when the sterile packages are stored.
p) Provide a barrier to the penetration of dust and particles, and resist moisture penetration.
q) Woven fabrics should be lint-free and also free of loose fibers.

r) Must not contain any toxic material or dyes that could produce a chemical reaction during the sterilization process. The toxic residue could be harmful to the patient and the members of the surgical team, who are handling the packaging material, and sterile team members, who are handling the contents.

s) Reusable packaging materials should be free of bleaches and detergents that could produce a chemical reaction during the sterilization process.

t) Promote the integrity of the seal that is used to secure items, so that content sterility is maintained. The seal should not spontaneously open, when the package is in sterile storage.

u) Incapable of being re-sealed, once the seal is broken or package is opened.

1.2. Specific characteristics related to rigid container systems are:

a) Easily open and provide for excellent sterile presentation of contents.

b) Contain a removable lid that is sealable with some type of locking device.

c) A broken locking device should be readily apparent.

d) Manufactured of sturdy anodized aluminum, stainless steel, plastic, or plastic-metal combination.

e) Allow removal of all moisture and prevent the collection of water in the bottom of a container.

f) Be permeable to the sterilizing agent and moisture

g) Allow complete removal of the sterilizing agent and drying of the contents and container itself.

h) Allow for easy, aseptic removal of the sterile contents for use on the sterile field.

1.3. Specific characteristics related to paper-plastic peel packs are:

a) Thickness of the plastic layer must be a minimum of 2 mm.

b) Plastic side should allow visualization of the content(s).

c) Pouch should be commercially heat sealed along the edges lengthwise. One end may be commercially heat sealed with the other end open for placement of the item(s) to be sterilized, and the open end is either heat

sealed, adhesive self-sealed, or sealed with chemical indicator tape. Or the pouch may have two open ends that must be heat-sealed.

d) The peel pack must allow the open end to be easily sealed to prevent tunneling (incomplete contact) of the seal.
e) The peel pack material must allow for total air removal.
f) Be permeable to the sterilizing agent and moisture.
g) Peel pack material must allow for complete removal of the sterilizing agent.
h) Peel pack material must allow for complete drying of the contents and drying of the packaging material itself.
i) Peel pack must permit the package to be opened in an aseptic manner that allows for easy removal of the sterile items without contamination.

1.4. When evaluating packaging material or a packaging system, SRU shall request and review the manufacturer's information to ensure it is appropriate for the method of sterilization to be used and to review and maintain a written copy of the sterilization validation studies.

1.5. SRU shall request a sample of the packaging product to evaluate and test the efficacy before making a selection and purchasing. The product should be tested in a manner to determine that it meets all the general and specific performance characteristics unique to the packaging material, including sterilization parameters with the use of a biological indicator and recording of the results.

2. The steps in the packaging process shall include:
   2.1. inspection;
   2.2. set assembly, with disassembly of multipart devices as per manufacturers' instructions;
   2.3. wrapping;
   2.4. and labeling

3. All instruments, equipment, and devices/ set of devices shall be packed for sterilization using an appropriate packaging material and process.
   3.1. The packaging material or system shall allow appropriate and thorough sterilization, maintain sterility until the package is opened for use, and permit the removal of the device without contamination.
   3.2. All SRU Technicians shall follow the manufacturer's instructions for the use of the steam sterilization packaging and container systems.
   3.3. Paper-plastic combination peel packs should be used for steam sterilization.
   3.4. Packaging and container systems for EtO sterilization should be able to withstand the physical conditions without breaking down as well as allow penetration of EtO and moisture and allow for proper aeration.
      a) SRU Technician should follow the manufacturer's instructions for the use of the EtO sterilization packaging and container systems.
      b) Paper-plastic combination peel packs can be used for EtO sterilization.
      c) Tyvek® combination peel packs can be used for EtO sterilization.
   3.5. Packaging and container systems for gas plasma sterilization should be able to withstand the physical conditions, without breaking down as well as allow penetration of the hydrogen peroxide plasma sterilizing agent.
      a) The manufacturer's written instructions should be followed for the use of packaging materials and container systems that are compatible with gas plasma sterilization. Not all packaging materials and container systems can be used with gas plasma sterilization. SRU Technicians should refer to the manufacturer's written information and results of studies verifying the packaging material or container system's use in gas plasma sterilization.
   3.6. The use of absorbable packaging material should be avoided; paper material and textiles can absorb the gas plasma sterilization, thus decreasing the effectiveness of the sterilization process.
   3.7. Only peel pack pouches that are entirely plastic (no paper is present) should be used in gas plasma sterilization.

3.8. For container systems that require a filter, the filter should be made of non-cellulose material.

3.9. Packaging and container systems for ozone sterilization should be able to withstand the physical conditions without breaking down and also permit penetration of the ozone sterilizing agent.

4. Reusable packaging materials should be laundered, inspected and properly stored between every use to preserve the packaging properties of the material. Single-use packaging materials should be properly stored to preserve the packaging properties of the material.

4.1. Reusable woven packaging materials must be laundered and inspected between each use. Laundering aids in the rehydration of the packaging material. Experience has shown that if the packaging product is too dry, superheating during steam sterilization and positive biological indicators can result.

4.2. All lints in the woven packaging material should be removed before use.

4.3. All woven packaging material should be inspected for holes, tears, and thinning of the material each time after laundering. It is recommended the inspection take place with the use of a lighted table. Defects should be repaired with the use of a vulcanized patch that is heat sealed onto the woven material. A patch should be placed on each side of the defect.

4.4. Defects should not be sewn. The needle from sewing creates multiple holes in the woven material, producing multiple routes of microbial entry to the sterile field.

4.5. Multiple laundering and defect repairs eventually cause the woven material products failure to meet the criteria for performance and must be retired.

4.6. There should be a tracking system, such as a marking grid or bar code system to track the number of times a woven product is laundered and sterilized. (2) The manufacturer of the woven products should provide

written recommendations for the number of times the product can be processed and used.

4.7. To further aid in the prevention of superheating, all types of packaging materials should be stored at the proper temperature and humidity for at least two hours before use. Storage at room temperature and humidity permit adequate steam penetration and prevention of superheating.

4.8. Room temperature and humidity should be monitored and recorded daily. The recommended temperature and humidity are 20° C to 23° C (68° F to 73° F); 30% to 60%.

5. The package or container shall have an externally visible chemical indicator to differentiate between processed and unprocessed packages.

6. The SRU Technician shall place an internal chemical indicator in each package or container to verify that sterilizer penetration has occurred.

7. Packaging materials (e.g., wrapped or container systems) shall allow penetration of the sterilizing agent and maintain sterility of the processed item after sterilization.

7.1. Packaging materials include wrapped perforated instrument cassettes, peel pouches of plastic or paper, and sterilization wraps (which can be either woven or unwoven).

7.2. Packaging materials should be designed for the type of sterilization process being used and should be appropriate for the items being sterilized.

8. Types and Use of Sterilization Packaging Materials[2] (according to CDC).

Sterilization Method	Packaging Material Requirements	Acceptable Materials
Steam autoclave	• Should allow steam to penetrate	• Paper • Plastic

Sterilization Method	Packaging Material Requirements	Acceptable Materials
		• Cloth • Paper/plastic peel packages • Wrapped perforated cassettes
Dry heat	• Should not insulate items from heat • Should not be destroyed by temperature used	• Paper bags • Aluminum foil • Polyfilm plastic tubing • Wrapped perforated cassettes
Unsaturated chemical vapor	• Vapors should be allowed to precipitate on contents • Vapors should not react with packaging material • Plastics should not contact sides of sterilizer	• Wrapped perforated cassettes • Paper • Paper/plastic peel packages

9. Wrapped packages should be prepared to facilitate ease of opening the package and transferring to the sterile field, while maintaining the sterility of the contents.
   9.1. The correct size wrapper should be chosen in order to ensure complete coverage of the contents and sterilization.
   9.2. The wrapper should not be too large in order to prevent air pockets from forming, which can inhibit the penetration and release of the sterilant. However, it should not be too small as to not allow adequate coverage of the contents and possibly tear at the corners.

9.3. Wrappers that will be used to establish a sterile field should be large enough to extend a minimum of six inches below the four sides of the table or basin ring.

9.4. Wrappers must be large enough to cover the hand of the individual opening it, if the package is to be handed to the CST in the scrub role, using sterile technique or transferred (tossing) to a sterile field.

9.5. Before wrapping an instrument tray, an absorbent lint-free linen towel should be placed between the bottom of the tray and wrapper to cushion the corners of the tray and prevent tearing, as well as serve to absorb the condensation during steam sterilization.

9.6. Density is a key factor related to the sterilization of items. The more densely items are packed, the greater the percentage that the sterilant will not contact the surface areas of all items, and drying will be inadequate.

10. The preparation of items for sterilization shall begin after decontamination and the three steps should be completed for all items to be sterilized: inspection, reassembly, and preparation.

10.1. Items should first be inspected for blood and soil that could be left after decontamination.

10.2. Instrument function should be tested to determine if the instrument needs repair, sharpening or replacement.

10.3. Manufacturer's instructions must be followed for the proper inspection and testing of powered instruments.

10.4. Manufacturer's instructions must be followed for the proper inspection and testing of endoscopic equipment.

10.5. Instruments with multiple parts usually should not be reassembled in order to make sure the sterilant contacts all surface areas. Manufacturer's instructions should be followed related to the disassembly and assembly of instruments with multiple parts, including if the instrument should remain disassembled for sterilization purposes.

11. The three principles that should be followed in the preparation of items to facilitate effective sterilization are: the sterilant comes into contact with all surface areas, instruments are positioned in a protective manner, and instruments are evenly distributed.

12. Packages shall be labeled prior to being sterilized.
    12.1. Labeling must be performed in order to allow the user to identify the contents of the package, in particular when woven and non-woven wrappers are used. It should also be performed as an aid for purposes of quality assurance, inventory control, and rotation of stock.
    12.2. If a marking pen is used to label wrapped packs, it should be non-toxic.
        a) The use of a non-toxic marking pen avoids toxins adhering to the packs or instruments.
    12.3. Information should be written on the chemical indicator (CI) tape or on the front, plastic portion of peel packs. The following information should be included:
        a) Package contents
        b) Date sterilized (for purposes of rotating packages)
        c) Identification of the sterilizer
        d) Sterilization cycle number
        e) Initials of the employee who prepared the package
    12.4. The use of a label gun that discharges printed labels can be used as a substitute for providing some of the information. The label should be placed on the chemical indicator tape or plastic of a peel pack.

DOCUMENTATION:

New Policy

DISSEMINATION:

1. Policies and Procedure Manual
2. Hospital Communicator

REFERENCE:

[1]Association of Surgical Technologists. (2009). *AST Standards of Practice for Packaging Material and Preparing Items for Sterilization*. AST. Retrieved May 6, 2022, from https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard_Packaging_Materials_Preparing_Items.pdf

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	Effective Date:	07-15-2022
	Document Type:	Policy
	Page Number:	12 of 12
	Department/Section:	Sterilization and Reprocessing Unit
	Document Title:	**POLICY ON THE PACKAGING OF SURGICAL INSTRUMENTS, EQUIPMENT AND DEVICES**

APPROVAL:

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Document Title:	**POLICY ON THE PACKAGING OF SURGICAL INSTRUMENTS, EQUIPMENT AND DEVICES**

KEY TASKS	PERSON RESPONSIBLE
1. Evaluates packaging materials prior to adoption and purchase	SRU Head
2. Inspects the items to be packed for completeness, cleanliness, functionality and presence of defects	SRU Technician
3. Ensures that the items are fully dried before packing	
4. Selects the appropriate/ recommended packing material for the item	
5. Packs the item for sterilization using the appropriate/ recommended packaging material and process	
6. Prepares the packages to be wrapped in a way that will facilitate ease of opening and transfer to the sterile field, while maintaining the sterility of the contents	
7. Places an internal chemical indicator in each package or container to verify that sterilizer penetration has occurred	
8. Labels packages before sterilization	
9. Lists the instruments in a pick sheet and ensures proper documentation	
10. Transports the packed items to the sterilization area	
11. Allows proper cooling of the packed instruments and checks for any compromise in the packaging	

APPROVAL:

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PURPOSE:

1. To reinforce best practices related to the selection and use of packaging material for the sterilization of items, including evaluation of the characteristics that are important to the selection of the packaging material.
2. To discuss general recommendations regarding the preparation of items for sterilization.

SCOPE:

Applies to all Sterilization and Reprocessing Unit (SRU) staff of Dr. Pablo O. Torre Memoorial Hospital

PERSON RESPONSIBLE:

SRU Technicians, SRU Head

PROCEDURE:

1. Evaluate packaging materials prior to adoption and purchase.
2. Inspect the items to be packed for completeness (if it is a set), cleanliness, functionality and presence of defects.
3. Ensure that the items are fully dried before packing.
4. Select the appropriate/ recommended packing material for the item.
5. Pack the item for sterilization using the appropriate/ recommended packaging material and process.
6. Prepare the packages to be wrapped in a way that will facilitate ease of opening and transferring to the sterile field, while maintaining the sterility of the contents.
7. Place an internal chemical indicator in each package or container to verify that sterilizer penetration has occurred.
8. Label packages before sterilization.

9. List the instruments in a pick sheet and ensure proper documentation.
10. Transport the packed items to the sterilization area.
11. After sterilization, allow proper cooling of the packed instruments and check for any compromise in the packaging before transferring to the storage area.

REFERENCES:

1. Association of Surgical Technologists. (2009). *AST Standards of Practice for Packaging Material and Preparing Items for Sterilization*. AST. Retrieved May 6, 2022, from https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard_Packaging_Materials_Preparing_Items.pdf
2. *Sterilization: Packaging & Storage | FAQs | Infection Control | Division of Oral Health | CDC*. (n.d.). CDC. Retrieved May 6, 2022, from https://www.cdc.gov/oralhealth/infectioncontrol/faqs/packaging-storing.html#:%7E:text=What%20types%20of%20packaging%20materials,be%20either%20woven%20or%20unwoven)
3. *The Sterile Supply Departments Quick Guide Manual*. (n.d.). Infection Control Directorate Ministry of Health-Kuwait. Retrieved May 29, 2022, from http://www.icdkwt.com/pdf/policiesandguidelines/decontamination/guidelines-english.pdf
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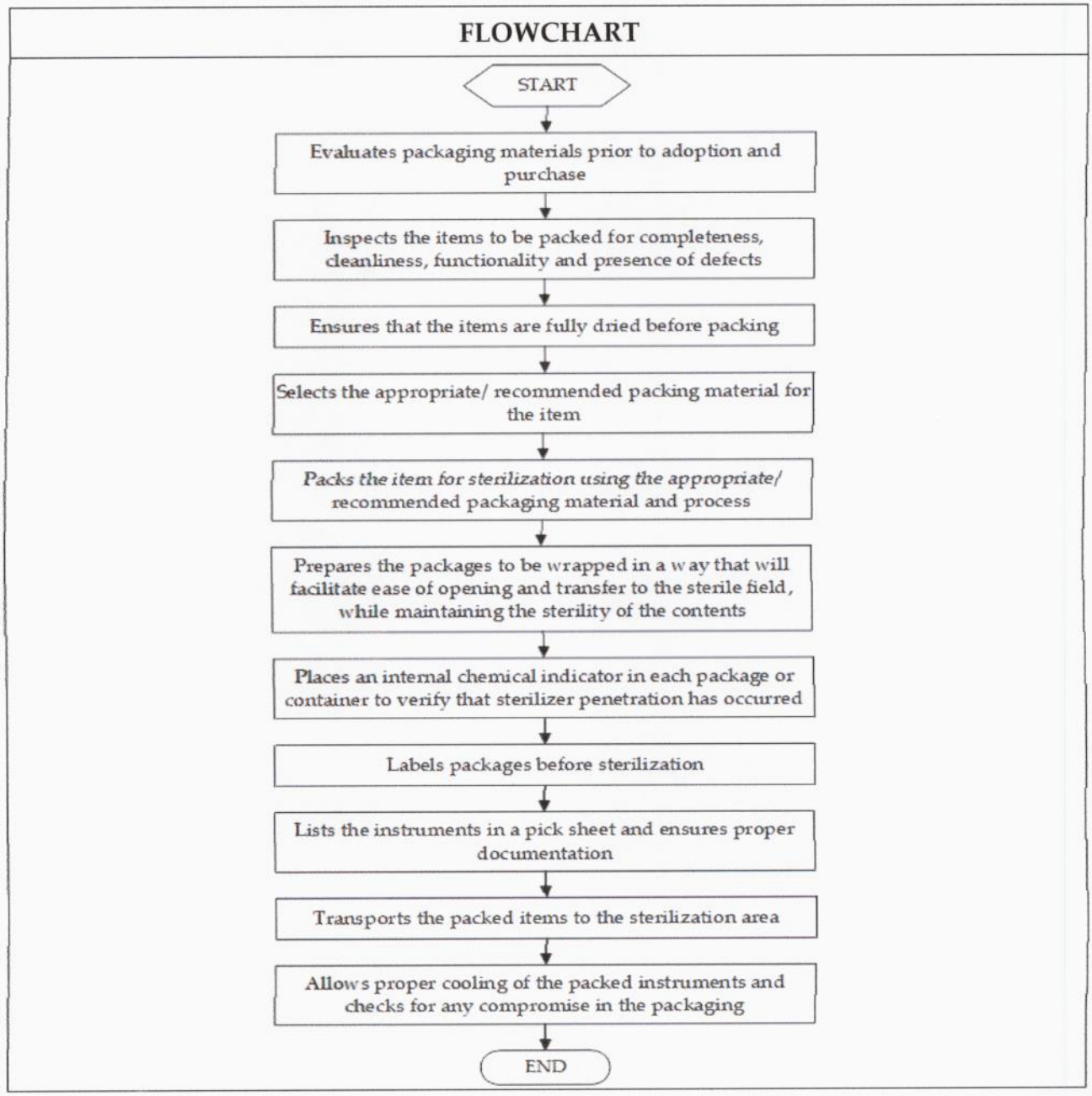
FLOWCHART



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