



New Packaging Methods and Best practice for sterile instruments in transition

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Learning Objective:

- ▶ To review the existing practices on packaging with latest technology available.
- ▶ To revisit the best practices to be followed for transportation of sterile supplies with an aim to sterility maintenance.

Packaging - Purposes And Criteria



- Class II medical device
- It is intended to **allow** sterilization of the enclosed device and also to **maintain sterility** of the product until it is used
 - ▶ **Tortuous path to bacteria**
- ▶ **Complete and secure enclosure of items(s)**
- ▶ **Tamperproof closure or seal**
- ▶ **Identification of contents**
- ▶ **Penetration and release of sterilizing agents**
- ▶ **Tear, puncture and abrasion resistance**
- ▶ **Maintenance of barrier properties**
- ▶ **Aseptic delivery of products**
- ▶ **Must withstand the physical conditions (temperature, moisture, pressure or vacuum) /compatible / weight bearing**
- ▶ **Not contain any toxic materials or dyes**

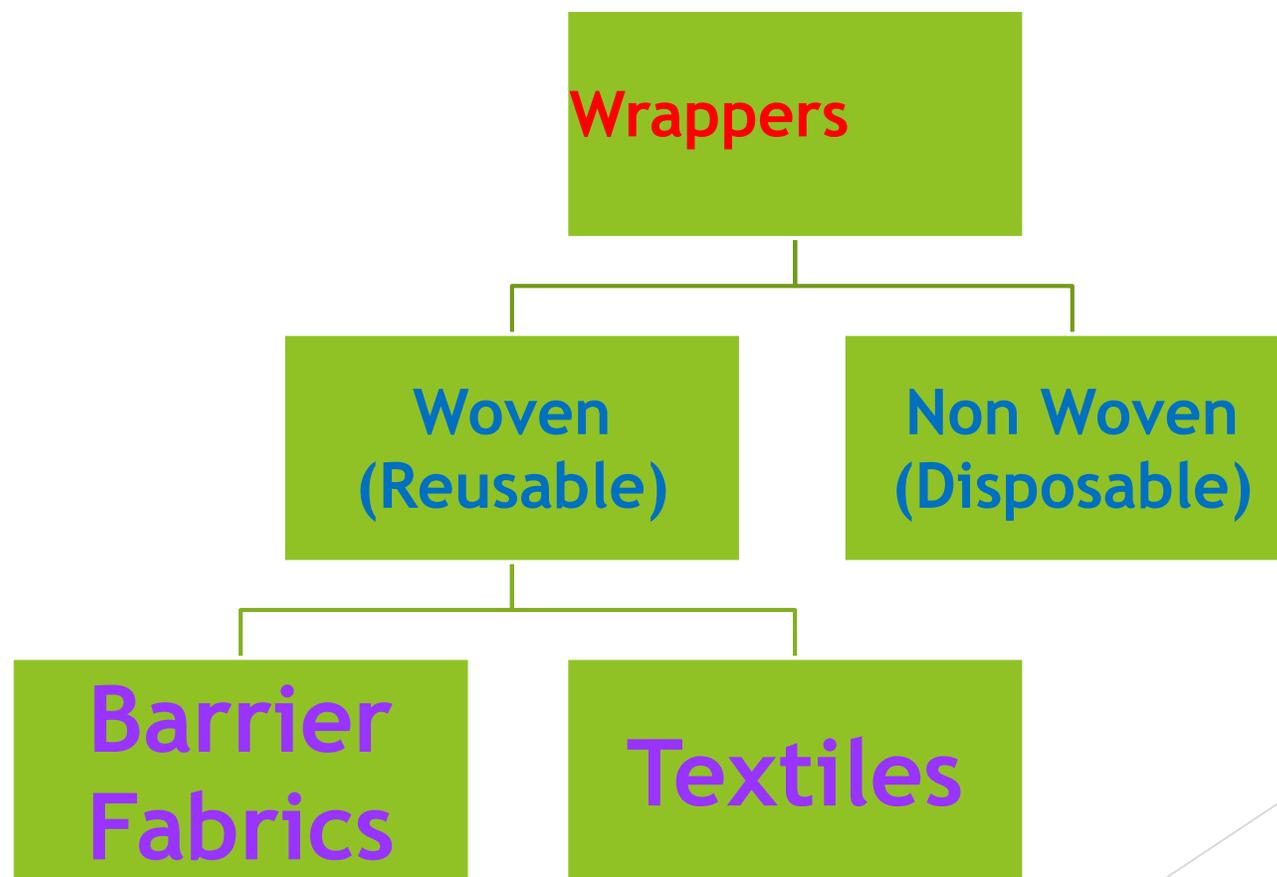
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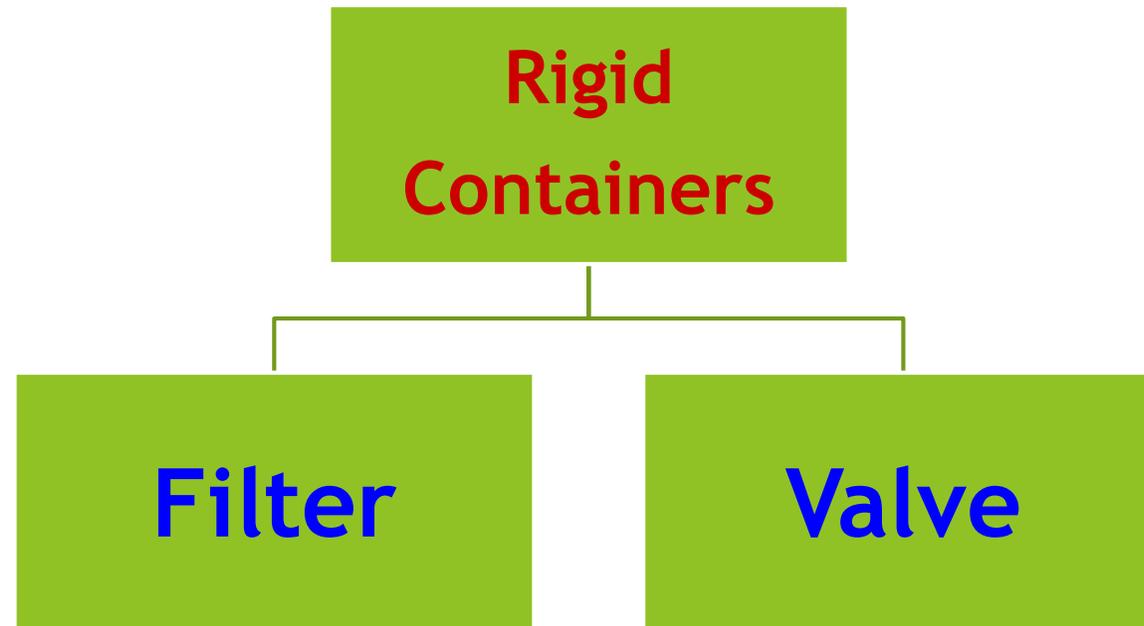


TYPES OF PACKAGING MATERIAL





TYPES OF PACKAGING MATERIAL



Flat Wrappers - Woven



▶ Linen



- ▶ Barrier properties -Diminish by repeated sterilization and laundering
- ▶ Thread count - 140 X140Um.
- ▶ Each use- Inspection for holes, worn spots and stains .
- ▶ Repairs - Mending of holes by thermal sealing.
- ▶ Double wrap

Flat Wrappers - Woven



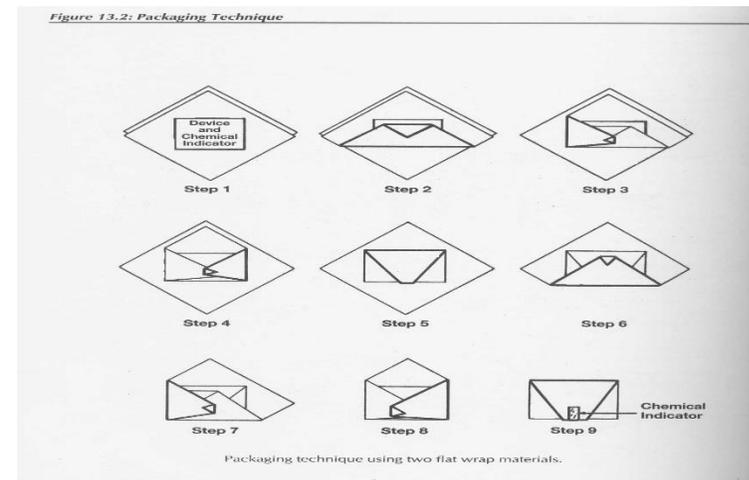
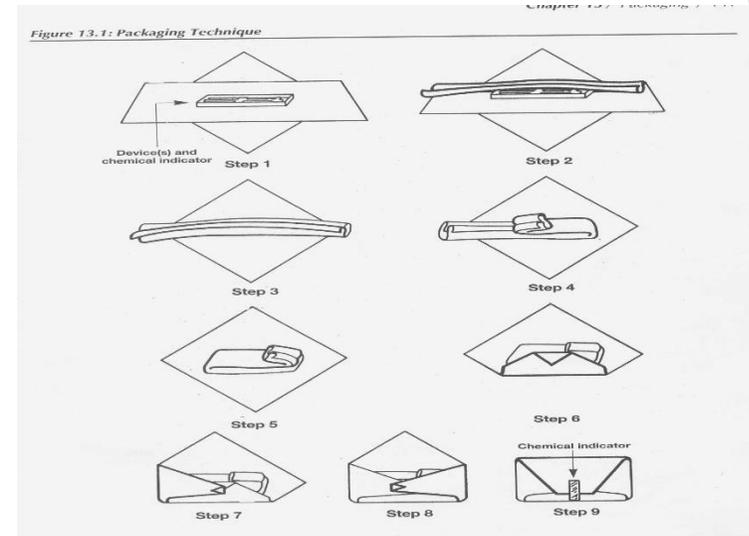
► Barrier Fabrics

- They are generally made of blends of cotton and polyester fibers .
- Higher Barrier properties than linen.

Flat wrappers- Packaging



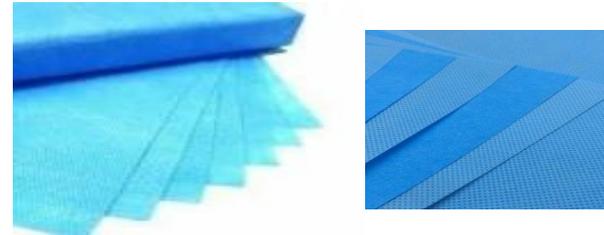
- ▶ The envelope fold is used for items that are opened and either handed to the scrubbed person or placed on the sterile field
- ▶ The square fold is used for linen packs and trays when the wrapper are used to create the sterile field. The material should be large enough to cover the area to be draped.
- ▶ There are two methods of packing, sequential and simultaneous



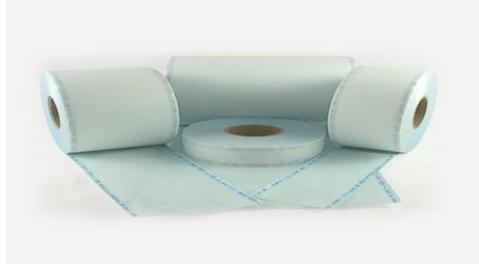
Non Woven Flat Wrappers



- ▶ Paper - Do not have good wet strength and tear easily.
- ▶ SMS/SMMS
- ▶ Fiber composition
- ▶ Web Formation
- ▶ Binding System
- ▶ Finishing treatment
- ▶ Sizes
- ▶ Gauge



Peel Pouches



- ▶ Characteristics- Transparency/Thermal stability/Physical Strength/Formability/sealability/biological barrier/disposability
- ▶ Combination of plain nylon film/ Polyethylene/polypropylene sealed to paper.

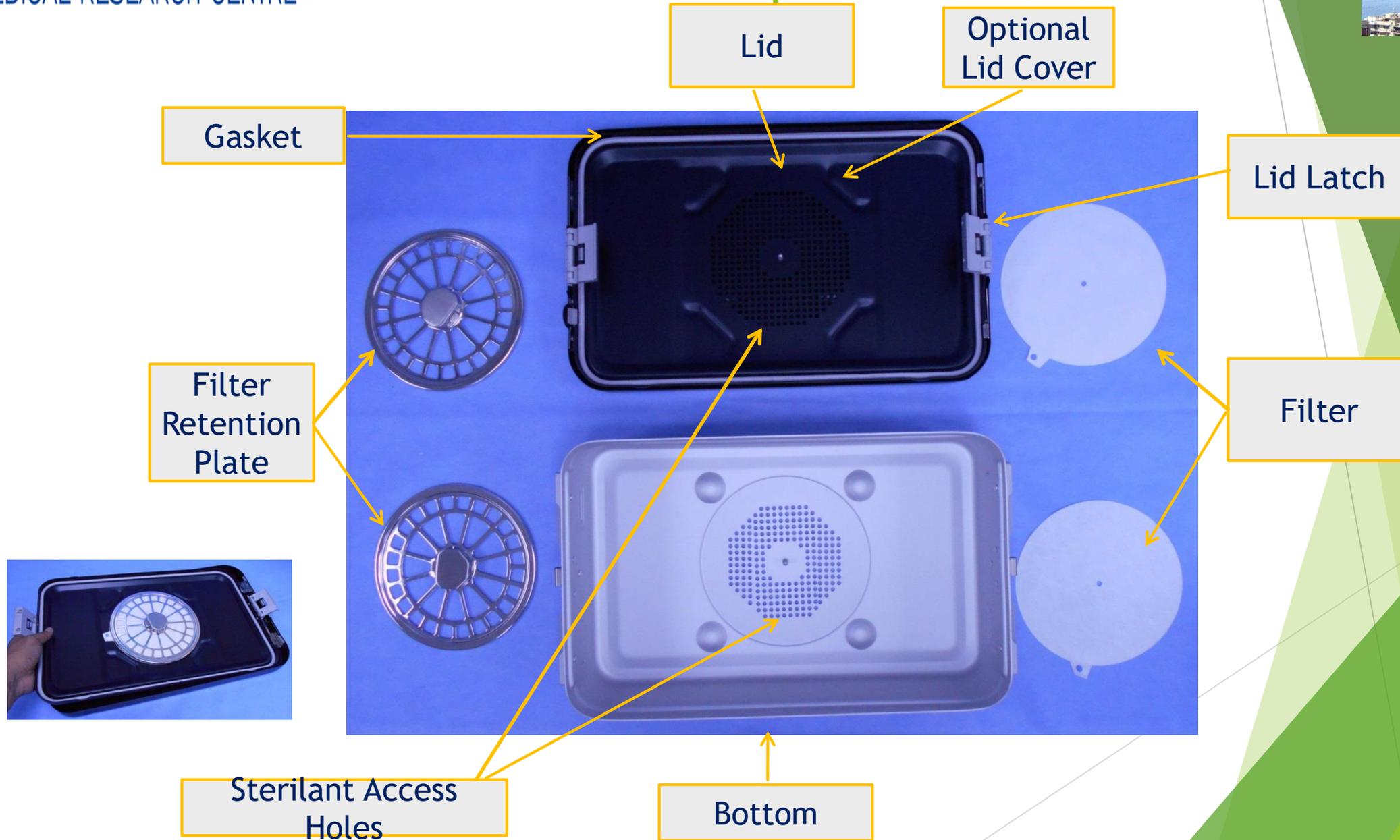
Rigid Containers



- ▶ Filters
- ▶ Valve



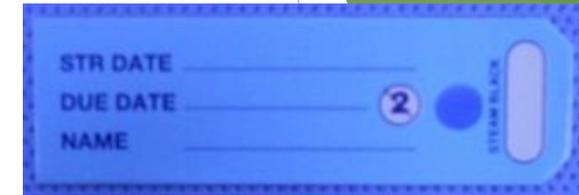
Sterilization Container Components - Inside



Processing Data Card



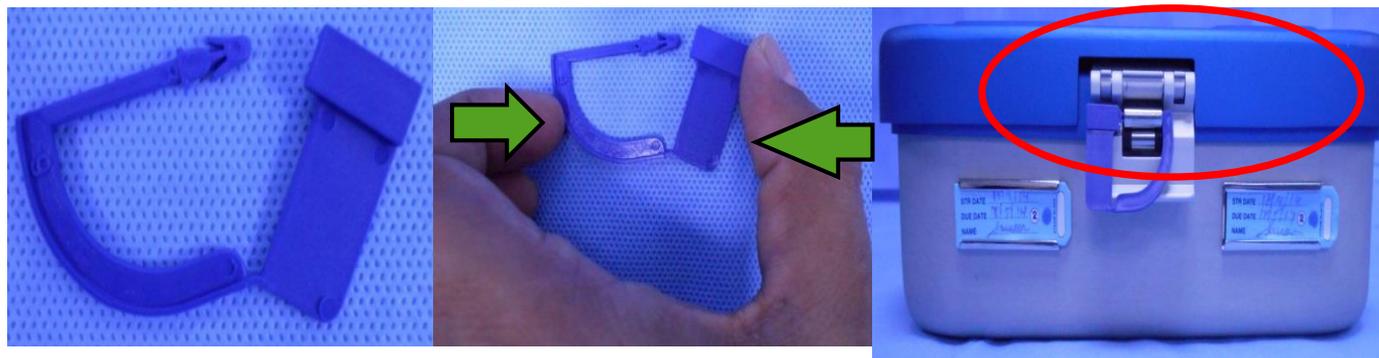
- ▶ Used to record processing information such as date, time, load, expiration date, etc. according to a facility's protocols
- ▶ Inserted on each side of the container in the data blocks. Be sure to insert the correct data card for the correct modality.
- ▶ Steam and EO use the Cellulose cards, and STERRAD will use the Non-Cellulose data card
- ▶ By design, the lid closure helps to secure the card in place so it should be inserted before placing the lid.
- ▶ The data cards are disposable and should only be used once



Tamper - Evident Lock



- ▶ Thread the guide on the tamper-evident seal through the lock holder and secure it.
- ▶ Repeat this process on the other latch



Container with valve and Standards

- ▶ ISO 11607 Part 1 and Part 2
- ▶ EN 868 Part 8
- ▶ DIN 58953 Part 9
- ▶ CE marking in compliance with MDD 93/42 EEC
- ▶ Approved for steam sterilization in compliance with EN 285 and validated in compliance with ISO 17665 Part 1, as well as gravity sterilization¹



Instrument Assembly



- ▶ The container basket should be at least 2” shallower than the top of the assembled container, and instruments should not protrude over the basket to avoid touching the lid. Stacking baskets however, can be used with a clearance of 1” or more.
- ▶ Containers should be validated for efficacy and dryness without the use of tray liners.
- ▶ Silicone mats can be used, but they may affect drying time
- ▶ Refer to the DFU for validated recommendations for container weights. According to AAMI guidelines, the total rigid container assembly weight should not exceed 25lbs including the container and instruments.



Opening the Container



- ▶ Rest base of thumbs against the upper latch plates for support
- ▶ Place fingers under bottom latch on both ends of the Container
- ▶ Gently pull upward and outward on Bottom latch. Simultaneously open both latches or open one side at a time. This disengages the Lid from the Bottom and breaks the Tamper-Evident Arrow to enable opening of the Container
- ▶ The Lid handles will move to the full upright position



Removing the Basket



- ▶ Remove the instrument Basket from the Container.
- ▶ Securely grasp the basket handles, making sure the sterile gown and gloves do not touch the outside of the container, the container edge (lip) or table.
- ▶ Lift the basket in a straight upward direction. Any additional baskets within the container are removed in the same manner.
- ▶ Discard all disposables; Filters, Data Card and Tamper-Evident Arrows according to hospital protocol.
- ▶ **5AFTER THE CONTAINER IS EMPTIED** and proven free of abnormalities, place the lid back on the container bottom and close the latches.



Cleaning



- ▶ If the container is not properly prepared, it may adversely affect the protective anodized finish.
- ▶ After each use clean with neutral pH
- ▶ Anything highly acidic or alkaline could permanently damage the anodized finish of the container.
- ▶ Do not use alcohol or any disinfectant to hand wash or wipe down.
- ▶ Be sure to thoroughly rinse off all residual chemicals.
- ▶ Inspect baskets and accessories for proper attachment and cleanliness.
- ▶ Accessories attached such as pins and dividers do not have to be removed to clean the baskets if they are not soiled.

Cleaning



- ▶ However, mats should be removed and cleaned separately since they obstruct the flow of water during the cleaning process. If silicone mats or other accessories are soiled, they should be scrubbed with a soft brush to reach hard-to-clean places.
- ▶ The components of the container can also be processed in a mechanical washer or cart washer; follow the equipment manufacturer's instructions.
- ▶ To avoid water collection, invert the components (upside down) so water runs out freely.
- ▶ The container components, though, should not be processed in a sonic washer.

Assembly



- ▶ Routine inspection is important.
- ▶ Gasket: ensure that it is free from cracks and tears and that it is properly seated in its retaining groove. There should also be a noticeable “bounce” when the container is opened, which indicates compression. Also inspect the gasket for a noticeable compression indentation formed by the upper lip of the container bottom.
- ▶ Edges: inspect the edges of the container lid and bottom to ensure they are free from sharp burrs or dents.
- ▶ Retention plates: ensure that the retention plate locks properly
- ▶ If any part does not function properly, it should be brought to the attention of your department head for servicing

Preventative maintenance checklist: What to look for...



Lid:

- ▶ Latch is bent
- ▶ Latch cannot swing up independently, indicating a worn spring
- ▶ Latch spring is bent or protruding
- ▶ Latch bracket is separated from lid
- ▶ Gasket contains cuts or holes or is shredding
- ▶ The seams of the gasket are separating
- ▶ Gasket is not properly seated in retaining groove
- ▶ Gasket exhibits visible degradation or color change
- ▶ Dents, which could affect the gasket's sealing capabilities

Bottom:

- ▶ Latch is loose or separating from container
- ▶ I.D. tag is missing
- ▶ Dents on upper lip of container, which comes in contact with the gasket

Filter Plate:

- ▶ Should be properly shape
- ▶ A distorted shape will not seal properly
- ▶ Bent lever
- ▶ Lever does not secure plate properly under indent
- ▶ Inadequate spring or compression

Abuse/Neglect Damage



- ▶ Incorrect or abusive handling practices
- ▶ Rough handling, lack of product knowledge
- ▶ Lack of routine inspection procedures
- ▶ Gaskets, bottom lip, lid, filter retention plates, Ignoring repair needs
- ▶ Lack of product knowledge or repair procedures
- ▶ Avoiding replacement needs
- ▶ Timely repairs/replacements are cost effective and critical to any preventive maintenance program

Benefits of Containers



- ▶ Control costs
- ▶ Reduce re-dos
- ▶ Green product
- ▶ Increase shelf life
- ▶ Improve sterile maintenance
- ▶ Standardize sets
- ▶ Reduce instrument damage
- ▶ Soiled containment

Best Practices for sterile supplies in transition



▶ INTERNAL TRASITION

- ▶ Immediate Unloading
- ▶ Minimum Handling
- ▶ Packs should not be hugged, squeezed, bumped into, leaned on, or touched while any carrying out any activities in sterile Area
- ▶ Dropped items during internal transport to be considered unsterile
- ▶ Should not dragged/ pushed against any surface as this could cause the wrappers to become loose or create a tear or hole
- ▶ No paper clips or Rubber Bands to hold packages together which can poke holes / constrict and crease or slice through the pack

Best Practices for sterile supplies in transition



- ▶ External Transportation
- ▶ Within the same premises
 - ▶ Enclosed Carts
 - ▶ Design of the cart
 - ▶ The carts should have a solid bottom to prevent dirt from entering as the wheels move
 - ▶ The top and bottom of the carts including wheels need to be washed periodically
 - ▶ The carts should be good condition as damaged carts can allow the entry of air with turbulence



- ▶ Cleanliness of trolley
- ▶ Cleanliness of Surfaces
- ▶ Hand Hygiene

External Transition/ Outside the premises

- ▶ Dust Covers



References :

Sterilization Technology - Edition 1997

[Sterilization containers - KLS Martin](#)

<https://www.klsmartin.com/en/products/sterilization-containers>

[Sterilization Container Systems | Aesculap USA](#)

www.aesculapusa.com/default.aspx?pageid=105

[Steelco S.p.A. - Washer disinfectors and Sterilizers - Sterilization ...](#)

<https://www.steelcogroup.com/us/products-catalogue/pharmaceutical-products/pharma...>

