Steriking® Bonded Wrap

Product references: BW1060; BW1075; BW1090; BW1100; BW1120; BW1140 ;BW2060; BW2075; BW2090; BW2100; BW2120; BW2140; BW4060; BW4075; BW4090; BW4100; BW4120; BW4140.

Steriking® Bonded wraps are intended for use as packaging material for reusable instruments in sterilization in health care establishments. The products are for single use only. Products are designed to be used by trained healthcare professionals. Benefit of wraps is to allow sterilization, maintain sterility and enable aseptic presentation of packed medical device.*

Steriking® Bonded wraps are ideal for packaging large items, such as basins or trays. Bonded wrap is two layers of SMS wrap sealed together with ultrasonic sealing process. Careful consideration should be given when choosing the wrapping grade, size, and technique.
It is critical that the sterilization wrap is compatible with your sterilization method. This includes allowing adequate air removal, sterilant penetration and drying in the sterilization process also for large, dense or heavy items. In the Table is presented Steriking® wrapping materials compatibility with different sterilization methods.

Steriking® wrap	Temp. Durability	Steam 121/134°C	Gas (FO/EO)	Irradiation	VH2O2
Bonded Wrap 100% polypropylene	140°C	YES	YES	NO	YES

Grade of sterilization wraps should be chosen according to the size, shape, and weight of medical device. The size of sterilization wrap should be large enough to cover the medical device but not too big to be wrapped several times around the medical device, as this could prevent sterilant penetration.

Packaging

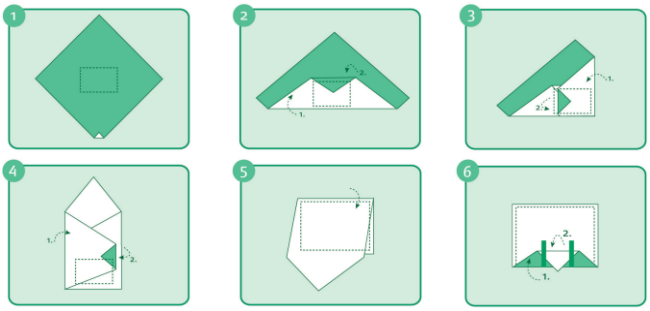
The item should not be wrapped too tightly as this could create holes or tears in the wrap. Size of the wrap should be large enough to facilitate the movement of the wrap during the sterilization cycle without ripping or tearing. Wrapping process in health care facilities is typically a manual process and therefore the validation of wrapping process is different from the validation of sealable pouches and reels (preformed sterile barrier systems). The packing and folding processes of wraps are critical, and therefore there should be a documented procedure (Standard Operating Procedure = SOP) for folding and closing of wraps, and that should be followed. The chosen wrapping method should allow aseptic presentation of the medical device.

Folding and closing of sterilization wraps

Wrapping techniques have been developed to provide a suitable tortuous path to prevent the ingress of contamination and assure aseptic opening. The most common wrapping techniques are the diagonal (envelope) fold and the parallel (parcel) fold.
For large packs the parallel fold is the preferred method.
For smaller packs the diagonal fold is the preferred method.
Videos for both methods are available on www.steriking.com

Instructions for diagonal packaging:

1. Place the tray or item to be sterilized in the center of the sheet so that its edges are at a right angle with the diagonals of the sheet.
2. Pull the sheet upwards across the edge of the tray (1.) and fold it parallel to the longitudinal edge so that the tray is fully covered. Fold the corner of sheet (2.) to form a triangle that provides aseptic opening.
3. Proceed as in the step 2. now form the right side.
4. Repeat again same process but now from the left side.
5. Form an open pocket at the top of the package on a longitudinal side.
6. Pull the last part of the sheet over the tray and tuck it under the earlier folds so that corner just shows to facilitate aseptic opening.



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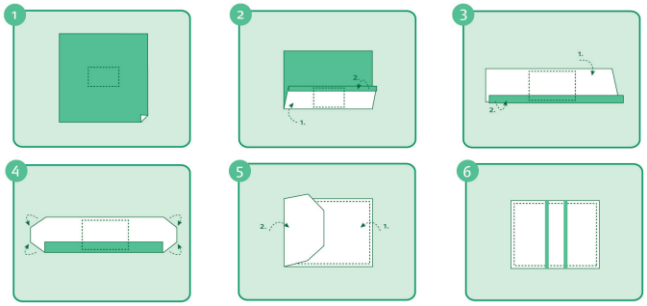
Instructions for parallel packaging:

1. Place the tray in the center of the sheet.
2. Pull the front edge of the sheet over the instrument tray (1.). Fold the edge of sheet (2.) outwards from the edge of tray.
3. Pull the back edge of the sheet over the tray (1.).
4. Fold the edge of sheet (2.) outwards.
5. Fold the sheet at the side and place over the tray.



Tray liners may be used under the tray to avoid wet loads and under the heavy trays to protect the packaging from damages. To make packaging system (SBS + protective packaging) fold two layers separately according to the selected wrapping technique.

The wrapping should be compact. If the wrap is too loose, it can create water puddles that can result in wet packs or it can leave openings that may cause contamination. If the package is too tight, it could hinder the sterilant from entering and leaving the package.

Closure

Closure system of Bonded wraps should provide evidence of tampering, therefore neutral or indicator tapes intended for sterilization are recommended for closure of the packs. Synthetic wrapping materials require stronger adhesive than pulp based wrapping materials. Only short piece of tape should be used for closing the pack. Ropes, strings, elastic bands, paperclips, or stables should not be used for closing the pack.

Writing on wraps should only take place on the tape or on additional label intended for sterilization. Writing instrument should not have a potential for creating a hole or puncture in the sterile barrier system, i.e. ballpoint pens should not be used. Only markers intended for appropriate method of sterilization should be used.

Loding the sterilizer

The sterilizer manufacturer should be consulted for the appropriate sterilizer loading configurations. Wrapped trays should be placed to the sterilizer shelf so that the bottom of the tray is parallel to the shelf.

If a sterilization cycle must be repeated due to a malfunction or a cycle is aborted before completion, packages must be repacked prior to being placed into another sterilization cycle.

Bonded Wraps are intended for single use only; product characteristics and performance cannot be guaranteed if the wrapping sheet is sterilized more than once.

Inspection

Sterilized packs should be handled with care and additional handling should be avoided. A pack must keep its integrity and facilitate aseptic presentation of the packaged sterile product. If the pack is damaged during sterilization, storing or transportation, the packed item shall be sent for re-packing and re-processing.

After sterilization, the packages and products must be allowed to cool down before handling, checking and sorting them. Each product is checked as to whether the packaging is intact, and the product is clean and dry. Wet packages are considered non sterile. If indicator tape has been used in closing of the pack the process indicator printed on the tape help distinguish between products that have or have not been processed but do not provide evidence of sterilization.

Storage and transportation

It is recommended that products shall be kept in their original closed transportation carton and are stored in dry and clean conditions protected from direct sunlight and excessive moisture before they are taken into use.

After sterilization the sterilized products are sorted for storage or delivery to the wards or other health care units. The products shall be stored in a dust-free place protected from sunlight, preferably in closed cabinets. A wrapped tray should never be dragged or stacked because that could damage the wrap. It is recommended that the storage place has a humidity of 30 to 60% and a temperature of 15-25°C.

The shelf-life of the sterilized items is always event related, and depends greatly on storage, handling and transportation conditions. Any unnecessary handling of the

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packages should be avoided, as this would increase the risk of contamination. In cases where the transport or storage circumstances are particularly challenging, protective packaging such as a pouch made of impermeable multi-layer film can be used to protect the sterilized packages. Wipak cannot state exact shelf-life for individual items. However, the shelf life of Wipak and Steriking® packaging materials has been tested in many occasions and conditions. Normally in health care facilities the storage time for wrapped packs is one to two months.

Note! Above statement does not take away the responsibility of the final packer as the final pack with the product inside can only be the responsibility of the health care facility who packed the item.

Aseptic presentation

The package should be visually inspected for moisture and any damage before the contents are placed on the sterile field. At the point of use it is essential that the packed medical device does not touch the outer surface or edges of the pack, because only the inside surface of the pack is sterile.
When opening large and / or heavy packages they need to be supported by a table or a tray. Assistance may be needed to prevent any contamination of the packed trays by accidentally touching the non-sterile outer surface of the packaging material. Double packaging ensures safe and sterile opening. The inner pack remains sterile even on its outside until it is removed.
When opening the wrapped tray, follow the next steps:

1. Break closing tape.
2. Open the wrap starting with the farthest wrapper flap or edges (parallel packing);
3. Each side of the flaps; and
4. The nearest wrapper flap.

Serious Incidents

If any serious incident occurs in relation to the wraps, those should be reported to Wipak and the national competent authority in which user is established.

Waste management

After use Steriking® sterilization wraps can be incinerated without producing toxic emissions. Of course, any contaminated product must be eliminated using a specialized method. Steriking® ProWrap SMX grades are made of pure polypropylene, and those can be also recycled if local possibilities for polypropylene recycling exists.

Steriking® is a registered trademark of Wipak.

We care that you pack safely!

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