Sterisheet Wrap™

STERISHEET® STERILIZATION WRAP

DESCRIPTION

Single use wrapping material – supplied non sterile – delivered as bulk of single sheets or interleaved solution, intended to create Sterile Barrier System (SBS) as packaging for terminally sterilized medical devices.
Available in different sizes and various interleaved associations.

Sterisheet Wrap™ and Sterisheet SMS™ by Sterisheet® are a complete range of sterilization wraps for use in sterilization centres and other healthcare facilities, where a sterilization process takes place, and for all packaging uses.

Product composition differs following the type of wrapping material selected:

1. **Standard or Soft Crepe Paper (52 to 60 g/m²):** made of cellulose fibers with water resistance additives.
   SterisheetWrap™ range
2. **Reinforced Soft Crepe Paper (52 to 70 g/m²):** made of cellulose fibers and synthetic binders.
   Sterisheet Wrap™ range
3. **Cellulose based Non Woven (57 to 78 g/m²):** made of cellulose fibers, synthetic binders and fibers.
   Sterisheet Wrap™ range
4. **SMS Non Woven (40 to 70 g/m²):** made of polypropylene
   Sterihseet SMS™ *range*

STORAGE PRIOR TO USE

The user must avoid all effects that could affect the Sterisheet® wrapping material shelf-life such as unnecessary hazards, strains, excessive light or UV radiation.
Keeping the material in its original packaging until use is recommended.

To prevent any damage from opening the case with a sharp instrument, use the easy tear-open tab.

Sterisheet® wrapping materials are to be stored in clean, ventilated and dry conditions, off the floor, above minimum temperature of 10°C and below a maximum temperature of 40°C.

Relative humidity should be between 30% to 60%.

PACKAGING INSTRUCTIONS

In order to assemble your SBS, wrap your medical device set in double layers using a sequential folding (*Figure 1)* according to your standard procedure.

Double sequential envelope folding is recommended to ensure optimal bacterial barrier efficiency and aseptic opening at the point of use.

Other folding method (e.g.square folding) are also applicable and are subjected to validation as a part of the qualification of the final package.

Using Sterisheet® interleaved solution provides you a ready-to-use secured SBS combination.

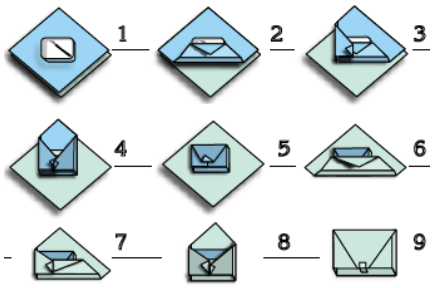

Figure 1 – Double sequential envelope folding

STERILIZATION INSTRUCTIONS

When loading the autoclaves, comply with the autoclaves manufacturer's instructions.

It is critical that process parameters are validated for each individual type of sterilization equipment and load configuration.

1) Steam sterilization (moist heat)

In compliance with EN 285 and EN ISO 17665.

Sterilization temperature from 121°C to 134°C may be used with plateau duration of maximum 20 min and 18 min respectively.

2) EO Sterilization

In compliance with EN 1422 and EN ISO 11135.

All of our wraps have been validated under the following typical sterilization cycle conditions:

- EO Concentration: 725 mg/L
- Temperature: 54°C
- Exposure Time: 90 minutes
- Humidity: 70%
- Aeration: 8 hours

For a different sterilization process please refer to your local regulation and/or contact your distributor.

STORAGE AFTER STERILIZATION

Sterile packs should be manipulated with care in order to keep the integrity of the pack.

Sterile packs must be stored in an area dedicated to sterile medical supplies, away from direct sunlight, humidity and contamination of any kind.

Storage duration should be determined according to your internal procedure.

Event-Related Sterility Maintenance Study on Sterile Barrier System using Sterisheet® wraps, simulating the real conditions of handling and storage of a hospital, supports no ingress of micro-organisms into the pack after at least 180 days.

However, this time point does not prevent Healthcare facilities from using established protocols to monitor sterility maintenance of the Sterile Barrier System.

POINT OF USE INSTRUCTIONS

Using clean cabinets, bins, trolleys, Sterisheet Autoclavable Tray™ or TitePack™ by Sterisheet® is recommended to bring the sterile packs from the storage room to the Operating Room (O.R.).

Prior to opening, it is recommended to inspect package for damage, wetness, or any sign of potential contamination. Inspect pack again after opening and before the use of sterile devices.

If any of these conditions (damage, wetness, etc…) are observed, do not use sterile devices and reprocess them with an unprocessed SBS.

Before entering the O.R., it is recommended that the outer wrap be removed so as not to contribute to introducing exterior contaminating elements.

WARNINGS AND PRECAUTIONS

Selection of SBS material:

- Stock rotation based on the production date given on the boxes,
- Choose the right size of wrap depending on the size of the tray to be packed,
- Choose the right type of material depending on the sterilizing agent used,
- Choose the adapted grade of wrap depending on the weight and shape of the tray to be packed.

Sterisheet® wrapping material is a single use product. In case of any incident during the sterilization cycle, the tray should be wrapped again using new wrapping material.
Sterisheet® wrapping material has not been designed to withstand additional treatment (chemical, detergent aerosol, etc...).

To ensure integrity of the pack:

- Protect the sharp ends of medical devices to be sterilized,
- Do not use any wrapping material if damaged (holes, creases, cracks, etc…),
- Do not use a sterilization wrap in case of unusual stain or foreign matter presence.

DISPOSAL

Landfill or incinerate the SBS based on local regulations and level of bio-contamination of the SBS after use.

FINAL REMARKS

The information provided are recommendations.
It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and trained personnel in the processing facility to achieve the desired result.
This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

CE