

Wrapping Sheet SMMS

Instructions For Use

Intended use:

Intended to create Sterile Barrier System (SBS) as packaging for terminally sterilized medical devices. Non-woven sheets are sterilization wraps for use in sterilization centers and other healthcare facilities, where a sterilization process takes place, and for all packaging uses. Applicable to be used with steam, ethylene oxide, formaldehyde, irradiation and plasma sterilization.

Directions for use:

1. Using clean cabinets, bins, trolleys, is recommended to bring the sterile packs from the storage room to the Operating Room (O.R.).
2. 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.
3. Before entering the O.R., it is recommended that the outer wrap be removed so as not to contribute to introducing exterior contaminating elements.
4. In order to assemble SBS, wrap medical device set in double layers using sequential folding (Figure 1) according to standard procedure. Double sequential envelope folding is recommended to ensure optimal bacterial barrier efficiency and aseptic opening at the point of use.

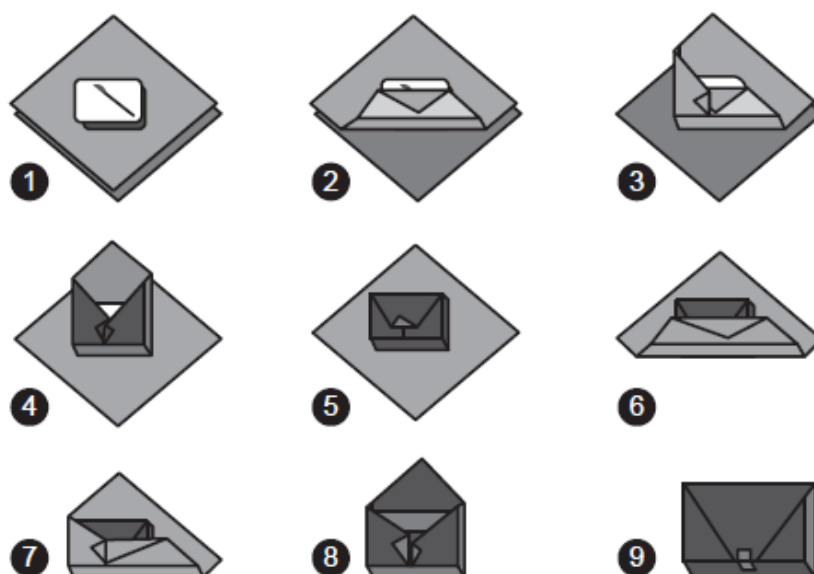


Figure 1 – Double sequential envelope folding

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

Remarks: The instructions provided are recommendations. It remains the responsibility of the processor to ensure that the processing is 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. Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Warning and Precautions:

1. Selection of SBS material:
 - ✓ Stock rotation based on the production date given on the packages.
 - ✓ 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.
2. Non-woven sheet is a single use product. In case of any incident during the sterilization cycle, the tray should be wrapped again using new wrapping material.
3. The non-woven sheet has not been designed to withstand additional treatment (chemical, detergent aerosol, etc.).
4. 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.).
5. Do not use a sterilization wrap in case of unusual stain or foreign matter presence

Storage prior to use:

1. To prolong non-woven sheets shelf life, avoid unnecessary hazards, excessive light, or UV radiation.
2. Keeping the material in its original packaging until use is recommended.
3. To prevent any damage from opening the case with a sharp instrument, use the easy tear-open tab.
4. Non-woven sheets wrapping materials are to be stored in clean, ventilated, dry conditions, off the floor, above minimum temperature of 50°F (10°C) and below a maximum temperature of 104°F (40°C). Relative humidity should be between 30% to 60%.

Storage after sterilization:

1. Sterile packs should be manipulated with care to keep the integrity of the pack.
2. Sterile packs must be stored in an area dedicated to sterile medical supplies, away from direct sunlight, humidity, and contamination of any kind.
3. Storage duration should be determined according to your internal procedure.

4. An event-related sterility maintenance study on SBS using InnoQ Non-woven sheets, 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.
5. However, this time point does not prevent healthcare facilities from using established protocols to monitor sterility maintenance of the Sterile Barrier System.

Shelf life:

5 years

Legal manufacturer:

Global SCP Medical Systems Pte. Ltd., Singapore