EN

Crosstex™ CSR Sterilization Wraps

REF SW12 / SW15 / SW18 / SW20 / SW24 / SW30
SW36 / SW40 / SW45 / SW48 / SW54

INSTRUCTIONS FOR USE

Single use Wrapping material, supplied non-sterile, delivered as single sheets, intended to create a Sterile Barrier System (SBS) as packaging for terminally sterilized reusable medical devices. In hospitals, clinic Central Supply Rooms (CSR) and related healthcare facilities.

For use in sterilization centers and other healthcare facilities, where sterilization processes take place and for all packaging uses.

Production composition: Reinforced, crepe paper (60 g/m²); made of cellulose fibers and synthetic binders.

STORAGE PRIOR TO USE

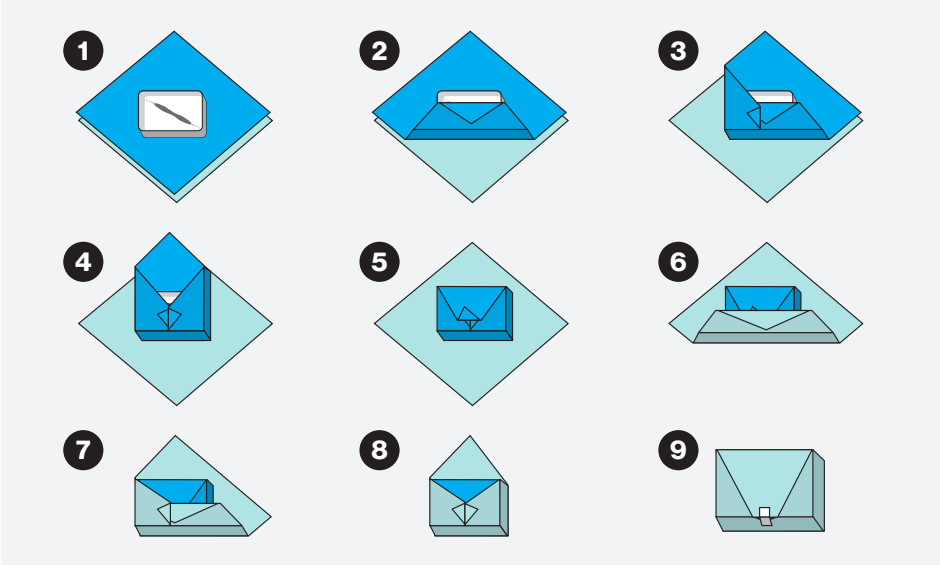
User must avoid all effects that could affect the Wrapping material shelf-life such as unnecessary hazards, strains, excessive light, or UV radiation, keeping the material in its original packaging until the point of use.

Wrapping materials are to be stored in clean, ventilated, and dry conditions, off the floor, above minimum temperature of 50°F (10°C) and below a maximum temperature of 104°F (40°C).

PACKAGING INSTRUCTIONS

Wrap medical device set in double layers using a sequential folding (see diagram below) 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.



Available in a variety of sizes:

12 in x 12 in (30.5 cm x 30.5 cm)	1,000/Case	SW12
15 in x 15 in (38.1 cm x 38.1 cm)	500/Case	SW15
18 in x 18 in (45.7 cm x 45.7 cm)	500/Case	SW18
20 in x 20 in (50.8 cm x 50.8 cm)	500/Case	SW20
24 in x 24 in (61 cm x 61 cm)	500/Case	SW24
30 in x 30 in (76.2 cm x 76.2 cm)	250/Case	SW30
36 in x 36 in (91.4 cm x 91.4 cm)	250/Case	SW36
40 in x 40 in (101.6 cm x 101.6 cm)	250/Case	SW40
45 in x 45 in (114.3 cm x 114.3 cm)	250/Case	SW45
48 in x 48 in (121.9 cm x 121.9 cm)	100/Case	SW48
54 in x 54 in (137.2 cm x 137.2 cm)	100/Case	SW54

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STERILIZATION INSTRUCTIONS

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

It is critical that the 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 269.6°F (132°C) may be used with plateau duration of 6 minutes.

2. EO Sterilization

   In compliance with EN 1422 and EN ISO 11135.

   All Wraps have been validated under the following typical sterilization cycle conditions:

   - EO Concentration: 725 mg/L
   - Temperature: 130°F (54°C)
   - Exposure Time: 90 minutes
   - Humidity: 60%
   - Aeration: 12 hours

For a different sterilization process refer to 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.

Event-related sterility maintenance study on Sterile Barrier System made of two sheets sequentially folded using Crosstex™ 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

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 use of the sterile device.

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

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

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WARNINGS AND PRECAUTIONS

Selection of Sterile Barrier System 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 and size of Wrap depending on:
  - The weight and shape of the pack to be wrapped.
  - The anticipated life cycle stresses as per handling, storage and distribution conditions.
  - Any additional specificity of your sterilization and product flow processes.

Crosstex™ Wrapping material is a single use product. In case of any incident during the sterilization cycle, the pack should be wrapped again using new Wrapping material

Wrapping material has not been designed to withstand additional treatment (chemical, detergent aerosol, etc.)

To ensure integrity of the pack:

- Protect sharp ends of medical devices to be sterilized.
- Do not use any Wrapping material if damaged (holes, tears, cracks, etc.)
- Do not use sterilization Wrap in case of unusual stains or loose extraneous particulates presence.

DISPOSAL

Landfill or incinerate the Sterile Barrier System based on local regulations and level of bio-contamination of the material after use.

ADDITIONAL INFORMATION

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.

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