Steriking® LT-Blueline Pouches with Tyvek

Steriking® Self sealable pouches and rolls are intended for use as packaging material for reusable instruments in Steris low temperature sterilization by hydrogen peroxide in health care establishments. The products are for single use only. Products are designed to be used by trained healthcare professionals. Benefit of pouches is to allow sterilization, maintain sterility and enable aseptic presentation of packed medical device.

Preformed sterile barrier systems made of porous material and laminate construction. The pouches are constructed from Tyvek®/plastic films. The self-sealed pouches are heat sealed prior to processing in the STERIS® Sterilization Systems.
These pouches are made from a plastic film and Tyvek that is heat sealed on three sides. The fourth side is left opened and will be self-sealed when used.

Packaging

When measuring the size, it is important to allow extra space for sealing the package and for a flap with which the package can then be easily opened. It is recommended that the packages should be filled to no more than 3/4 of their length. Empty space should be allowed around each instrument. The medical device should be oriented to ensure aseptic presentation - in other words positioned correctly inside the pack to enable easy removal of the packaging. Steriking® pouches are marked with a symbol indicating the correct peeling direction.

Where double packaging is implemented, it is important to position porous material against porous material and laminate against laminate because penetration of sterilant is only possible through the Tyvek® side. The inner packaging must not be folded so that the passage of sterilant remains unhindered.

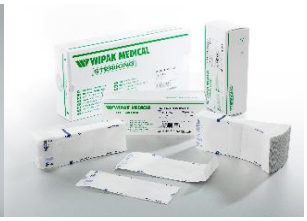
Limitations for Use

LT-Blueline Pouches and Rolls are not suitable for sterilization by hot, dry air or by steam.

Sealing

All seals, including closure seal/seals should be smooth without folds, bubbles, or wrinkles.
The seals need to be strong to withstand the most vigorous sterilization process and handling. A manual test should be carried out for controlling the seal strength.

Self-sealable pouches are featured with adhesive strip allowing tight, impermeable closing of a pack. The closing flap is pre-folded to facilitate the closure. When closing the self-seal pouch the flap shall be folded along the pre-folded line. Flap should be pressed firmly against the laminate from the center working outwards to ensure a good, even seal. Apply even pressure while moving thumbs. Repeat at least three times to ensure a clean and air-tight seal. After closure it must be checked that the seal is free of air channels and sealed from end to end.
Closures that compress the package should not be used, (e.g., ropes, strings, elastic bands, paperclips, staples or similar items).



Labeling and writing

Writing or printing on pouches should only take place on the film side or on the Tyvek® outside the seals. 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. If labels are used they must not impede the sterilization process, i.e. must not block the breathable area of the package. Labels must not cover the seals or any necessary information such as LOT-number etc.

Loading the sterilizer

Packages should be placed in the sterilizer loosely allowing the sterilizing agent to penetrate the pack. 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.
The products are intended for single use only; product characteristics and performance cannot be guaranteed if sterilized more than once.

STERIS® Cycles

Compatible with STERIS® V-Pro® Sterilization Cycles:
Lumen Cycle
Non Lumen Cycle
Flexible Cycle

Device lumen dimensions and weights:

Flexible Cycle: 1 lumen max and 1 mm min ID x 1050 mm max length for all pouch sizes.
Lumen Cycle: 1 lumen max for all pouch sizes.
1 mm min ID for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm

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2 mm min ID for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm
125 mm max length for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm
250 mm max length for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm

Max Weights:
1.234 pounds for pouch sizes below (Flexible, Lumen, and Non-Lumen Cycles) 300 x 450 mm
250 x 400 mm
190 x 330 mm

.122 pounds for pouch sizes below (Flexible and Lumen Cycles) 130 x 380 mm
130 x 270 mm
90 x 250 mm
90 x200 mm

.204 pounds for pouch sizes below (Non-Lumen Cycle) 130 x 380 mm
130 x 270 mm 90x250mm 90 x200 mm

Inspection

After sterilization each product is checked as to whether the packaging is intact, the changes communicated by indicator have taken place, and the product is clean and dry. In any unclear or ambiguous situation (e.g. wetness in pack) items should be considered as unsterile.

Storage, Transportation and Shelf Life

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.

It is recommended that the products are put to their end use within 3 years of manufacture. The recommended “Best before” date and the manufacturing date are stated on the carton label.

After sterilization the products are sorted for storage or delivery to the wards. The products should be stored in a dust-free place protected from sunlight, preferably in closed cabinets. It is recommended that the room climate has a relative humidity of 30 to 70 % and a temperature of 15-25°C.

Maintenance of pack sterility is not only dependent on the packaging material and the method of sterilization: it is also dependent on handling, transport and storage conditions. Any unnecessary handling of the packages should be avoided, as this would increase the risk of contamination. The level of protection is considerably enhanced by using a minimum of two layers - in other words by double pouching. The maintenance of Sterility is tested to be up to 1 year post sterilization

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.

Fiber-free opening and aseptic presentation

Follow the opening direction indicated on the pack. The seals on the upper corners of the packs should be unattached first. The package should then be opened by pulling the laminate away from the Tyvek® material slowly and evenly. Open only ⅓ - ⅔ of the packaging length. 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 instrument / instrument sets 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.

Steriking LTSS Self Seal Pouches

Art. Code	Size
LTSS1	90 x 200
LTSS2	90 x 250
LTSS4	130 x 270
LTSS4A	130 x 380
LTSS5A	190 x 330
LTSS6	250 x 400
LTSS7	300 x 450

Serious Incidents

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

Waste management

After use Steriking® sterilization pouches and rolls can be incinerated without producing toxic emissions. Of course, any contaminated product must be eliminated using a specialized method.

CE

We care that you pack safely!

WIPAK

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