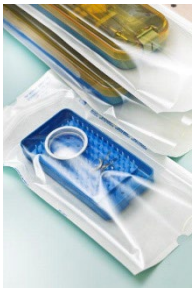
Steriking® LT-Blueline Pouches with Tyvek

Steriking® Heat 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 device is placed inside the pouch and the four side is sealed.

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 required, it is important to position porous material against porous material and laminate against laminate because penetration of air and steam is only possible through the paper side. The inner packaging must not be folded so that the passage of sterilant remains unhindered.

Limitations for Use

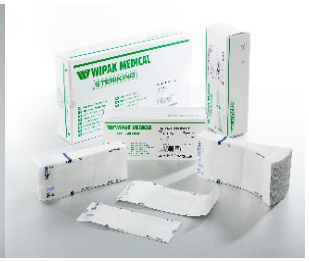
LT-Blueline Pouches and Rolls are not suitable for sterilization by hot, dry air or by steam.

Sealing

All seals, including closure seal/seals should be smooth, i.e. without folds, bubbles, or wrinkles. The plastic film turns a darker shade where the sealing has taken place, making it easy to check that the seal is intact. Heat sealing devices must be capable of attaining the sealing conditions suitable for each specific sterile barrier system construction. Correct temperature, pressure and sealing time/speed combination need to be met. Preferably, only sealing devices manufactured and intended for medical use should be used.

The sealing temperature shall be in the range of 120°-130°C (248-266°F). As a recommendation the sealing force should be at minimum 95 N and at maximum 120 N. The sealing time of heat-sealer is not normally adjustable; the speed of heat-sealer is usually from 8 m/min to 10 m/min. The needed parameters might vary due to the quality and type of the sealer used.

The seals need to be strong to withstand the sterilization process and handling yet providing a clean peel. Closing too strongly should be avoided. A manual test should be carried out for controlling the seal strength. 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.

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STERIS® Cycles

Compatible with following sterilization cycles:
V-Pro® MAX and Max 2 Flexible Cycle
V-Pro® 1 Plus Lumen Cycle
V-Pro® 1 Plus Non-Lumen Cycle

Device lumen dimensions:

V-Pro® MAX and Max 2 Flexible Cycle: 1 lumen x 1 mm min ID x 1050 mm max length for all pouch sizes.
V-Pro® 1 Plus Lumen Cycle: 1 lumen x 1 mm min ID for all pouch sizes. For pouch sizes 250x500mm, 250x390mm, 205x390mm, max length of 125 mm. For all other pouch sizes, max length of 50 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 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 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 humidity of 30 to 60% 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.

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 LTS Flat Pouches

Art. Code	Size
LTS7520	75 x 200
LTS1025	100 x 250
LTS1530	150 x 300
LTS1644	160 x 440
LTS1660	160 x 600
LTS2038	205 x 390
LTS2538	250 x 390
LTS2550	250 x 500

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.

We care that you pack safely!

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