Steriking® See-Through Pouches and Rolls

Product references: See list on the last page of the IFU.

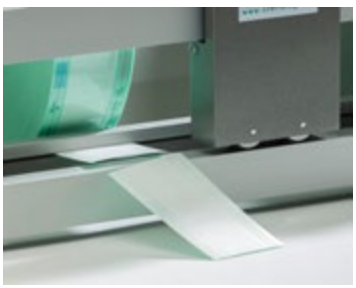
Steriking® See-Through Pouches and Rolls are intended for use as packaging material for reusable instruments in sterilization by steam, ethylene oxide and formaldehyde in health care establishments. The products are for single use only. Products are designed to be used by trained healthcare professionals. Benefit of Preformed sterile barrier system 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 come in two forms:

1. The continuous **roll** type is sealed along both edges. The roll is unwound and cut to the desired length. The device is placed between the two layers and both ends are sealed.
2. The second form is precut to a specific size and sealed on its three sides. The device is placed inside the **pouch** and the fourth side is sealed or closed by tape (Self-sealable pouches).

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 and minimum of 2 cm of 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® rolls 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

See-Through Pouches and Rolls are not suitable for sterilization by irradiation, by hydrogen peroxide, or by hot, dry air, or at the temperatures over 140°C.

* official product groups listed on the last page of IFU

Sealing

All seals, including closure seal/seals should be smooth, i.e. without folds, bubbles, or wrinkles. The colored 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 165°-200°C (329-392°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 most vigorous sterilization process and handling, yet providing a clean peel. Closing too strongly should be avoided when sealing rolls as one of the seals needs to be opened fiber free. 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 paper 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 press while moving thumbs. Repeat at least three times to ensure a clean and air-tight seal. After closuring it must be checked that the seal is free of air channels.

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 paper 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, indicators etc.



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Loading the autoclave

If possible, the packages should be placed upright in the sterilizer, using partitions if necessary. If it is not possible to place the packages upright, they can be placed flat with porous material facing down. The packages should not be folded and they must not touch the chamber walls.

The basket should not be packed too full, as the packages expand during the sterilization process and they must also be allowed to breathe freely. If a sterilization cycle must be repeated do to a malfunction or a cycle is aborted before completion, products must be repacked prior to being placed into another sterilization cycle.

Pouches and rolls are intended for single use only; product characteristics and performance cannot be guaranteed if the pouch or roll is sterilized more than once.



Inspection

After sterilization, the packages and products must be allowed to cool down before handling, checking and sorting them. Each product is checked as to whether the packaging is intact, the changes communicated by the process 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.

Type 1 process indicator printed on the packaging help distinguish between products that have or have not been processed, but do not provide evidence of sterilization. Indicators with a higher classification convey information on whether the sterilization process has attained the parameters controlled by the indicator.

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 paper material slowly and evenly to prevent the fibers from breaking and thereby possibly causing contamination. 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.



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.

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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.

Product groups and references:
Steriking® See-Through Heat-Sealable Pouches: S1; S2; S3; S4; S5; S6; S7; S7A; S8; S9; S10; S10A; S11; S12; S13; S14; S15; S16; S17; S18; S19; S20; S21; S22; S23; S24; S25; S26; S27; S28; S29; S30; S31; S32; S33; S34; S35; S36; S37; S38; S2030; S2070; S1-3P; S2-3P; S3-3P; S4-3P; S5-3P; S6-3P; S7-3P; S7A-3P; S8-3P; S9-3P; S10-3P; S10A-3P; S11-3P; S12-3P; S13-3P; S14-3P; S15-3P; S16-3P; S17-3P; S18-3P; S19-3P; S20-3P; S21-3P; S22-3P; S23-3P; S24-3P; S25-3P; S26-3P; S27-3P; S28-3P; S29-3P; S30-3P; S31-3P; S32-3P; S33-3P; S34-3P; S35-3P; S36-3P; S37-3P; S38-3P; S2030-3P; S2070-3P

Steriking® See-Through Gusseted Pouches: B30; B31; B32; B33; B34; B35; B36; B37; B38; B30-3P; B31-3P; B32-3P; B33-3P; B34-3P; B35-3P; B36-3P; B37-3P; B38-3P

Steriking® See-Through Heat-Sealable Rolls: R39; R40; R41; R125; R42; R43; R44; R45; R46; R47; R39-3P; R40-3P; R41-3P; R125-3P; R42-3P; R43-3P; R44-3P; R45-3P; R46-3P; R47-3P; R39/100; R40/100; R41/100; R42/100; R43/100; R44/100; R45/100; R46/100; R47/100; R49/100; R39-3P/100; R40-3P/100; R41-3P/100; R42-3P/100; R43-3P/100; R44-3P/100; R45-3P/100; R46-3P/100; R47-3P/100; R49-3P/100; R39/31; R40/31; R41/31; R42/31; R43/31; R44/31; R45/31; R46/31; R47/31; R49/31; R39-3P/31; R40-3P/31; R41-3P/31; R42-3P/31; R43-3P/31; R44-3P/31; R45-3P/31; R46-3P/31; R47-3P/31; R49-3P/31

Steriking® See-Through Gusseted Rolls: RB50; RB51; RB52; RB53; RB54; RB55; RB56; RB57; RB58; RB59; RB50-3P; RB51-3P; RB52-3P; RB53-3P; RB54-3P; RB55-3P; RB56-3P; RB57-3P; RB58-3P; RB59-3P

Steriking® See-Through Self-Sealable Pouches; SS1; SS2; SS3; SS4; SS4A; SS5; SS5A; SS6; SS7; SS10; SS-T1; SS-T2; SS-T3A; SS-T4; SS-T4A; SS-T5A; SS-T6; SS-T7

Steriking® is a registered trademark of Wipak.

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