Steriking® See-Through Pouches and Rolls

Product groups:
Steriking® See-Through Heat-Sealable Pouches, Steriking® See-Through Heat-Sealable Rolls, Steriking® See-Through Self-Sealable Pouches

Steriking® See-Through Pouches and Rolls are intended for use as packaging material for reusable instruments in sterilization by steam and ethylene oxide 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 until used and enable aseptic presentation of packed medical device.

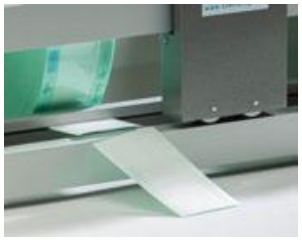
Preformed sterile barrier systems made of **porous material and transparent film** construction come in two forms:

1. The continuous **roll** type is sealed along both edges. The roll is unwound and cut to the desired length. One end of the pouch cut from the sterilization roll is sealed. The device is placed inside the pouch between the two layers, and the other end is then 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).

Recommended sterilization cycles

Process	Temperature Setting	Exposure Time	EO Concentration	Drying/Aeration Time
Steam, Gravity Cycle	250°F (121°C)	30 min	N/A	25 min dry time
Steam, Pre-vacuum Cycle	270°F (132°C)	4 min	N/A	20 min dry time
Steam, Pre-vacuum Cycle	275°F (135°C)	3 min	N/A	16 min dry time
Ethylene Oxide (EO)	131°F (55°C)	60 min	725–735 mg/L	8 h aeration at 140°F (60°C)

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 packages be filled to approximately three-quarters of their length, with approximately 3/4 inches of free space maintained 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.



When double packaging is used, packages should be arranged with the porous material facing porous material and the transparent film facing transparent film to facilitate air removal and sterilant penetration. The inner package should be placed flat within the outer package and should not be folded or configured in a manner that could impede sterilant penetration or drying. Use only validated double-package configurations.

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 temperatures over 140°C.

Sealing

Heat Sealing pouches and rolls

All seals shall be smooth and continuous, without folds, wrinkles, bubbles, channels, voids, or other visible defects.
Heat sealing equipment shall be designed and maintained for medical packaging applications and capable of producing consistent seals. Sealing shall be performed using validated process parameters in accordance with the instructions provided by the sealing equipment manufacturer and the sterile barrier system manufacturer.

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The recommended 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 completed seal shall provide package integrity throughout sterilization, transportation, handling, and storage while allowing aseptic presentation at the point of use.

After sealing, inspect the seal for:

- Continuous sealing from end to end
- Uniform appearance along the entire seal
- Absence of channels, folds, wrinkles, bubbles, or burn-through
- No evidence of incomplete sealing

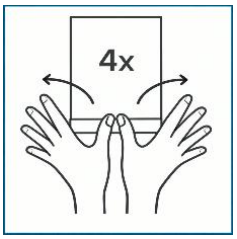
Seal quality should be routinely verified according to facility procedures. A manual inspection and peel evaluation should be performed when appropriate to confirm seal integrity and opening performance.
Closures that compress the package shall not be used (e.g., strings, elastic bands, paper clips, staples, or similar items).

Self-Sealing Pouches

All seals, including the closure seal, shall be smooth and continuous, without folds, wrinkles, bubbles, channels, or other visible defects. Self-sealing pouches incorporate an adhesive closure system designed to provide a secure package seal.

To close the pouch:

1. Remove the protective liner from the adhesive strip.
2. Fold the closing flap along the pre-folded line.
3. Press the flap firmly against the film side of the pouch, starting in the center and moving toward both edges.
4. Apply even pressure across the entire seal area.
5. Repeat the sealing motion at least three times to achieve a uniform seal.



After closure, inspect the seal to verify that:

- The closure is completely sealed from end to end.
- No channels, gaps, folds, wrinkles, or bubbles are present.
- The package remains flat and undamaged.

The completed seal shall maintain package integrity throughout sterilization, handling, transport, and storage while allowing aseptic presentation. Closures that compress the package shall not be used (e.g., strings, elastic bands, paper clips, 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 instruments should not have the 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 numbers etc.

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Loading the autoclave

If possible, packages should be placed on edge in the sterilizer using racks or dividers to maintain separation. Packages on edge should be oriented from paper side to plastic side. When placement on edge is not feasible, packages may be placed flat. Packages shall not be folded or bent and shall not come into contact with the sterilizer chamber walls.



The sterilizer basket or carriage shall not be overloaded. Packages must be arranged to allow adequate circulation of the sterilant and facilitate drying during and after the sterilization cycle. Care should be taken to prevent compression of packages.

If a sterilization cycle must be repeated due to a malfunction, or if the cycle is interrupted or aborted before completion, the products shall be repackaged before being subjected to 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 should be inspected to ensure that the packaging is intact, and the product is clean and dry. In any unclear or ambiguous situation (e.g., wetness in the pack, visible stains, or other impurities), items should be considered unsterile.



Storage and transportation

It is recommended that products should 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.



After sterilization the product maintains sterility of the enclosed device until used. 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 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.

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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.



Steriking® is a registered trademark of Wipak.

We care that you pack safely!

WIPAK

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