



How to use



Product Name:
Rolls and pouches for SOGEVA sterilization

Product Description:
SOGEVA sterilization rolls and pouches are made of a multi-layer film made of PET/PP copolymer and medical grade paper. By changing color, Class 1 process indicators for steam, ethylene oxide offer visual confirmation that sterilization conditions have been met.

Directions for use:
SOGEVA sterilization rolls and pouches are designed to provide healthcare professionals with an effective method of containing medical devices intended for sterilization by steam, ethylene oxide or formaldehyde. It is intended to allow sterilization of the included medical devices and also to maintain the sterility of the closed device until the time of use.

Indicator Color Change:
SOGEVA sterilization rolls and pouches are equipped with Class 1 process indicators printed with non-toxic, water-based ink. The indicators comply with ISO 11140-1. SOGEVA chemical process indicators provide a clear and precise color change after sterilization.

- The Class 1 Steam Indicator changes from **blue to dark green** after being exposed to the steam sterilization process.
- The Class 1 Ethylene Oxide Indicator changes from **pink to orange** after exposure to the ethylene oxide sterilization process.
- The Class 1 formaldehyde indicator changes from **green to yellow** after being exposed to the formaldehyde sterilization process.

How to use:

1. **SOGEVA sterilization pouches** are ready for use. SOGEVA rolls for sterilization must be cut to the required length.
2. Do not use if the package is damaged. Do not reuse. Single-use product.
3. Form an envelope by sealing one of the open ends of the roll portion with a calibrated sealing device and via a validated sealing process.
The recommended sealing temperature is between 170 °C and 190 °C (338 - 374 °F), for a duration of operation of 1-4 seconds.
4. Cover the sharp ends of the tools with a guard to prevent punctures and cuts.
5. Place the item to be sterilized in the pouch. Do not fill envelopes to more than 75% of their capacity. Always leave a minimum of 1.5 cm (0.6 inches) of space between the instrument and each sealed edge of the pouch to avoid excessive tension of the sealed parts.
6. Before closing, manually remove as much air as possible from the bag.
7. Seal the open end of the pouch with a calibrated sealing device, via a validated sealing process.
8. During use, avoid stress on the sealed parts; fill the bag by keeping it horizontal on a flat surface.
9. When loading pouches into the sterilizer, place them in the basket so that the foil sides are facing the foil sides and the paper sides are facing the paper sides.
10. **Bag** should be placed in the basket or tray in an upright position and not too close together, so that a hand can pass between them.
11. **Allow to dry** for at least 20 minutes after pre-vacuum steam sterilization.
12. **When removing pouches from the sterilizer**, Handle them carefully to avoid tearing. Store pouches away from sunlight, water, and other liquids.
13. Do not use wet envelopes. If you change the pouch, repeat the sterilization process.
14. To open the envelope, use your thumb and forefinger to hold the paper side and the thumb and forefinger of your other hand to pull the film side. Always open the envelope in the direction of opening. For perfect removal of the film, open the pouch slowly and carefully.

Lot number:
SOGEVA Sterilization Rolls and Pouches are supplied with a LOT number printed on medical grade paper. The LOT number allows the traceability of the product during the manufacturing process. If you have any complaints or feedback, you need to store the LOT number and provide a picture.

Storage conditions:
Sterilization packaging must be protected from light liquids and excess moisture. If the paper side of the envelope is wet, do not use it anymore and dispose of it as specified.

Duration of sterility:
Sterilized pouches and rolls must be stored in clean, closed cabinets, with controlled humidity and temperature. It is recommended to maintain the temperature between 8 and 35 °C and the humidity between 30 and 70%. Maintaining sterility with these controlled parameters will allow the product to be sterile for up to a maximum of 6 months and in any case not beyond the expiry date (Table 1. DIN 58953:8-2010).

Shelf life / expiry date:
The shelf life (pre-sterilization) of SOGEVA sterilization rolls and pouches is 5 (five) years from the date of manufacture to the recommended storage and handling conditions. The product must be used within 5 years from the date of manufacture. The expiration date and manufacturing date are printed on the inner label and shipping box label. It is intended to allow sterilization of the included medical devices and also maintain the sterility of the closed device until the time of use.

Any serious incident occurring in relation to the device must be reported to the manufacturer and the competent authority of the user's member state and/or patient.

Disposal instructions:
Dispose of used or damaged sterilization rolls and pouches in autoclavable biohazard bags, not in regular waste bags.



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