

**Product Description**

Sterilization reels and Pouches are single used package which holds medical Instruments during Sterilization process. Using these products improve the sterilization quality.

By using these products, the instruments could be stored sterilized for longer period of time.

Our products comply with ISO 11607-1 and EN 868-5.

Please note that all serious accidents which occur in connection with the medical device (e.g. death or serious deterioration in the state of health of a patient) which were presumably caused by the device, must be reported to the manufacturer and the relevant authority of the member state, in which the user and/or patient resides.

**Storage**

Pouches should be stored in a cool and dry place. A good stock rotation is recommended. Advised storage temperature is between 0-40 °C (32-104 °F) and relative humidity between 30-70%.

The product should be stored away from direct sunlight, UV light and moisture.

**Shelf life before sterilization:**

In optimal using and storage conditions, shelf life expected is of 5 years from manufacturing date.

**Disposal**

Please refer to the local/national regulations regarding waste disposal.

PLEASE NOTE: Label contaminated roll and pouches and dispose of them in the designated special waste (e.g. in biohazard bags).

**EU-Authorized Representative address**

Sterifast, Parque Empresarial do Padrão Nº 11 5460-343 Boticas Portugal.

## How to use

### **PAPER/FILM FLAT AND GUSSET POUCH**

Directions: Place items to be sterilized into sterilization pouch. Seal the pouch with a heat-seal machine. The sealing temperature should gradually increase by one degree until it reaches the desired temperature. The temperature range shall be between 160-210 °C within 5 to 8 seconds.

Use a pouch rack to eliminate stacking of the sterilization pouches, if possible. Check that pouches are dry upon removal.

Stored in the original packaging (transparent wrap).

Indicators: Type I Chemical indicators printed on pouches, will change color after sterilization process. Chemical indicators are only process indicators and they can never confirm sterility. To validate the sterilizing process please use type 5 and 6 indicators. Type 6 Chemical indicators should be used with biological indicators to verify sterilization has been completed.

### **SELF-SEALING PAPER/FILM POUCH**

Directions: Place items to be sterilized into sterilization pouch. Before peel off strip, fold slightly the sealing zone, to mark the folding line. Peel off strip from adhesive band, fold along and press down firmly to seal adhesive strip. Make it from center outwards. Adhesive must cover both paper and plastic, avoiding any bubble or hole. Use a pouch rack to eliminate stacking of the sterilization pouches, if possible. Check that pouches are dry upon removal.

Indicators: Type I Chemical indicators printed on pouches, will change color after sterilization process. Chemical indicators are only process indicators and they can never confirm sterility. Type 6 Chemical indicators should be used with biological indicators to verify sterilization has been completed.

### **PAPER/FILM FLAT AND GUSSET ROLL**

Directions: Place items to be sterilized into sterilization roll and cut to the desired length. The length tolerance of this product is  $\pm 0.3\%$ .

Seal the two opens with a heat-seal machine. The sealing temperature should gradually increase by one degree until it reaches the desired temperature. The temperature range shall be between 160-210 °C within 5 to 8 seconds.

Use a pouch rack to eliminate stacking of the sterilization pouches, if possible. Check that pouches are dry upon removal.

Stored in the original packaging (transparent wrap).

Indicators: Type I Chemical indicators printed on pouches, will change color after sterilization process. Chemical indicators are only process indicators and they can never confirm sterility. Type 6 Chemical indicators should be used with biological indicators to verify sterilization has been completed.

Note1: Please pay attention to the process indicator printed on the rolls and check them for the right color change.

**TYVEK®/FILM FLAT POUCH (VH2O2 / Plasma)**

Directions: Place items to be sterilized into sterilization pouch Seal the pouch with a heat-seal machine. The sealing temperature should gradually increase by one degree until it reaches the desired temperature. The temperature range shall be between 115-150 °C.

Indicators: Type I Chemical indicators printed on pouches, will change color after sterilization process. Chemical indicators are only process indicators and they can never confirm sterility. Type 6 Chemical indicators should be used with biological indicators to verify sterilization has been completed.

Note: protected from acids and bases. Keep away from sterilizer, before and after sterilization process.

**TYVEK®/FILM FLAT ROLL (VH2O2 / Plasma)**

Directions: Place items to be sterilized into sterilization roll and cut to the desired length. The length tolerance of this product is ± 0.3 %.

Seal the pouch with a heat-seal machine. The sealing temperature should gradually increase by one degree until it reaches the desired temperature. The temperature range shall be between 115-150 °C.

Indicators: EO and Type I Chemical indicators printed on pouches, will change color after sterilization process. Chemical indicators are only process indicators and they can never confirm sterility. Type 6 Chemical indicators should be used with biological indicators to verify sterilization has been completed.

Note1: protected from acids and bases. Keep away from sterilizer, before and after sterilization process.

Note2: Please pay attention to the process indicator printed on the rolls and check them for the right color change.

**Relative Symbols**

For more information use IFU



Keep dry



Factory address



Do not re-use



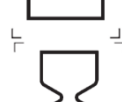
Date of manufacture



Do not use if package is damaged



Expiration date



Temperature range



Lot number



CE mark



Keep away from sunlight



**Limitation**

1. The application and method of using this product is according to the label and IFU.
2. Do not use if the sterile barrier system is damaged.
3. This product is disposable.
4. Use the earliest materials received first.
5. The user should mention the product Lot No., placed at reel plastic core, on all pouches to allow tracking of product in the future.
6. When placing pouch containing tools inside the tray, make sure that they do not stack on top of each other.
7. When two Pouches are used, the inner Pouch must be able to move in the outer Pouch to prevent the two Pouches from sticking.
8. Place the sterilization material in the pouch. Fill to a maximum of 75 % of the pouch volume. For instruments with a greater height, keep a greater distance from the seal seam.
9. The instruments should be positioned so that they can be moved easily using the tool handle itself (especially in the case of sharp items).
10. To improve the performance of the drying process, Place the pouch with the transparent side face down (in contact with the tray) and with the paper face up.
11. Items must be packed separately.
12. When arranging the packs, pay attention to the fact that the film part of the pack does not cover the paper side of the other pack and does not prevent the penetration of the sterile agent.
13. The overall width of seal(s) shall be not less than 6 mm. for ribbed seals, the sum of the widths of the ribs shall be not less than 6 mm. According to EN 868-5.
14. In the case of using Steam Autoclave, to avoid risk of burning wait until the product cool down.
15. When placing the packs inside the autoclave, make sure that the weight of the item placed inside the autoclave corresponds to the weight mentioned for the cycle recommended by the autoclave manufacturer.
16. Do not use reels and pouches that have become wet. Repeat the sterilization process with a new roll or pouch.
17. Fill the pouches horizontally on a flat surface to avoid stressing the sealing seams.
18. Leave a minimum distance of 1.5 cm between the item to be sterilized and the seal seams to ensure an even air flow during sterilization.
19. Hold the paper side to open the pouch. Slowly pull off the plastic side in the direction the peel arrow to get a clean peel result.
20. Before sealing, remove as much air as possible from the pouch.
21. Place the pouches on edge in baskets, containers or foil holders for optimal drying. Make sure there is enough space between the pouches to ensure an even air flow during sterilization. Do not stack pouches on top of each other on trays or baskets.