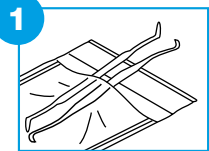


Self-Seal Sterilization Pouches

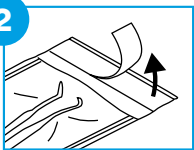
- en** Self-sealing sterilization pouches
- nl** Sterilisatiezakjes met zelfklevende sluiting
- fr** Sachets de stérilisation auto-adhésifs
- de** Sterilisationsbeutel mit selbstklebendem Verschuß
- pl** Samozamykające się torebki sterylizacyjne
- da** Selvklæbende autoklavepose
- sv** Självförlutande steriliseringspåsar
- no** Selvforseglende steriliseringsposer
- fi** Itsesulkeutuvat sterilointipussit
- es** Bolsas de esterilización
- pt** Bolsas de esterilização
- it** Buste per sterilizzazione
- hr** Kese za sterilizaciju
- sl** Sterilizacijske vrečke
- sk** Sterilizačné vrecká
- cs** Sterilizační sáčky

Product #	Description
84 18 72	Self-Sealing Sterilization Pouches 57x105 mm
84 18 74	Self-Sealing Sterilization Pouches 70x230 mm
84 18 76	Self-Sealing Sterilization Pouches 83x135 mm
84 18 80	Self-Sealing Sterilization Pouches 90x230 mm
84 18 83	Self-Sealing Sterilization Pouches 90x530 mm
84 18 84	Self-Sealing Sterilization Pouches 135x350 mm
84 18 85	Self-Sealing Sterilization Pouches 135x260 mm
84 18 86	Self-Sealing Sterilization Pouches 190x280 mm
84 18 87	Self-Sealing Sterilization Pouches 252x350 mm
84 18 88	Self-Sealing Sterilization Pouches 300x430 mm



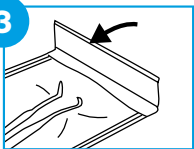
1

en Place item in pouch
 nl Plaats item in het zakje
 fr Placer l'article dans le sachet
 de Artikel in den Beutel legen
 pl Umieścić przedmiot w torebce
 da Læg genstande i posen
 sv Lägg föremålet i påsen
 no Legg varen i posen
 fi Aseta tuote pussiin



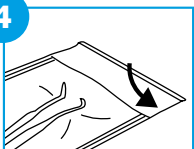
2

en Peel off protective strip from adhesive band
 nl Verwijder de beschermstrip van de plakband
 fr Retirer le film protecteur de la bande adhésive
 de Den Schutzstreifen vom Klebeband entfernen
 pl Odkleić pasek ochronny z taśmy klejącej
 da Skræl beskyttelsesstrimlen fra klæbebandet
 sv Dra av skyddsremsan från det självhäftande bandet
 no Trekk av beskyttelsesremsen fra limbåndet
 fi Irrota liinanauhan suojanauha



3

en Fold over paper flap
 nl Vouw de papieren flap om
 fr Plier le rabat de papier le long du pli
 de Die Papierklappe an der Faltlinie umfalten
 pl Zagiąć papierową zakładkę
 da Fold papirklap ved foldelinjen
 sv Vik över pappersflik
 no Brett over papirklaffen
 fi Taita paperiläpän päälle



4

en Press down firmly from the center outwards
 nl Druk stevig vanuit het midden naar buiten
 fr Presser fermement à partir du centre vers l'extérieur
 de Von der Mitte nach außen hin fest andrücken
 pl Mocno docisnąć od środka do brzegów
 da Tryk godt ud fra midten
 sv Tryck ned ordentligt från mitten och utåt
 no Trykk godt ned fra midten og utover
 fi Paina tiukasti keskeltä ulospäin

1. Product description

Sterilization Packaging Pouch/Reel is a packaging material suitable for pressure steam sterilization and ethylene oxide sterilization with sterilization indicators. It is made by heating sealed medical dialysis paper and transparent colored PET/PP composite film. It is suitable for the sterilization process, providing protection after sterilization, and distinguishing between unsterilized and sterilized products through the sterilization process indicator.

The medical devices are inserted into the Pouch/Reel, sealed, and then sterilized for the EtO or Steam Sterilization Process. The heat-sealed pouch are heat sealed prior to sterilization processing. After completion of the sterilization process, the Pouch maintain sterility of the enclosed medical devices until the seal is opened.

The Pouch/Reel is printed with a chemical indicator bar that changes from Pink to Yellow (EtO) or Blue to Dark grey (Steam) when exposed to EtO gas or Steam vapor during process. The EtO and Steam Chemical Indicator offers an additional way to verify processing in the sterilization cycle. The Chemical Indicator should be used in addition to, not in place of, the biological indicator. The EtO and Steam Chemical Indicators do not signify sterilization; they only indicate that the indicator has been exposed to the EtO or Steam.

2. Scope of use

Suitable for sterilization packaging of medical devices sterilized by pressure steam or ethylene oxide.

3. Instruction for usage

- 3.1. Please select the appropriate packaging pouch based on the size of the medical device (medical device should not exceed 3/4 of the packaging). Place the clean and dry medical device in the pouch to ensure sealing completely. Implementing the sterilization method and following the sterilization operation specifications.
- 3.2. The placement of sharp devices should be opposite to the peeling direction (to ensure safe peeling).
- 3.3. Colours during (STEAM) steam sterilisers: The indicator changes from blue to dark grey under the conditions of temperature 121°C, lasting 15-20 minutes, or temperature 134°C, lasting 3-5 minutes of steam sterilization.
- 3.4. Colours during (EO) chemical sterilisation process: The indicator changes from pink to yellow under the conditions of ethylene oxide concentration 500-800mg/L, temperature 50-60°C, relative humidity 40-80%, for 2-4 hours, Aeration time of 7 days at 18°C.
- 3.5. Dry heat sterilization exceeding 140°C is not applicable.
- 3.6. Store the finished sterilization pouches in a dry, clean area and protect from light.
- 3.7. When needed, peel the sterilization pouch to retrieve the items according to instructions.

4. Precautions

- 4.1. The reference temperature for heat sealing is 180°C - 220°C, pressure is 0.2 - 0.6MPa, sealing time is 2 - 6 seconds.
- 4.2. Before using, check the sealing integrity of the sterilization pouches. Do not use if the packaging is damaged.
- 4.3. Disposal of used sterilization pouches: sending to landfill or incinerating under supervision.
- 4.4. This product should not be used as an indicator of sterilization effectiveness. Color changing only indicates that the product has undergone the sterilization process and should not be used as a sterile indicator.
- 4.5. This product is for single-use only. Reusing is prohibited.
- 4.6. Storage conditions: :Store at room temperature 10-40°C, humidity 30-65% RH, and avoid light.

5. Date of Expiry

The storage valid for five years, and the sterile shelf life after sterilization is two years.