STERIS
Life Sciences

STERILIZATION POUCHES WITH PET FILM

TECHNICAL DATA

GENERAL DESCRIPTION

STERIS offers a comprehensive portfolio of autoclave bags, sterilization pouches, covers, and sheets manufactured from DuPont™ Tyvek®[1] non-woven spunbonded olefin material. These products help to maximize efficiencies in production while maintaining a microbial barrier to protect surfaces of critical components and equipment. The customized and unique solutions are designed to save time, improve compliance, and reduce the risk of contamination. Please note that these products are not for use in the reprocessing of medical devices.

Sterilization pouches with PET film are available as clean-peel clear film pouches or as clear film tubing, comprised of a Tyvek® layer and a polyester-based flexible film layer. The pouches are secured using an adhesive self-seal or by a heat-sealing process and are available in many sizes to simplify component preparation before sterilization. The tubing is secured using a heat seal and is available as rolled material to offer maximum flexibility in sizing at the point of use. The pouches have a unique chevron peel design for easy opening without the use of tools that improves aseptic presentation at the time of use.

The Tyvek® material used in STERIS pouches is puncture-resistant, extremely durable, and ideally suited for steam sterilization in an autoclave. During sterilization, the Tyvek® material allows for efficient air removal, steam penetration, and drying while serving as an effective microbial barrier. The clear film side offers excellent clarity combined with strength and durability.

FEATURES	BENEFITS
Low particulate generation	Ideally suited for use in isolators, restricted access barrier systems (RABS), and ISO 5 cleanroom environment
Easy-to-open chevron peel	Pouches can be opened without tearing or cutting, helping to keep particulate counts low
	No tools required to open the pouch
Breathable yet hydrophobic	Highly effective air removal and vapor penetration during steam sterilization
	Does not retain moisture, facilitating drying after steam sterilization
	Compatible with vaporized hydrogen peroxide (VHP) decontamination processes
Clear film side that allows parts to be seen	Easily identify which parts are in which pouches
Superior microbial barrier properties	Protect critical product contact surfaces
	Easily maintain sterility assurance levels, with greater than 99.99% spore retention
Tear and puncture-resistant	Securely holds items with sharp points, corners, or edges
Variety of sizes	Numerous standard size options
	Customized sizes to meet specific needs and ensure proper fit
STERIS Quality Systems and Manufacturing Controls	Products manufactured under Quality Systems designed to support the needs of pharmaceutical and biotechnology companies governed by 21 CFR § 210, 211, 820

1 DuPont™ and Tyvek® are trademarks or registered trademarks of affiliates of DuPont de Nemours, Inc.

PRODUCT OPTIONS

	Self-Seal Pouch	Heat-Seal Pouch	Heat-Seal Tubing
Material	Tyvek® spunbonded polyolefin/ PET film	Tyvek® spunbonded polyolefin/ PET film	Tyvek® spunbonded polyolefin/ PET film
Color	White/clear	White/clear	White/clear
Sizes	Variety of sizes available	Variety of sizes available	Variety of sizes available
Easy-to-open chevron peel	Yes	Yes	N/A
Steam sterilization process indicator	Optional	Optional	Optional

PRODUCT PROPERTIES

Table 1: Typical Properties for PET-based Adhesive Laminate Film Layer

Attribute	Test Method	Typical Value (US)	Typical Value (International)
Physical			
Substrate Basis Weight	TAPPI T410	39.7 lb/3,000 ft^2	64.7 g/m^2
Yield	Calculated	10,882 in^2/lb	15.4 m^2/kg
Thickness	ASTM F2251	2.6 mil	66 µm
Mechanical			
Tensile (MD)	ASTM D882	7,200 psi	50 MPa
Tensile (CD)	ASTM D882	7,200 psi	50 MPa
Elongation (MD)	ASTM D882	110%	110%
Elongation (CD)	ASTM D882	90%	90%
Puncture Resistance (Sealant Side)	1/16” Radius Probe	6.0 lb_f	27 N
Puncture Resistance (PET Side)	1/16” Radius Probe	6.0 lb_f	27 N
Permeation			
OTR	ASTM D3985	7.4 cc/100 in^2/24 hr	115 cc/m^2/24 hr
WVTR	ASTM F1249	0.3 g/100 in^2/24 hr	4.6 g/m^2/24 hr

Table 2: Typical Properties for Tyvek® Non-woven Spunbonded Olefin Layer

Attribute	Test Method	Typical Value (US)	Typical Value (International)
Physical			
Substrate Basis Weight	ASTM D3776	2.2 oz/yd^2	74.7 g/m^2
Yield	Calculated	9,426 in^2/lb	13.4 m^2/kg
Thickness	ASTM D1777	7.8 mil	199 µm
Mechanical			
Tensile (MD)	EN ISO 1924-2	46 lb/in	205 N
Tensile (CD)	EN ISO 1924-2	49 lb/in	219 N
Elongation (MD)	EN ISO 1924-2	20%	20%
Elongation (CD)	EN ISO 1924-2	24%	24%
Elmendorf Tear (MD)	ASTM D1424	0.7 lb/in	3.2 N
Elmendorf Tear (CD)	ASTM D1424	0.9 lb/in	4.0 N
Mullen Burst	ISO 2758	175 psi	1,207 kPa
Permeation			
Porosity – Gurley	TAPPI T460	22 sec	NA
Porosity – Bendtsen	ISO 5636-3	NA	540 mL/min
Thermal Properties			
Remains stable through the steam cycle at a maximum temperature of 260°F (127°C).			

STEAM PROCESS INDICATOR

Sterilization pouches with PET film are available round steam chemical indicators, made without lead, designed for use in steam sterilization processes operating at 121°C/1 bar. Once through the steam sterilization process, the indicator changes to a color easily distinguishable from the unprocessed indicator. Steam sterilization process indicators distinguish steam exposed products from unexposed products, but do not indicate successful sterilization.

APPLICATIONS AND USAGE

Parts and equipment to be steam-sterilized in an autoclave are inserted between the layers of an appropriately sized pouch (Figure 1).

Closing the pouches is a simple procedure. For self-seal pouches, expose the adhesive strip (Figure 2), then fold at the delineated perforations at the open end of the pouch. Next, press the adhesive strip to the pouch, creating an integral seal along the entire width of the pouch (Figure 3). Once the pouches are sealed, they can be placed in the autoclave for steam sterilization. For heat-sealed pouches and tubing, a heat sealer is required to secure the items within the pouch. The pouch or tubing must be placed within the heat sealer without wrinkles or folds around the seal area to ensure an integral seal is created.

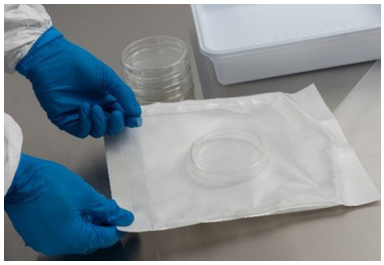

Figure 1: An item within the sterilization pouch

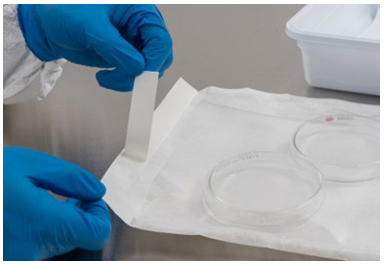

Figure 2: Exposing the adhesive strip on the self-seal sterilization pouch

Figure 3: Items within the sealed pouch

After the sterilization cycle and once the load has cooled, the sterilization pouches are removed from the autoclave. The chevron peel design allows for easy opening within controlled environments. The pouch is opened by peeling the film away from the Tyvek® material (Figures 4 and 5). Once opened, the inner surface of the pouch can be used as a sterile working surface, increasing sterility assurance and aseptic presentation of the item(s) at the time of use.

Figure 4: Grasping the two sides of the pouch at the chevron

Figure 5: Peeling open the pouch

In some cases, there are advantages to double wrapping the items in two sterilization pouches prior to sterilization. Again, the pouches must be appropriately sized to ensure the best sterilization performance. After the autoclave cycle is complete, the double wrapping allows for transitioning the items from one cleanroom classification to the next (or through a material handling airlock) by removing the outer pouch layer. This practice protects the higher classified area from potential contamination that may have been introduced to the surface of the outer pouch during transport and handling.

STORAGE AND SHELF LIFE

Sterilization pouches from STERIS are designed for stability over a long period, provided proper storage and handling practices are followed. Aging studies have been conducted on the materials of construction, demonstrating stability to three years if properly stored and handled.

Recommended storage conditions:

- Temperature: 45-85°F (7-29°C)
    - Wider extremes can be tolerated.

- Temperatures below 45°F/7°C do not harm the product; however, condensation may form if the material is taken from a cold area into a warm area and used immediately.

- Humidity: 30-60% relative humidity
  - Wider extremes can be tolerated; however, storage within this range before use in an autoclave is recommended to minimize condensation formation.
- Do not store near sources of heat or in direct sunlight.
- Protect outer packaging from damage (tears, punctures, etc.).

Expiration date for all products: The expiration date is printed on the label and is 36 months from the date of manufacture.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

For further information, please contact:

STERIS Life Sciences

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-444-9009
www.STERISLifeSciences.com