

**GENERAL DESCRIPTION**

STERIS offers a comprehensive portfolio of autoclave bags, sterilization pouches, covers, and sheets manufactured from DuPont™ Tyvek®<sup>1</sup> non-woven spunbonded olefin material. These products help to maximize efficiencies in production while maintaining a sterility 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 HDPE film are available as a translucent film pouch or as translucent film tubing, comprised of a Tyvek® layer and a high-density polyethylene (HDPE) flexible film layer. The pouches are secured 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 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 air removal, steam penetration, and drying while serving as an effective microbial barrier. The HDPE film side offers clarity combined with strength and durability.

**FEATURES**

**BENEFITS**

Low particulate generation

Breathable yet hydrophobic

Clear film side that allows parts to be seen

Superior microbial barrier properties

Tear and puncture resistant

Variety of sizes

STERIS Quality Systems and Manufacturing Controls

Ideally suited for use in isolators, restricted access barrier systems (RABS), and ISO 5 cleanroom environments

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

Easily identify which parts are in which pouches

Protect critical product contact surfaces

Easily maintain sterility assurance levels, with greater than 99.99% spore retention

Securely holds items with sharp points, corners, or edges

Numerous standard size options

Customized sizes to meet specific needs and ensure proper fit

Products manufactured under Quality Systems designed to support the needs of pharmaceutical and biotechnology companies governed by 21 CFR § 210, 211, 820

**PRODUCT OPTIONS**

	<b>Self-Seal Pouch</b>	<b>Heat-Seal Pouch</b>	<b>Heat-Seal Tubing</b>
Material	Tyvek® spunbonded polyolefin/HDPE film	Tyvek® spunbonded polyolefin/HDPE film	Tyvek® spunbonded polyolefin/HDPE film
Color	White/clear opaque	White/clear opaque	White/clear opaque
Sizes	Variety of sizes available	Variety of sizes available	Variety of diameters available
Steam sterilization process indicator	Optional	Optional	Optional

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

## PRODUCT PROPERTIES

**Table 1: Typical Properties for HDPE Film Layer**

Attribute	Test Method	Typical Value (US)	Typical Value (International)
<b>Physical</b>			
Substrate Basis Weight	TAPPI T410	42.1 lb/3,000ft <sup>2</sup>	69 g/m <sup>2</sup>
Yield	Calculated	10,260 in <sup>2</sup> /lb	14.5 m <sup>2</sup> /kg
Thickness	ASTM F2251	3.0 mil	76.2 μm
<b>Mechanical</b>			
Tensile (MD)	ASTM D882	>5,000 psi	>34.5 MPa
Tensile (CD)	ASTM D882	>4,000 psi	>27.6 MPa
Elongation (MD)	ASTM D882	>300%	>300%
Elongation (CD)	ASTM D882	>500%	>500%
Puncture Resistance (HDPE Side)	ASTM F1306 1/16 Radius Probe	3.0 lb <sub>f</sub>	13.3 N

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

Attribute	Test Method	Typical Value (US)	Typical Value (International)
<b>Physical</b>			
Substrate Basis Weight	ASTM D3776	2.2 oz/yd <sup>2</sup>	74.7 g/m <sup>2</sup>
Yield	Calculated	9,426 in <sup>2</sup> /lb	13.4 m <sup>2</sup> /kg
Thickness	ASTM D1777	7.8 mil	199 μm
<b>Mechanical</b>			
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
<b>Permeation</b>			
Porosity – Gurley	TAPPI T460	22 sec	NA
Porosity – Bendtsen	ISO 5636-3	NA	540 mL/min
<b>Thermal Properties</b>			
Remains stable through the steam cycle at a maximum temperature of 260°F (127°C).			

## STEAM PROCESS INDICATOR

Sterilization pouches with HDPE film are available with 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.

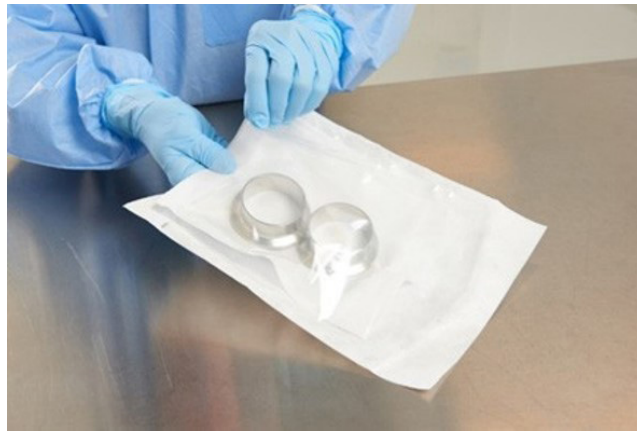
## APPLICATIONS AND USAGE

Parts and equipment to be steam sterilized in an autoclave are inserted between the layers of an appropriately sized pouch. For heat-seal pouches and tubing, a heat sealer is required to secure the items within the pouch. The pouch must be placed within the heat sealer without wrinkles or folds around the seal area to ensure an integral seal is created.

Once the pouches are sealed, they are placed in the autoclave for steam sterilization. After the sterilization cycle and once the load has cooled, the sterilization pouches are removed from the autoclave and can be easily opened using scissors, a knife, or another cutting device. 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.

In some cases, there are advantages to double wrapping the items in two pouches before 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.



**Figure 1: Double pouching for transport.**  
The outer pouch is slightly larger than the inner pouch

---

## 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 Corporation  
5960 Heisley Road  
Mentor, OH 44060-1834 • USA  
440-354-2600 • 800-444-9009  
[www.STERISLifeSciences.com](http://www.STERISLifeSciences.com)