

GENERAL DESCRIPTION

STERIS offers a comprehensive selection 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 bags are comprised of a flexible, drapeable, soft-structure Tyvek® material. The bags are secured using a drawstring or by a heat-sealing process and are available in customized sizes or as continuous tubing to simplify component preparation before sterilization.

The Tyvek® material used in sterilization bags from STERIS 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.

FEATURES

BENEFITS

Low particulate generation

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

Breathable yet hydrophobic

Highly effective air removal and vapor penetration during steam sterilization

Does not retain moisture, facilitating drying after steam sterilization

Superior microbial barrier properties

Compatible with vaporized hydrogen peroxide (VHP) decontamination processes

Protect critical product contact surfaces

Tear and puncture-resistant

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

Variety of sizes

Securely holds items with sharp points, corners, or edges

Numerous standard size options

STERIS Quality Systems and Manufacturing Controls

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

Material	Tyvek® spunbonded polyolefin
Color	White
Sizes	Variety of sizes available
Steam sterilization process indicator	Optional

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

PRODUCT PROPERTIES

Table 1: Typical Properties for Tyvek® Non-woven Spunbonded Olefin

Attribute	Test Method	Typical Value (US)	Typical Value (International)
Basis Weight	ASTM D3776 EN ISO 536	1.20 oz/yd ²	40.7 g/m ²
Delamination	ASTM D2724	0.08 lb _f /in	0.36 N/2.54 cm
Tensile Strength, MD	ASTM D5035 EN ISO 1924-2	8 lb _f /in	35 N/2.54 cm
Tensile Strength, CD	ASTM D5035 EN ISO 1924-2	9.2 lb _f /in	41 N/2.54 cm
Elongation, MD	ASTM D5035 EN ISO 1924-2	11%	11%
Elongation, CD	ASTM D5035 EN ISO 1924-2	18.9%	18.9%
Mullen Burst	ASTM D774 ISO 2758	47.9 psi	330 kPa
Gurley Hill Porosity	TAPPI T460 ISO 5636-5	21 sec/100 cc-in ²	21 sec/100 cc-in ²
Hydrostatic Head	AATCC TM 127 EN 20811	40 in/H ₂ O	102 cm/H ₂ O
Thermal Properties	Remains stable through the steam cycle at a maximum temperature of 250°F (127°C).		

STEAM PROCESS INDICATOR

Sterilization bags 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 into an appropriately sized sterilization bag. The drawstring feature allows for easy bag closure without the use of tape or a heat-sealer. It is recommended to use a “gooseneck” method for closure to create a tortuous path for protection of the sterilization bag contents. The gooseneck closure is created by first tightening the drawstring, then gathering the open end of the bag, twisting one full rotation, folding over, and securing with the drawstring (Figure 1). Alternatively, the sterilization bag can be secured using a heat-sealer or autoclave tape.



Figure 1: A gooseneck closure

Continuous tubing comes in varying widths and can be cut to different lengths to form different bag sizes. This provides additional flexibility to the user to create multiple bag sizes. Both ends need to be heat sealed closed.

After the sterilization cycle and once the load has cooled, the sterilization bags are removed from the autoclave. If a gooseneck closure were used, the bag is easily opened by untying the drawstring, unwinding the bag material, and loosening the drawstring. The gooseneck method has advantages over tape or heat-sealing, as no cutting tools are needed, and fewer particles are generated during the opening

process. Once opened, the equipment can be aseptically removed from the sterilization bag.

In some cases, there are advantages to double wrapping items prior to sterilization. For example, in Figure 2, a stopper bowl is first covered with an elasticized cover, then placed in a sterilization bag. After steam sterilization, the stopper bowl with the elasticized cover in place is removed from the sterilization bag for installation on the filling line. The elasticized cover remains in place, protecting the product contact surface until the time of use.



Figure 2: A stopper bowl is placed into a sterilization bag

STORAGE AND SHELF LIFE

Sterilization bags 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:



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