

**GENERAL DESCRIPTION**

STERIS offers a comprehensive selection 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 microbial barrier to protect surfaces of critical components and equipment. 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.

Elasticized covers provide a fast, convenient way to protect open containers and parts during preparation for steam sterilization. Made from a flexible, drapeable form of Tyvek® material, elasticized covers from STERIS are readily customized to fit a variety of products. For example, items may range from large, bulky stopper bowls to containers and parts with small openings, such as flasks, beakers, media bottles, valves, pipes, hoses, sanitary fittings, and carboys. The elastic allows the cover to be easily placed and ensures proper fit around the opening.

The Tyvek® material used in STERIS elasticized covers 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. Moreover, after sterilization, these covers can remain in place on the parts up until they are put into use, thereby minimizing the risk of any subsequent contamination.

**FEATURES**

**BENEFITS**

Low particulate generation

Breathable yet hydrophobic

Superior microbial barrier properties

Tear and puncture-resistant

Variety of sizes

Form fitting

Easy application and removal

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

Protect critical product contact surfaces

Securely covers items with sharp points, corners, or edges

Numerous standard size options

Customized sizes to meet specific needs and ensure proper fit

Close fit improves ease of application and removal

No excess material improves sterilization performance

Reduces time and labor needed to prepare items for autoclaving

No external materials (tape, rubber bands, etc.) necessary

Ensures a reproducible process when covering items across workers and shifts

Enhances aseptic presentation at the time of use

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

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

## PRODUCT OPTIONS

<b>Sizes</b>	Variety of standard and custom sizes available
<b>Closure</b>	Available as an elasticized cover or with Tyvek® drawstrings
<b>Steam sterilization process indicator</b>	Made without lead, round chemical indicators are available for covers 20" in diameter or larger

## PRODUCT PROPERTIES

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

Attribute	Test Method	Typical Value (English units)	Typical Value (Metric units)
Basis Weight	ASTM D3776 EN ISO 536	1.20 oz/yd <sup>2</sup>	40.7 g/m <sup>2</sup>
Delamination	ASTM D2724	0.08 lb <sub>f</sub> /in	0.36 N/2.54 cm
Tensile Strength, MD	ASTM D5035 EN ISO 1924-2	8 lb <sub>f</sub> /in	35 N/2.54 cm
Tensile Strength, CD	ASTM D5035 EN ISO 1924-2	9.2 lb <sub>f</sub> /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 <sup>2</sup>	21 sec/100 cc-in <sup>2</sup>
Hydrostatic Head	AATCC TM 127 EN 20811	40 in/H <sub>2</sub> O	102 cm/H <sub>2</sub> O
Thermal Properties	Remains stable through the steam cycle at a maximum temperature of 250°F (127°C).		

**Table 2: Other Materials**

Thread	Polyester
Elastic	Latex-free synthetic tape

## STEAM PROCESS INDICATOR

Elasticized and drawstring covers size 20" in diameter or larger 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 & USAGE

Elasticized covers provide an effective means of quickly and easily protecting critical product contact surfaces. Simply stretch the cover over the stopper bowl, flask, fitting, or other item to be sterilized, then pull the sides of the cover downwards over the opening. The elastic holds the cover securely in place, while the cover should fit loosely over the top of the item but without excess folds or bunching of the cover material.



**Figure 1. To apply an elasticized cover, stretch it over the opening, then pull the sides downward**



**Figure 2. Properly sized and applied covers achieve a close fit optimized for steam sterilization**

The simplicity with which elasticized covers can be applied results in a repeatable and reproducible process, particularly compared to wrapping items with sheets of cellulose-based paper and autoclave tape. Ease of application is especially significant when covering large openings on bulky items, such as stopper bowls, as well as when manipulating covers on narrow openings of small items, such as hoses or tubing. Furthermore, since no cutting of paper or tearing of tape is required to remove elasticized covers, particulate generation during the removal process is greatly reduced.

Because of the ease with which elasticized covers are removed, they can remain in place after autoclave sterilization until the item is placed into service, ensuring the protection of critical product contact surfaces. For example, stopper bowl covers remain on the bowl while the bowl is installed and remain in place during isolator or RABS decontamination; the covers are only removed immediately before filling. In this way, aseptic presentation is ensured to the point of use.

To further ensure that aseptic processing conditions are maintained, it is recommended to double bag items before sterilization. After the elasticized cover is applied, the item is placed inside an appropriately sized sterilization bag or Tyvek®/film bag (see Figure 3). This outer bag is removed after the item has been delivered to the filling line or other production area, while the elasticized cover remains in place until the point of use.



**Figure 3. Double bagging of covered items to maintain sterility during transport**

Elasticized covers from STERIS are also frequently used in oral solid dose manufacturing. Applications include covering access ports in tanks and covering the ends of process hoses. The breathability of these covers allows freshly cleaned process hoses to dry while protecting the interior of the hose from contamination.

## STORAGE AND SHELF LIFE

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Elasticized covers 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

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### 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.

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### For further information, please contact:



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