

GENERAL DESCRIPTION

The Purefit™ Sterilization Wrapping System from STERIS consists of a comprehensive selection of autoclave bags, 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 Purefit products are not for use in the reprocessing of medical devices.

Elasticized covers are used to protect critical surfaces of open containers and parts after steam sterilization. Proper wrapping of parts with an appropriately sized STERIS Purefit elasticized cover before autoclaving ensures effective steam penetration and air removal during sterilization, maintenance of sterility during transport and storage, and ease of aseptic presentation at the filling line.

Purefit elasticized covers are comprised of a drapeable, uncoated Tyvek® material. This uncoated flexible Tyvek® material has been developed specifically with the needs of pharmaceutical manufacturers in mind – no surface treatments, effective microbial barrier, low particulate generation, and puncture resistant. It is an ideal material for use in steam sterilization applications.

Purefit elasticized covers are available in a wide range of customizable sizes. Large covers are well suited for covering stopper bowls, bunkers, and hoppers, while on the other end of the spectrum, the Purefit mini covers provide a convenient way to cover small openings such as on valves, pipes, hoses, sanitary fittings, media bottles, and carboys. The elasticized opening allows these covers to be easily placed and easily removed. Due to the ease of removal, elasticized covers can be left in place on the parts after sterilization up until they are put into use, thereby minimizing the risk of any subsequent contamination.

FEATURES

BENEFITS

Constructed from uncoated Tyvek® material

Low particulate generation

Breathable yet hydrophobic

Superior microbial barrier properties

Tear and puncture-resistant

Variety of sizes

Form fitting

Easy application and removal

Mitigates risk of residues deposited on critical surfaces during autoclave steam sterilization

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 holds 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

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

PRODUCT PROPERTIES

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

Attribute	Test Method	Typical Value (US)	Typical Value (International)
Basis Weight	ASTM D3776	1.22 oz/yd ²	41 g/m ²
Delamination	ASTM D2724	0.08 lb _f /in	0.36 N/2.54 cm
Gurley Hill Porosity	TAPPI T460	20 sec/100 cc	20 sec/100 cc
Thickness	EN ISO 534	6 mils	152 µm
Tensile Strength, MD	EN ISO 1924-2	7.6 lb _f /in	34 N/2.54 cm
Tensile Strength, CD	EN ISO 1924-2	6.4 lb _f /in	28 N/2.54 cm
Elongation, MD	EN ISO 1924-2	10%	10%
Elongation, CD	EN ISO 1924-2	15%	15%
Elmendorf Tear, MD	ASTM D1424	2.4 lb _f	10.6 N
Elmendorf Tear, CD	ASTM D1424	1.9 lb _f	8.5 N
Mullen Burst	ISO 2758	53 psi	365 kPa
Puncture Resistance	EN 863	2.7 lb _f	12 N
Hydrostatic Head	AATCC TM 127	44 in H ₂ O	112 cm H ₂ O
Bendtsen Air Permeability	ISO 5636-3	741 ml/min	741 ml/min
Microbial Barrier	ASTM F1608	~4 log reduction value	~4 log reduction value
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

Purefit elasticized and drawstring covers size 20" in diameter or larger are available with lead-free, round steam chemical indicators, 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

Purefit elasticized covers provide an effective means of quickly and easily protecting critical product contact surfaces. Simply stretch the Purefit 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 a Purefit elasticized cover, stretch it over the opening, then pull the sides downward



Figure 2: Properly sized and applied Purefit elasticized covers achieve a close fit optimized for steam sterilization

The simplicity with which Purefit 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 Purefit elasticized covers, particulate generation during the removal process is greatly reduced.

Because of the ease with which Purefit covers are removed, they remain in place after autoclave sterilization until the item is needed, ensuring the protection of critical product contact surfaces. For example, Purefit stopper bowl covers remain on the bowl while the bowl is installed and remain in place during isolator or RABS decontamination; the Purefit covers are only removed immediately before filling. In this way, the critical surfaces are protected until 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 Purefit sterilization bag or pouch (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

Purefit elasticized covers 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 Purefit covers allows freshly cleaned process hoses to dry while protecting the interior of the hose from contamination.

STORAGE AND SHELF LIFE

Purefit products 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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