STERIS
Life Sciences

PUREFIT™ STERILIZATION BAGS

TECHNICAL DATA

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.

Sterilization bags are used to protect critical surfaces of components and equipment after steam sterilization. Proper wrapping of parts in an appropriately sized STERIS Purefit bag 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 sterilization bags 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 sterilization bags can be closed with tape, a heat sealer, or with an optional drawstring. Use of a drawstring enables the bag to be closed and opened without the need for additional equipment or supplies. Purefit sterilization bags are available in a large range of customizable sizes as well as in continuous form tubing. The tubing form provides users with the flexibility to cut different lengths of bags to fit their processes; both ends of the cut tubing would need to be taped or heat sealed closed.

FEATURES	BENEFITS
Constructed from uncoated Tyvek® material	Mitigates risk of residues deposited on critical surfaces during autoclave steam sterilization
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 Compatible with vaporized hydrogen peroxide (VHP) decontamination processes
Superior microbial barrier properties	Protect critical product contact surfaces 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 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_2O	112 cm/H_2O
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).		

STEAM PROCESS INDICATOR

Purefit sterilization bags are available with round steam chemical indicators that are made without lead and are 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 Purefit 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 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 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 Purefit sterilization bags are removed from the autoclave. If a gooseneck closure was 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 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 a Purefit elasticized cover, then placed in a Purefit 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: The equipment is placed into a Purefit sterilization bag

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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