

GENERAL DESCRIPTION

STERIS offers a comprehensive portfolio of autoclave bags, sterilization pouches, covers, and sheets manufactured from DuPont™ Tyvek®¹ non-woven spunbonded olefin material. These products provide a protective barrier between critical parts, components, and equipment, and viable and nonviable particulate that may be present in the production environment. Convenient and intuitive to use, these products save time and maximize efficiency while reducing the risk of contamination and simplifying compliance with cGMP protocols. Please note that these products are not intended for use in the reprocessing of medical devices.

Equipment covers provide a convenient and effective way to protect machines, carts, trolleys, shelves, racks, pallets, and other equipment in production areas. Covering equipment and fixtures is the best practice for both terminally sterilized and aseptically processed drug products. Using equipment covers ensures GMP compliance and simplifies conformance with drug processing protocols.

Made from Tyvek® material, STERIS equipment covers present low particulate risk, making them suitable for use in cleanroom environments. They are also puncture-resistant, extremely durable, moisture-resistant, and breathable, making them suitable for use in general-purpose areas and storage facilities. The items are packaged within a rigid Tyvek and Mylar film pouch that has a thickness of 2.35-2.50 mil.

STERIS equipment covers can be customized to fit the unique size and shape of any equipment.

FEATURES

BENEFITS

Variety of sizes and shapes

Customized sizes and shapes to meet specific needs, ensuring easy application and removal

Variety of flaps, panels, and openings

Designs for large equipment, cylindrical equipment, irregularly shaped fixtures, etc.

Easy identification of the item being covered

Easy access to items placed on covered shelves and racks

Non-woven spunbonded olefin material

Breathable, allowing wet equipment to dry underneath the cover

Hydrophobic, no moisture retained within material

Durable, resistant to tearing and puncturing

Low particulate generation, suitable for use in cleanrooms

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

PRODUCT OPTIONS

Material	Tyvek®; coatings available for specific applications
Sizes	Variety of standard and custom sizes available
Colors	White, GMP print, yellow, gray
Openings	Any side or section of a cover can be made into an openable flap or panel
Closures	Elastic, drawstring, hook-and-loop fasteners, snaps, zippers
Pre-sterilized	Optional
Other	Viewing windows, document pouches, multiple-ply

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

APPLICATIONS & USAGE

STERIS equipment covers serve many purposes in pharmaceutical production facilities:

Reduce cross-contamination and improve powder containment. Protective covers are a simple yet extremely effective way of reducing cross-contamination in powder handling environments. Keeping equipment covered as they are moved from various production rooms through intermediate areas prevents powders on one line from contaminating powders on another line.

Cover equipment and fixtures in supporting areas. Covering recently cleaned equipment with STERIS covers minimizes the particulate and bioburden content that could build up on the equipment before it is reintroduced into critical cleanroom areas. Similarly, covering fixtures in supporting clean areas that hold in-process materials, containers, and other equipment helps maintain aseptic conditions.

Protect against particulate contamination in critical areas. Keeping clean equipment covered until installation helps protect critical product contact surfaces up to the point of use. STERIS covers are available pre-sterilized for use in ISO 5 or other classified cleanrooms.

Help contain viruses during the manufacture of vaccines. In vaccine manufacturing facilities, viruses may be present on equipment surfaces. By covering dirty equipment while they are moved to cleaning areas, an extra layer of protection is provided to production workers and the environment.

Keep production and laboratory areas organized. Keeping idle equipment, shelves, racks, and other items covered contributes to a visually organized, auditor-friendly environment. STERIS covers are available in various colors, which can be used to differentiate among different rooms, departments, staging areas, equipment types, etc. Additional options include clear viewing windows to identify the covered item easily, document pouches to hold records related to the covered item, and access panels that lift or roll back to allow access to shelves and racks.

Protect autoclaved items from possible contamination. STERIS autoclave cart covers are equipment covers intended for steam sterilization. Covering an entire autoclave cart before sterilization helps maintain the sterility of all items on that cart as they are removed from the autoclave and moved throughout the facility.



Covered equipment in supporting areas



Protecting against particulate contamination in critical areas



Panels that fold back or roll up to allow access to shelves

STORAGE AND SHELF LIFE

STERIS equipment covers 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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