Sterility Assurance and Contamination Control for Product Contact Surfaces

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Scan to learn more about the Purefit™ sterilization wrapping system.

Introduction

Preparation of parts and equipment used in parenteral manufacturing is critical for successful sterilization and protection throughout the aseptic manufacturing process. In order to maximize efficiencies in production, pharmaceutical, biotechnology and medical device organizations must streamline pre and post sterilization cycle productivity.

STERIS Barrier Products are customized bags, pouches, tubing, wrappers, and covers manufactured from Tyvek® non-woven spunbonded olefin material.[1] These products maximize efficiencies in production, while maintaining a microbial barrier to protect surfaces of critical parts and equipment. The material used greatly impacts potential microbial and particulate control on and around critical surfaces.

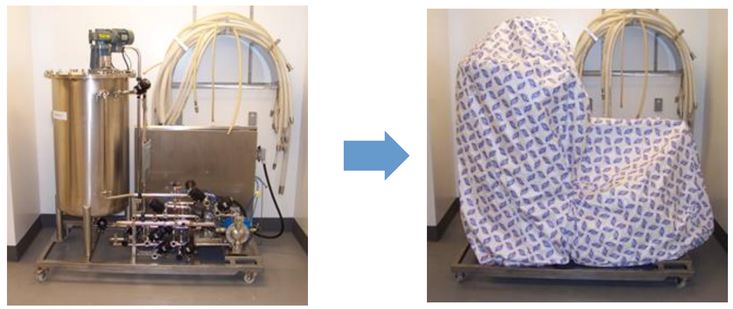
Purefit™ Sterilization Wrapping

Table 1: Advantages of Purefit Sterilization Wrapping over Cellulose

Constructed of 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
Superior microbial barrier properties	Greater than 99.99% spore retention
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
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

Protective Equipment Covers

Protective equipment covers protect clean equipment from possible contamination prior to use. The covers are customized to include elastic, snaps, and/or zippers to best fit large and/or complicated equipment.



The Purefit products and application recommendations ensure compliance with EudraLex Annex 1, Section 8.48 which states, “Where materials, equipment, components and ancillary items are sterilized in sealed packaging or containers, the packaging should be qualified for minimizing the risk of particulate, microbial, endotoxin/pyrogen or chemical contamination, and for compatibility with the selected sterilization method.”[2]

Laboratory Studies

Microbial Barrier Properties

Sterilized surfaces must remain free from microbial contamination during an aseptic manufacturing process. The raw materials used in Purefit sterilization wrapping and equipment covers is more effective than cellulose material at microbial retention, and therefore provides superior sterility assurance when used as a covering for critical surfaces. ASTM F1608-00, “Standard Test Method for Microbial Ranking of Porous Packing Materials (Exposure Chamber Method)”, is an aerosol challenge to determine the passage of airborne bacteria (*Bacillus atrophaeus*, ATCC#9372).[3]

Table 2: ASTM Test Results for Microbial Barrier Effectiveness

Sample Material	Control Colony Forming Units (cfu)	Average Result (cfu)	Log Reduction Value (LRV)
Rigid Purefit Raw Material	1.3×10^7	6.1×10^2	4.32
Flexible Purefit Raw Material Unsterilized	1.9×10^6	1.5×10^2	4.10
Flexible Purefit Raw Material Sterilized	2.1×10^6	1.0×10^2	4.32
Kraft Paper	1.4×10^7	1.1×10^5	2.11
Blue Paper	1.3×10^7	8.0×10^4	2.21

Test results indicate the materials used in Purefit products prevent passage of greater than 4 log microorganism population. These materials are >99.99% effective at spore retention.[4]

Particle Generation Properties

Peeling open a sealed Purefit sterilization pouch generates less than one-tenth the number of particles (0.5 and 5 microns in size) compared to a cellulose / film pouch. This is especially important when opening pouches containing pre-sterilized (irradiation, ethylene oxide) items and autoclaved equipment in critical environments (Grade A / Class 100 cleanrooms), where minimizing particles is imperative.[5]

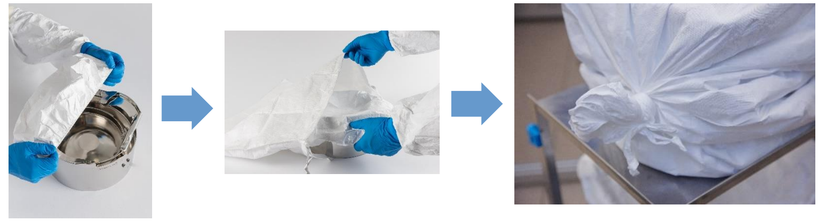
Simulation Testing

The process of wrapping and unwrapping equipment using Purefit bags and covers is faster and generates significantly fewer particles when compared to using cellulose-based materials. The difference is greatest when the equipment and/or operations are complex.

A laboratory simulation was conducted, and the results showed that preparing a stopper bowl for sterilization using Purefit wrapping materials was completed in less than 30% time and generated fewer than 20% particles compared to using blue paper and tape. Likewise, unwrapping was completed in 70% less time and generated 50% fewer particles using the Purefit materials.[6]

Recommendations

Critical surfaces (product contact areas on a stopper bowl or filling needle, for example) are protected using a Purefit elasticized cover. Covered equipment is then placed into a larger Purefit drawstring bag or pouch as secondary protection during sterilization, storage, and transport to the manufacturing area. An elasticized cover acts as the primary barrier, while the drawstring bag adds a second layer of protection. Utilizing a “gooseneck” style closure for the bag ensures a tortuous path to prevent microbial and particulate ingress.



Sterility assurance is maximized by using two layers of wrapping to protect product contact surfaces of equipment that is autoclave sterilized.

Aseptic Line Set Up

Using the Purefit elasticized cover and sterilization bag with drawstring allows the critical surfaces to be protected during line set up. Operators performing the critical manipulations remove the stopper bowl from the sterilization bag to install the equipment onto the filling line. The elasticized bowl cover is left in place, until immediately prior to use.

Summary

As demonstrated in laboratory and simulation studies, STERIS Purefit sterilization wrapping products allow for increased operational efficiencies, as well as improved microbial and particulate control around critical surfaces, resulting in maximized sterility assurance.

References:

1. Tyvek is a registered trademark of E.I. DuPont deNemours and Company.
2. EudraLex, Volume 4, Annex 1, “Manufacture of Sterile Medicinal Products”, 22.08.2022
3. Standard Test Method for Microbial Ranking of Porous Packing Materials (Exposure Chamber Method), ASTM F1608-00, Reapproved 2004.
4. Microbial Barrier Testing for Sterilization Wrapping Systems, Technical Tip 455-200-0001, STERIS Corporation, 2017 and 2021.
5. Barrier Product Solutions Tyvek® Sterilization Wrapping System versus cellulose Based Materials, Laboratory Report, Aaron Mertens, STERIS Corporation 2017.
6. Barrier Product Solutions Tyvek® Sterilization Wrapping System versus cellulose Based Materials, Laboratory Report, Aaron Mertens, STERIS Corporation 2020