Particulate Contamination is a Concern for Critical Product Contact Surfaces

STERIS
Life Sciences

Draft EU Annex 1 Revision, Section 8 on Production and Specific Technologies states "The presence of materials liable to generate particulates and fibres should be minimized in cleanrooms."

Recent FDA Audit Observations have identified sterilization wrapping as the source of blue cellulose particulate material in pharmaceutical drug product.

WHAT DOES THIS MEAN TO YOU?

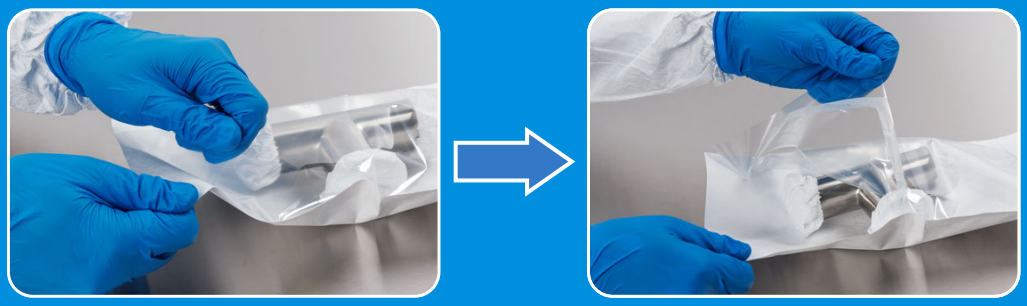
Materials of cellulose/paper origin should be evaluated for risk to the process if used in the cleanroom. This is especially critical for sterilization wrapping, as it is in direct contact with product contact parts and equipment.

STERIS Barrier Product Solutions (BPS) sterilization wrapping products are constructed of a spunbonded polyolefin material, which is manufactured, processed and packaged in a certified cleanroom environment. Not only do the BPS solutions minimize particulate introduction into critical processes, they also have superior microbial barrier properties when compared to cellulose materials.

TECHNICAL INFORMATION

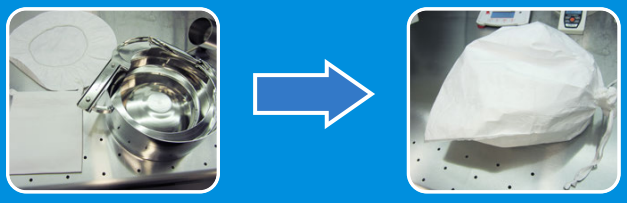
Particle Generation Data

Peeling open a sealed BPS pouch generates less than one-tenth the number of particles (0.5 and 5 microns in size) compared to a cellulose 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/ISO 5 cleanrooms), where minimizing particles is imperative.

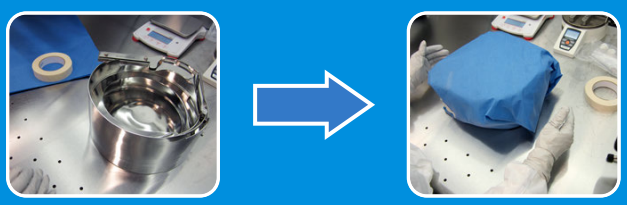


A laboratory simulation was conducted, demonstrating the process of wrapping and unwrapping equipment using BPS is faster and generates significantly fewer particles when compared to using cellulose based materials. The difference is greatest when the equipment and/or operations are complex.

STERIS Barrier Product Solutions Wrapping



Cellulose Blue Wrap



Recommendation

STERIS Barrier Product Solutions (BPS) sterilization wrapping should be used instead of cellulose based sterilization wrapping. The BPS material protects critical surfaces, without introducing paticulate of cellulose/paper origin.

The product contact surface on the stopper bowl is protected using a fitted, elasticized BPS cover.

Covered equipment is placed into a BPS bag 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.

Product contact surfaces of a filling needle assembly are protected using BPS covers.

Filling Needle and Tubing Assembly with ends covered are placed within a BPS polyolefin/film sterilization pouch.

After sterilization, the assembly is removed from the sterilization pouch. Filling needles remain protected until the primary cover is easily removed in an aseptic manner at the time of use.

To learn more about Barrier Product Solutions, refer to the following STERIS Technical Tips:
Technical Tip #0001, “Microbial Barrier Testing for Sterilization Wrapping Systems”
Technical Tip #0002, “Recommended Methods for Closure of Sterilization Wrapping Systems”