

Protective Sleeves for Sterile Suites

Critical Cover® ComforTech® Sleeves for Sterile Suites

This new line of sleeves for use in sterile suites is the ultimate in protection to guard against contamination and bioburden in your environment. Our sterile suites sleeves are manufactured using advanced technologies and utilize innovative materials guaranteed to deliver a totally unique performance and comfort for the wearer, while protecting your environment from employee and external contamination. Our sleeves for use in sterile suites are sterilized to a Sterility Assurance Level (SAL) of 10^{-6} .

Alpha Pro Tech sterile sleeves are recommended for use in all sterile environments where bioburden levels and/or diversity present a compelling risk to the environment, product or research work. For industrial use only.

Innovative Garment Design

- Low particle counts to limit any additional contamination from entering your controlled environment
- High filtration rate to contain employee bioburden and particulate contamination while offering comfort to your employees
- The sleeves allow the natural process of evaporative cooling by allowing vapor from perspiration to pass right through the material keeping you cool and comfortable
- ComforTech® material provides a barrier to particles, biologicals, fluids and an extensive list of chemicals (test results available upon request)
- Our sleeves are sonically welded the entire length of the sleeve. This provides extra security against bioburden and particle contamination



Cat No. Size
MS-01J76-8ST Univ.
MS-01J76-4ST XL

Irradiated 10^{-6} ,
tapered sleeve,
tunneled elastic both ends,
sonic welded seams

300/case
(150 pair individually
packaged in a heat-sealed bag)

Our Sterility Assurance

Our sterile suites sleeves are manufactured under strict Quality System Guidelines.

- Sleeves are gamma radiation to yield a minimum Sterility Assurance Level (SAL) of 10^{-6} . All irradiated products undergo proper sterilization validation in strict accordance with AAMI/ISO 11137 and EN 550. Quarterly dose audit testing is performed to verify any factors in seasonal climate changes.
- Our irradiation facility is audited and certified by TUV. The certification covers Provision of Irradiation sterilization for single use Medical Devices in compliance with EN 552/A1:1999 and ISO 11137:1995. Our facility is also EN ISO 9001:2000 certified for a Quality Management System.

State-of-the-Art Packaging

We want to help you meet the challenging needs in your critical environment. Our packaging is designed to eliminate cross contamination risks. These unique packaging standards deliver dramatic process time reductions, cost reductions and process improvements through the use of a multi-level vacuum heat sealed packaging system. This packaging system ensures that contamination does not migrate from one process step to the next.

Outer Master Carton

- All exposed seams on the master carton are taped to ensure no additional contamination will penetrate the seams. This will eliminate any contamination during transportation or storage of the product.



Carton taped closed w/corner labels and Certificate of Sterility

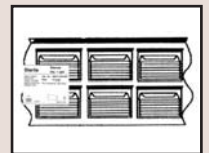
Internal Packaging

- Once you have discarded the cardboard box, you can now store the product in the carton liner. We have included an additional Certificate of Irradiation attached to the carton liner. This certificate will accompany the product until the time of use and provides additional traceability.



Carton Liner w/Certificate

- We provide a tertiary and secondary vacuum heat sealed bag surrounding the primary packaging. This feature will drastically reduce the cost and time to disinfect and wipe down the primary packaging as well as the cost of wipers and cleaning agents.



Tertiary Vacuum Heat Sealed Bag w/product information label

All Product Packaged in Lots of 25

- We have added an extra level of protection with our secondary vacuum heat-sealed packaging. This packaging surrounds 25 pair of sleeves.



Secondary Vacuum Heat-Sealed Bag

Primary Product Packaging

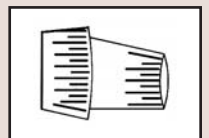
- All sleeves are individually packaged in pairs in easy-tear bags allowing the user to easily open. Our easy-tear bags require less exertion and movement to open the bag, which will reduce the release of contamination in your environment. The primary packaging easy-tear bags are vacuum heat-sealed and labeled with product information and fully traceable lot number.



Primary Vacuum Heat Sealed Bag w/product information label

Garment Folding Protocol

- The wider end of sleeve is cuffed down to expose the sleeve interior so it can be donned without touching the exterior.



Folded Sleeve

U.S. Patent No. 5,867,825 and additional Patent Pending

Because conditions of use are out of Alpha Pro Tech's control, Alpha Pro Tech makes no warranties, expressed or implied, and assumes no liability as to the performance of these products for a particular use.