Instructions for KNF CRP

Sterilization Bags and Breather Tubing®

Description

KNF CRP's second generation series of Sterilization Bags and Breather Tubing are constructed utilizing DuPont's Tyvek® 1059B bacterial barrier breather strips and a co-polymer polyethylene. Sterilization Bags and Tubing are used for packaging, sterilization and storage of pharmaceutical, food and biological products, and manufacturing equipment. They are designed to allow the removal of air, allow the penetration of steam or gas, and yet act as a bacterial barrier. The LB853 Sterilization Bags and LT853 Breather Tubing have a standard 4" Tyvek breather strip with optional 6" and 8" Tyvek breather strips for more rapid evacuation. Both are available as standard Ultraclean (very low interior particle counts) or commercially clean (low particle count) products.

Operation

The Sterilization Bags are manufactured, tested and packaged in a Class M3.5 (100) clean room. To maintain the integrity of the product, bags and tubing are triple packaged for transportation from our facility to the customer's plant. The bags are packed in pre-determined quantities, depending on size or customer requirements, in the first barrier bag of Ultraclean Nylon 6 material. This bag is evacuated, sealed, then placed in a second barrier bag made of 6 mil Low Density Polyethylene, which is evacuated and sealed. At this point either one or two packages of double packed product is then placed in a third barrier bag of 6 mil Low Density Polyethylene, evacuated and sealed. These packages, along with a Certificate of Conformance label indicating cleanliness levels, customer P.O. number, quantity, size, date of manufacture and lot number, allow for complete traceability of all products. They pass from our clean room operation to our shipping department, placed in shipping cartons, labeled and shipped to our customer.

Upon receipt, the customer should carefully open the carton to avoid damage to the enclosed bags, and the packages are moved near the clean room. The third outer barrier bag is wiped off using a tacky cloth to remove any gross contamination from the exterior of the bag that was picked up during shipment. At this point the operator places the package into the pass thru and carefully removes and discards the outer bag, leaving the double wrapped product in the pass thru.

This double wrapped package can now be stored in the clean room until needed, then moved to the production site. The second barrier bag is again wiped down with a tacky cloth or approved clean room wipe. Once production begins, the final barrier bag is removed carefully by opening the package with a slitting or slicing motion of a stainless steel scissor or razor knife. The required number of Sterilization Bags are removed and the barrier bag can be resealed to protect remaining product from contamination. Unused bags in a single or double barrier bag may be stored indefinitely.

Once the product to be sterilized has been placed in the Sterilization Bags, the final seal is made by either hot bar or impulse seal. We recommend the use of impulse sealers for a more positive seal. The best results can be achieved by using a test bag and determining the proper temperature, dwell and pressure before production begins. Once this has been established, it should be documented and referred to during production. The best seals will be achieved by allowing the heat to pass through

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the layers of polypropylene into the Tyvek strip (this is based on the design of the Sterilization Bags being used). A Carleton (or equal) burst tester is excellent to validate the sealing process and establish set parameters for the validation of the seals.

When equipment or parts are to be packed and sterilized, caution should be employed to prevent sharp or defined edges from cutting or puncturing the Sterilization Bag. After carefully placing the product or equipment into the Sterilization Bag, the bag can now be sealed to protect the item from contamination and prepare the product for sterilization. Careful attention should be given to the handling and placement of the bags with the product into the sterilization chamber.

The bags are now ready to be sterilized. In all cases, it is important that the breather strip be exposed to the atmosphere of the sterilization chamber and not be covered by another bag or face the shelving. This will afford the maximum breathability of the pouch during the sterilization cycle. The autoclave loading should be done by carefully placing the bags on a multi-shelved open rack or cart for maximization of space. If it is necessary to overlap the Sterilization Bags, make sure the breather strips are exposed; however, we do not recommend this practice.

Sterilization

Autoclave – a tried and tested procedure which is recommended as a practical method to achieve the best sterilization results.

Preconditioning:

1. Slowly draw a vacuum on the autoclave chamber (5 to 10 minutes) three times. If rapid evacuation is employed, heat seals are stressed and can weaken or burst the seals. If it is necessary for the procedure to draw a quick vacuum on the chamber, we recommend the use of our Sterilization Bags with a 6" or 8" breather strip to accommodate the evacuation.

Sterilization:

2. Bring the autoclave up to a not-to-exceed 121–123°C and introduce steam into the chamber for a 30 to 60 minute cycle.

3. Slowly exhaust the steam for approximately 60 minutes.

4. Use a 2-hour post drying, cooling and vacuum cycle, drawing the vacuum slowly.

5. Finally, vent the autoclave chamber for 30 minutes, equalizing the pressure in the autoclave chamber.

6. Remove the product from the autoclave for immediate or later use.

7. The preceding is a basic format; however, based on product packaged, density of product, chamber loading, pasteurization and evacuation ranges, a thorough validation program and full documentation is **strongly recommended** for each company and product being

examined or sterilized. Contact the manufacturer of your sterilization equipment for more detailed information.

ETO Sterilization

Time and temperature must be established on the basis of product packaged, density loading of the chamber, distribution of product, pressurization ranges, evacuation cycles, etc. Because of the variations, no specific recommendations can be offered. For validation purposes a test program is suggested with documentation of all procedures and cycle times.

Note: After all ETO sterilization, a holding cycle of 14 days is normally required to verify sterility testing as well as permit the thorough escape of low residual levels of ethylene oxide.

Post Sterilization Storage and Use

Once removed from the sterilization cycle the pouches may go directly into a sterile filling operation or parts use. However, the unique ability of this pouch allows transportation from a sterile area to a non-sterile area without the loss of sterile integrity of the product enclosed in the pouch. This ability also allows for short-term storage before final use in a non-sterile or sterile area. DuPont has conducted shelf life studies on Tyvek 1059B and 1073B which may indicate storage or shelf life of a sterile product up to five years. Information is available from DuPont and KNF CRP on this study. The only precaution is to wipe down the exterior of the package with IPA or other sanitizing agent prior to entry into a sterile area. Some customers have used a double Sterilization Bag package system to accommodate this practice. However, the practice of double bagging product with the use of Sterilization Bags should be approached carefully and with research of proper size bags and cycle times, to adjust for the double barrier properties and restricted breathing of the two layers of Tyvek. It is of utmost importance that the layers of Tyvek are lined up and on the same side of the package so as not to restrict the equalization of pressure within the bags.