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Look for Toughness and Reliability When Choosing Single-Use Beta Bags

*Bags constructed of high-quality materials will help ensure
leak- and contamination-free operation*

By Rob Weber

Introduction

Many well-known companies have chosen to highlight the robustness, toughness, reliability and durability of their products as a way of marketing them to the consumer. Some of the classic examples of this approach are the “Takes a licking and keeps on ticking” commercials for Timex watches and the ads featuring a gorilla using and abusing a piece of American Tourister luggage.

While everyone would like a watch or suitcase to continue to perform even when subjected to an elevated level of abuse, a product’s reliability and durability become increasingly important during the development, manufacture and transfer of Life Science products like pharmaceuticals and biopharmaceuticals that feature the use of Active Pharmaceutical Ingredients (APIs). In this case, the production and

supply system demands safe, efficient, leak- and contamination-free handling of all raw materials, finished products and waste by-products throughout the entire manufacturing and supply process. This critical process has been given a name: “aseptic,” meaning “free from contamination caused by harmful bacteria, viruses or other microorganisms.”

Beta Bags Enter The Picture

Most Life Science aseptic-manufacturing operations require the use of cleanrooms, isolators or gloveboxes that allow raw materials, finished products and waste products to be moved into and out of them. Traditionally, in these applications, stainless-steel or hard-plastic Beta containers were filled with the solid objects that needed to be moved within the production process. In many cases, these objects were crucial to the process, such as vials, stoppers and syringes, though they could be more mundane, such as pens and pads of paper that were used by the technicians to make notes.



The transfer process occurred when a full Beta container was attached by a technician to the Alpha port on the wall of the containment chamber. Once attached properly, the Alpha port could be opened and the items within the Beta container retrieved for use. The goal here is to ensure that all of the items are kept sterile so that the production process would not become compromised.

Central Research Laboratories® (CRL), Red Wing, MN, USA, a world leader in the design, development and production of remote-handling and containment solutions for use in the Life Science market, offers a full portfolio of single-use beta bags for use in aseptic-manufacturing applications.

The drawback to the use of hard-sided, multi-use Beta containers is that they need to be cleaned and revalidated before they could be used in another product-transfer process. The invention of Single-Use Beta Bags has eliminated this costly and time-consuming step in the aseptic-manufacturing chain as the bags can simply be disposed of after their use with a new one taking their place for the next transfer activity. In other words, single-use beta bag systems improve operational efficiency through a reduction in the downtime and cost needed to clean and revalidate a multi-use system. When used in conjunction with a compatible Alpha port, fully sterilized single-use beta bags will facilitate leak- and contamination-free transfer of sterile components into and out of isolation, along with the safe removal of any toxic components or waste by-products, as well as any multi-use Beta container.

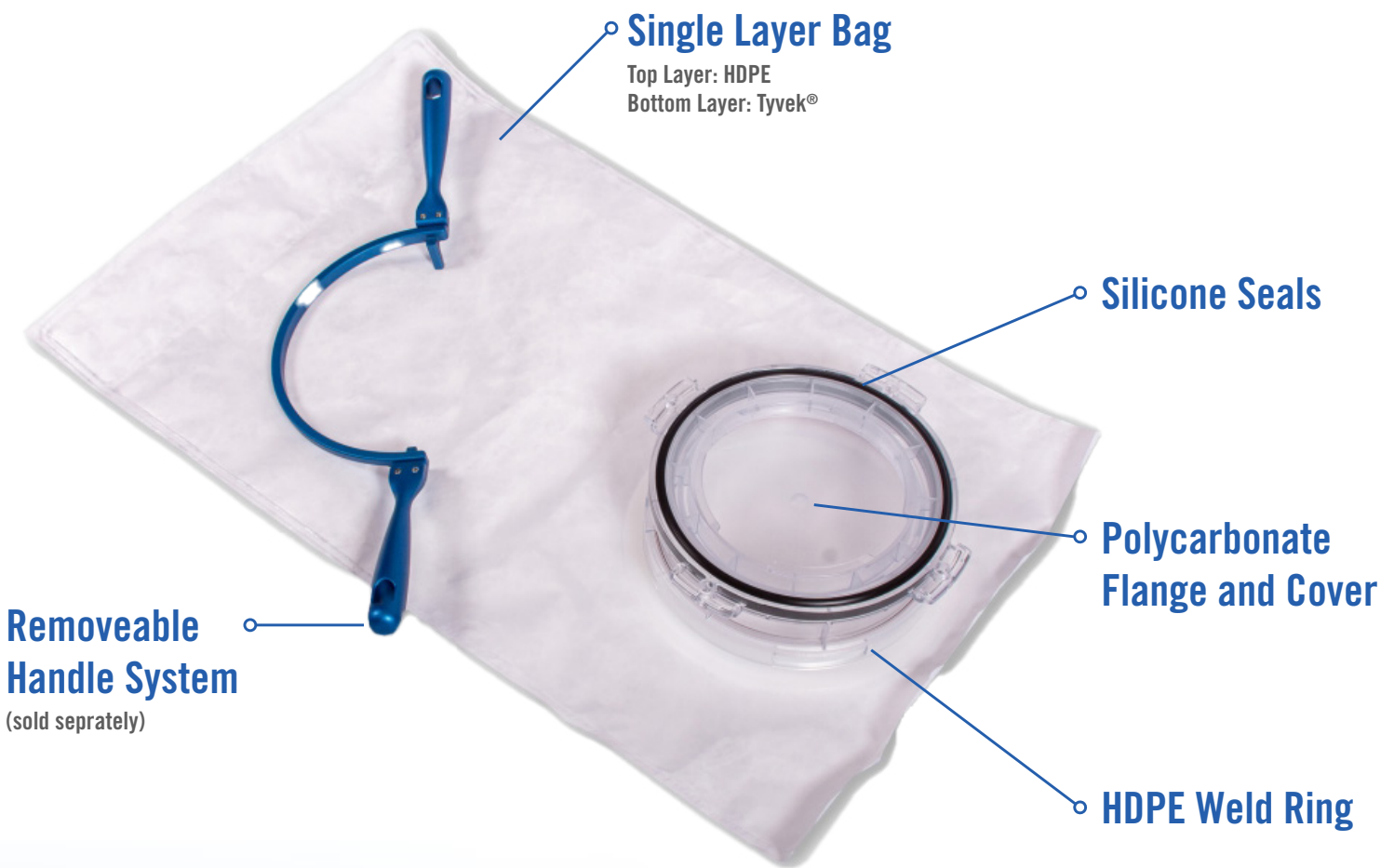
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Knowing that complete product containment and the maintaining of a sterile working environment are of the utmost importance in aseptic Life Science manufacturing routines, CRL's single-use beta bags – all of which are proudly manufactured in the United States – bring together sheets of Tyvek®, a lightweight, tear-resistant synthetic material made from high-density spun-bound polyethylene fiber, and a high-density polyethylene (HDPE) plastic with a high strength-to-density ratio. These components are glued together to form a strong, tear-free bond that makes the beta bags resistant to water, abrasion, bacterial penetration and aging, which makes them nearly indestructible. The welding of the Tyvek and HDPE sheets also takes place in a controlled cleanroom environment to ensure that a contaminant-free beta bag is produced.



Finished single-use beta bags have an HDPE weld ring attached to one side that is permanently mated to a polycarbonate flange. The polycarbonate flange is what docks the bag assembly to the isolator, cleanroom or glovebox's Alpha port. To help them reach a wider array of users, CRL single-use beta bags have been designed to be compatible with many different Alpha port system designs, including the popular DPTE® XS Alpha Port models. This added benefit can aid sterile-product manufacturers who would prefer to have more beta bag supply options at their disposal.

In addition to their robustness, CRL single-use beta bags feature a sterile barrier that allows an autoclave sterilization process to be performed on the beta bags after they are manufactured. So, once they have been acquired by the user and they are filled with components, the beta bags can be autoclaved or gamma sterilized on-site, which helps contribute to the creation of a sterile, contamination-free work environment.



Finally, in an interesting recent development, a handful of enterprising Life Science manufacturers have begun to find creative new ways to use single-use beta bags to transfer not just solids, but fluids, notably for the filling of vials or syringes. These beta bags incorporate tubing and connectors that allow the fluids to be transferred through them from a storage vessel to various applications within a cleanroom, isolator or glovebox. Because of their Tyvek and HDPE materials of construction, CRL single-use beta bags can excel in these types of innovative applications since they are tear-resistant, which reduces the risk of leaks or spills occurring, which is critical to maintaining a sterile manufacturing environment.

Conclusion

Creating and maintaining an aseptic-production environment is critical in all Life Science manufacturing operations. This means that the highest levels of sterility must be maintained at all times. It also requires that all components in the production process work harmoniously, with very little chance that the anti-contamination chain is broken.

That's why CRL Single-Use Beta Bags feature a manufacturing process that teams Tyvek and HDPE plastic. This combination forms a nearly indestructible layer of protection that helps reliably ensure that leak- and contamination-free operation is achieved in crucial product-handling applications throughout the aseptic-manufacturing process. In other words, it can help to think of another classic advertising campaign when contemplating your next beta bag purchase: "When the going gets tough, the tough get CRL Single-Use Beta Bags."

About The Author:

Rob Weber is the Manager of Products & Proposals for Central Research Laboratories® (CRL), Red Wing, MN, USA, which is a DESTACO company. He can be reached at rweber@destaco.com. CRL possesses more than 75 years of innovation experience in the development of remote-handling systems, including Telemanipulators, Transfer Systems, Glove Ports and Waste Drum Transfer Systems. CRL's industry-leading technology helps its customers safely and efficiently handle hazardous and sterile materials in Nuclear and Life Science applications around the world.



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