

# Four Things to Consider When Selecting Beta Bags



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## INTRODUCTION

The development, manufacture and handling of Life Science products like pharmaceuticals, biologics and biosimilars that feature Active Pharmaceutical Ingredients (APIs) require safe, efficient, contamination-free handling of all raw materials and finished products throughout the entire breadth of the production process. Specifically, this process must be what is known as “aseptic,” meaning “free from contamination caused by harmful bacteria, viruses or other microorganisms.”

Maintaining a sterile chain of custody does not just mean the finished product. A truly sterile production

process demands that all components used in a clean room or isolator environment be kept contaminant-free at all times or risk compromising the end product. Playing a critical role in this process are beta bags. Before selecting a beta bag brand or model, however, the aseptic-process operator should first consider four things:

### 1. What is the Main Purpose of Beta Bags?

Alpha ports (sealed openings) are used in clean rooms and isolators to give operators access to various components during an aseptic-production process. These ports allow the operator to retrieve items ranging from vial stoppers to syringe plungers,

hand wipes to cable ties, and simple pen and paper – and they all must be kept sterile to avoid compromising the production process.

The easiest way to provide contamination-free access to the items is through the use of a beta bag that can be docked to the Alpha port. Beta bags are manufactured in a clean room, but before use they must be sterilized to ensure an aseptic environment is maintained. In this case, two forms of sterilization are available: autoclaving, which uses steam heat and pressure to kill any bacteria or viruses, and gamma sterilization, which uses gamma rays that are a form of high-energy electromagnetic radiation to kill any potential contaminants.

Most beta bag models are constructed of high-grade plastics that are tear and leak resistant and feature a flange that directly connects to the isolator's Alpha port, with newer models being designed to be compatible with different models or styles of Alpha ports.

## **2. How Do Single-Use Beta Bags Improve Aseptic-Processing Operations Compared to Traditional Procedures?**

At their most basic, single-use components and systems eliminate the need for cleaning operations at the end of production runs while enabling the production process to meet all relevant regulatory-compliance parameters. This makes single-use beta bags a convenient alternative to multi-use component-holding systems that require cleaning. Single-use beta bag systems improve efficiency through a reduction in the downtime and cost needed to clean and revalidate a multi-use system. When used in conjunction with an Alpha port, fully sterilized single-use beta bags help facilitate leak-free transfer of sterile components into isolation, as well as the removal of any toxic components or waste.

Single-use beta bags are generally constructed of sheets of Tyvek® – a high-density, tear-resistant polyethylene fiber – and a high-density polyethylene (HDPE) plastic with a high strength-to-density ratio. These two sheets are welded together to form a strong, tear-free bond that helps ensure leak-free operation. The welding of the Tyvek and HDPE sheets also happens in a clean room environment to deliver a contaminant-free beta bag.

The single-use beta bags are welded to an HDPE weld ring that is permanently mated to a polycarbonate flange to complete the beta bag system. The polycarbonate flange is used to dock the bag assembly to the isolator's Alpha port. A recent advance in beta bag production allows the beta bag's

flange to be compatible with numerous Alpha port designs. This added benefit can aid sterile-product manufacturers who would prefer to have more beta bag supply options at their disposal.

## **3. What is the Typical Size and Capacity of a Beta Bag?**

Beta bags are available in various sizes delineated by a measurement in millimeters. The delineation is based on the approximate maximum width in millimeters of an object that can fit through an open Alpha port with a beta bag attached, though the maximum cylinder diameter of the object that can pass through the Alpha port is generally 15-20 mm (0.6-0.8 inches) smaller than the model size. In this vein, a typical beta bag size is 190 mm, or 7.5 inches, which means it is compatible with an Alpha port that can accommodate an object from 170 to 175 mm (6.7-6.9 inches) in width.

In terms of capacity, a 190 mm beta bag can hold volumes up to 25 liters (6.6 gallons); to ensure the beta bag can accommodate this weight, a 10-kilogram (22-pound) strength test is performed before the bag is certified for use. Users must be aware that at volumes that high, weight can become an issue, so caution must be taken when handling a full bag or attaching it to an Alpha port.

## **4. Can Your Supplier Deliver Single-Use Beta Bags on Time?**

The best beta bags in the world are useless to the user if they are sitting in a supply warehouse, on a loading dock or the bed of an idled delivery truck. Therefore, the most important question to consider before choosing a brand of beta bag might be whether or not the supplier can deliver the product when and where you need it.

This can be problematic when dealing with large beta bag manufacturers. While they can manufacture the most per volume, the size of their operation may make it difficult for them to address the unique and changing needs of every individual client, which can result in supply-chain issues. In some instances, operators may be asked to purchase beta bags in “one size fits all” or “inconvenient” quantities that are not in tune with the customer's specific needs. New customers may also not be able to get a timely supply of beta bags as existing customers get priority. Also, a large supply operation can have delivery lead times of as long as 30 to 50 weeks that can leave the user – pun intended – holding the “bag” while waiting for a beta bag shipment.

For more than 75 years, Central Research Laboratories® (CRL), Red Wing, MN, USA, has been a leader in the design, development and production of remote-handling and containment solutions used in many Life Science applications

around the world. In that time, CRL has built up a base of customer-service experience and knowledge that enables it to reliably know the supply-chain needs of its clients and deliver what they need, when they need it in order to keep production processes running smoothly and on schedule.

Today, that includes CRL's new Single-Use Beta Bag product line. While all of CRL's Single-Use Beta Bags are manufactured in the United States, the company has built a distributor network around the globe, all of which are stocking product that can be shipped anywhere the customer is located. This network gives CRL the nimbleness needed to meet all client supply needs and requests, each and every time.

## CONCLUSION

Beta bags have become an indispensable component in the aseptic-processing production chain, and their new single-use configurations promise to create even more benefits for their users, particularly in the areas of efficiency, cost and time savings while delivering the expected level of contamination prevention. Recognizing this, CRL has developed a new single-use beta bag product family that goes beyond improvements in cost, efficiency and contamination prevention by being compatible with additional styles of Alpha ports. The result is a new standard in single-use beta bag design, usage and availability, allowing for even greater flexibility in aseptic-production processes.

## ABOUT THE AUTHOR

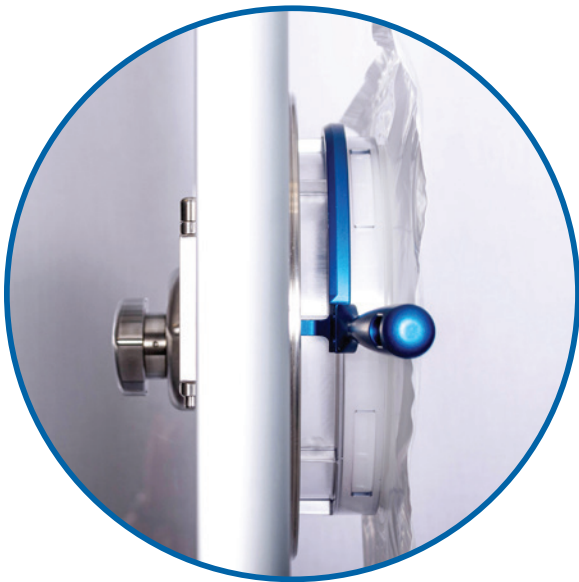
Jim Peterson is a Sales Manager for Central Research Laboratories® (CRL), Red Wing, MN, USA. He can be reached at [jpeterson@destaco.com](mailto:jpeterson@destaco.com). CRL possesses more than 75 years of innovation experience in the development of remote-handling systems, including Telemanipulators, 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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Single-Use Beta Bag docked to  
Clean Rapid Transfer Port (CRTP)