



## Single-Use Beta Bag

The CRL Single-Use Beta Bag is a safe, efficient, and cost-effective solution for aseptic production. This single-use system provides contamination-free transfer of components into isolation or removal of toxic components out of isolation. Used in conjunction with Alpha port systems, sealed containment and sterility of the environment are maintained.

The Single-Use Beta Bag system consists of Tyvek® and high-density polyethylene (HDPE) bag layers connected to a Beta flange which mates the entire assembly to the Alpha port on an isolator. Once filled with components, these bags can be autoclaved and connected for filling line production. Bag customization is also available to meet specific application needs based on component, processing, and production parameters.

In addition to its proprietary design, CRL has also developed a Single-Use Beta Bag flange that is compatible with other Alpha port designs currently available. This allows manufacturers more flexibility with additional beta bag options available at their disposal.

## SPECIFICATIONS

### MATERIALS:

#### Flange and Cover:

High Temperature Polycarbonate

**Beta Seal:** FDA Approved Silicone

**O-Ring:** FDA Approved Silicone

**Weld Ring:** HDPE

**Bag:** Tyvek® (1073B) and HDPE

### CLEANLINESS:

**Particulate:** USP<788>

**Endotoxin:** < 0.125 EU / mL

### ENVIRONMENT:

Assembly is designed to be steam sterilized at 121°C for 30 minutes by the customer.

Recommended storage conditions are 55-80°F (13-27°C) and 30-60% Relative Humidity.

### BAG DIMENSIONS:

25" (635mm) length, useable

16.5" (419mm) width, useable

Approximate volume of 25 L

### ASSEMBLY:

Assembled in an ISO cleanroom

### PACKAGING:

Product double bagged with polyethylene cleanroom bag.

### TESTING:

- Pressure decay leak test at 5" water
- Independent lab testing of cleanliness
- Tyvek® weld peel and dye penetrant test
- Visual inspection