CRL Central Research Laboratories
a DESTACO company

Single-Use Double Bag

The CRL Single-Use Double Bag is a safe and efficient transfer solution for aseptic manufacturing. This single-use system provides contamination-free transfer of components into and removal of components from isolation. When used in conjunction with Alpha port systems, sealed containment and sterility of the environment are maintained.

The Single-Use Double Bag consists of Tyvek® and high-density polyethylene (HDPE) bag layers double-welded to a weld ring and connected to a Beta flange that docks 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.

CRL's Single-Use Double Bags are designed to dock with major 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: Each side has two layers.
One side: DuPont Tyvek® 1073B
Other side: HDPE film

CLEANLINESS:

Particulate: Particulate ≥ 10 µm, NMT 20 #/mL
Particulate ≥ 25 µm, NMT 3 #/mL

Endotoxin: ≤ 0.125 EU/mL

ENVIRONMENT:

Assembly is designed to be steam-sterilized one time at 121°C (250°F) for 30 minutes by the customer.

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

BAG DIMENSIONS:

45.0" (1,143 mm) length, usable
16.5" (419 mm) width, usable
16" (406 mm) length, inner bag chute
Approximate fill volume of 40 L

ASSEMBLY:

Assembled in an ISO Class 8 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