

mdi AseptiSac™ Beta Bags are designed for safe transfer of sterile products like single use assemblies, environmental monitoring items, cleaning materials etc., and to handle waste, i.e. safely removing items such as toxic waste, broken vials, ampules, syringes and used wipes from the isolator or filling line.

mdi offers single use filling lines which are pre-validated, pre-assembled, pre-sterilized systems with bags, tubing, connectors, filling needles etc., placed inside AseptiSac™ Beta Bag for easy and secure insertion and removal.

These beta bags come with a special port for attaching sterilizing grade filtration assemblies to the disposable filling line from outside, to facilitate easy pre-use post-sterilization integrity testing (PUPSIT) of filters.

Sizes Available: Beta Port

- 105 mm
- 190 mm

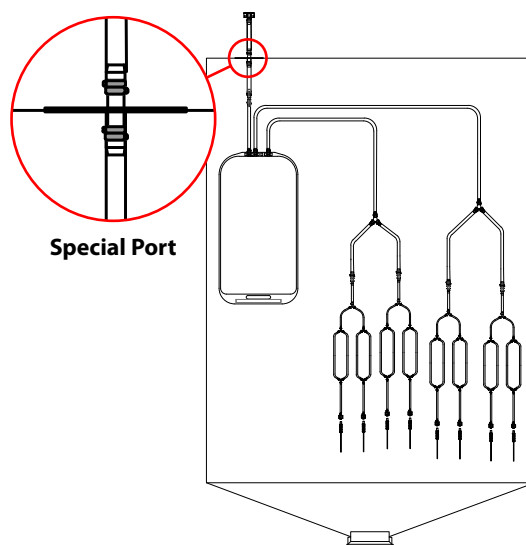
Beta Bag Film	Ultra-Low Density Polyethylene (ULDPE)
Beta Port	High Density Polyethylene (HDPE)

Applications

- Pre-gamma sterilization bagging of:
 - Complete single use filling lines
 - Critical filling line components such as seals and bungs
- Safe removal of waste materials

Unique Performance Advantages

- 100% Integrity tested
- Fast and easy contamination free transfer
- Special port for connecting PUPSIT assembly
- Increased flexibility and reduced manufacturing time
- Minimize validation costs
- No decontamination
- No cleaning validation
- Minimized manual intervention



Specifications

Bioburden Levels

Bioburden level is < 1000 cfu/bag as per ISO 11737-1

Bacterial Endotoxin Levels

Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amoebocyte Lysate (LAL) test as per USP <85>

Fiber Release

Passes test as per USP and comply with USFDA Title 21 CFR Part 210.3(b)(6) for fiber release

Particle Release

The filtrate complies with USP <788> test for particulate matter in injections