

Single Use Systems (SUS) are increasingly being used in biopharmaceutical, and cell and gene therapy manufacturing processes. Aseptically disconnecting single use components such as bags from a single use assembly being used is a critical process requirement.

mdi AseptiDlink™ sterile disconnectors are designed to provide a fast and smooth, leak free aseptic disconnection of single use systems. This allows the user to maintain sterility during disconnection while doing away with pinch clamps and tube welders.

Unique Performance Advantages

- Reliable aseptic disconnection even in non sterile areas
- Fast and easy single step disconnection
- Carefully selected materials of construction for minimum extractables

Specifications

Sizes Available

- 1/4" Hose Barb
- 3/8" Hose Barb
- 1/2" Hose Barb

Materials of construction

Fluid Contact Parts	Polycarbonate
O-ring Seal	Platinum Cured Silicone
Flow Path Springs	316 Stainless Steel

Microbial Ingress

Exhibit absolute resistance to microbial ingress against a challenge of 10⁷ org/mL

Burst Pressure

> 4 bar (60 psi)

Operating Temperature

4-40 °C

Sterilization by Gamma Irradiation

Sterilizable upto 50 kGy



Applications

Sterile disconnection from processing equipment and components such as:

- Single use bioreactors
- Filter capsules
- Single use bags
- Sampling systems
- Transfer lines

Regulatory Compliance

Bioburden Levels

Bioburden level is < 1000 cfu/device 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>

Biosafety

Passes the Biological Reactivity Tests, *In Vivo* for Class VI plastics as described in USP <88>

Extractables

Passes NVR test as per USP <661>

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