

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

3/8" Hose Barb

#### Materials of construction

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

#### Microbial Ingress

Exhibit absolute resistance to microbial ingress against a challenge of  $10^7$  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 ANSI/AAMI/ 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