

# AseptiLink™ ST

## Steam Through Connectors

DATASHEET

### Product Description

**mdi AseptiLink™ ST** steam through connectors are designed to provide safer, secure and validated connection for transfer of sterile fluids. This connector enables integration of steamable hard piped processing systems to gamma sterilized disposable flow paths in single use assemblies.

**mdi AseptiLink™ ST**, as part of the gamma irradiated single use disposable assembly is connected to stainless steel vessels/piping through its sanitary flange inlet connection. This connection is steam sterilized, along with SS component of the process flow, effecting a sterile connection between the two.

### Sizes Available



*AseptiLink™ ST* with 25 mm Sanitary Flange Inlet  
3/8" Hose Barb Steam and Fluid Outlet



*AseptiLink™ ST* with 50 mm Sanitary Flange Inlet  
1/2" Hose Barb Steam and Fluid Outlet

DST ALSTXXX2404D

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### Unique Performance Advantages

- No extraneous contamination: Completely closed, steam sterilizable connection
- No steam through into the environment
- No requirement of condensate drain tubing
- Carefully selected materials of construction for minimum extractables

### Validated for

The *AseptiLink™* ST Steam Through connector is designed and validated to meet all regulatory as well as functional requirements such as:

- Absolute resistance to microbial ingress
- Sterilization by gamma irradiation
- Low bioburden
- Bacterial endotoxins  $\leq 0.25$  EU/ml
- Biosafety
- No leakages
- High burst strength

### Specifications

#### Materials of Construction

**Body:** Polysulfone

**Seal Material:** Platinum Cured Silicone

**Operating Temperature:** 4 - 40 °C

**Pressure Leak Test:** Passes at 45 psi

**Steam sterilization:** 135 °C for 30 minutes, 1 cycle

**Gamma Sterilization:** Upto 50 kGy

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### Specifications

#### Microbial Ingress

Exhibit absolute resistance to microbial ingress against a challenge of  $10^7$  org/mL

#### 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>.

Passes the Biological Reactivity Tests, *In Vitro* for Cytotoxicity as described in USP <87>.

#### Total Organic Carbon

Meets the WFI requirements of USP <643> for Total Organic Carbon

#### Conductivity

Meets the WFI requirements of USP <645> for Conductivity

#### 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

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### Quality Management Systems

**mdi** AseptiLink™ ST steam through connectors are well designed products with in-built quality assurance. ISO-9001:2015 Certified Quality Management System, careful selection of raw materials, validated production processes and testing procedures based on international standards and guidelines such as CFR, PDA, and ASTM, ensures manufacture of consistently high quality connectors.

### Manufacturing Systems

These are manufactured in clean rooms certified by external agencies and monitored in-house for viable and non viable particles. Employee hygiene, change rooms, gowning and de-gowning procedures and continuous monitoring of the areas is an essential part of these facilities. These facilities have been designed for unidirectional work flow with appropriate change rooms for personnel and pass boxes for material movement.

### Product Availability

**mdi** AseptiLink™ ST steam through connectors are only available as part of **mdi** single use systems.

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