Membrane Technologies

AseptiLink™ SV

Steam To Connectors

DATASHEET

Product Description

mdi *AseptiLink™ SV* Connector is 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™ SV*, as part of the gamma irradiated single use disposable assembly is connected to stainless steel vessels/piping through its 25mm/50mm sanitary flange inlet connection. This connection is steam sterilized, along with SS component of the process flow, effecting a sterile connection between the two.

PATENT PENDING PATENT PENDING

Sizes Available:

50mm Sanitary Flange with 3/8" Hose Barb

25mm Sanitary Flange with 3/8" Hose Barb

DST ALSVXXX2404D

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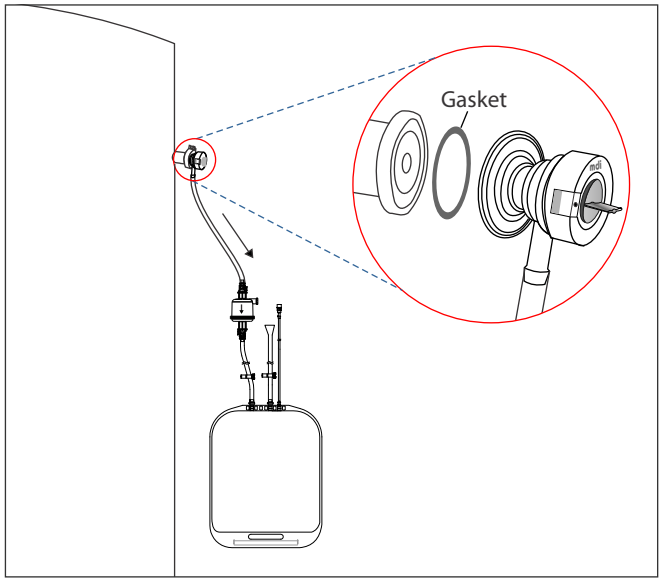
Unique Performance Advantages

- No extraneous contamination: Completely closed, steam sterilizable connection
- No steam through into the environment
- No requirement of condensate drain tubing



Validated for

The *AseptiLink*™ SV Steam To 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 ≤ 0.25 EU/ml
- Biosafety
- No leakages
- High burst strength

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Specifications

Material of construction
Main Body: Polysulfone
Gasket: Silicone

Operational Radius: 66 mm

Operating Temperature: 4 - 40 °C

Pressure Leak Test: Passes at 2.5 bar (40psi)

Steam sterilization: 135 °C for 30 minutes, 3 cycles

Gamma Sterilization: Upto 50 kGy

Number of actuations: 5 times

Typical water flow rates: 5lpm @ 2psi

Toxicity
Passes Bioreactivity test, *In Vivo*, as per USP <88> for Class VI plastics

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

Endotoxin Testing
Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

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
Complies with USP <788> test for particulate matter in injections

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Quality Management Systems

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

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