

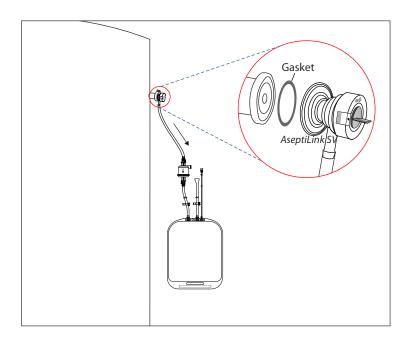
AseptiLink SV

Steam Sterilizable Valved Connector

Patent Pending

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 50 mm sanitary flange inlet connection. This connection is steam sterilized, along with SS component of the process flow, effecting a sterile connection between the two.



Unique Performance Advantages

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



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

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

Cytotoxicity: Passes Biological Reactivity Tests,

In Vitro, USP <87> for cytotoxicity

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

 $\textbf{Particle Release:} \ Complies \ with \ USP < 788 > \ test$

for particulate matter in injections