mdi
Membrane Technologies

AseptiLink SC
Genderless Sterile Connector

DATASHEET

Single Use Systems (SUS) are increasingly being used in the biopharmaceutical manufacturing process. Aseptically connecting single use components to form a usable assembly or to connect a SUS to another single use or a reusable system, for example a sterile media bag to a bioreactor, is a critical requirement.

MDI *AseptiLink SC*, genderless connectors are designed to provide a fast and convenient aseptic connection between two processing streams, such as a container to a sampling line, media bags to a bioreactor or a filtration assembly to a filling line, without the need of a biocontainment hood. In other words, it provides a validated robust connecting mechanism within sterile as well as non sterile environments, while eliminating the need for sophisticated and complicated hardware.

Application

Aseptically connects:

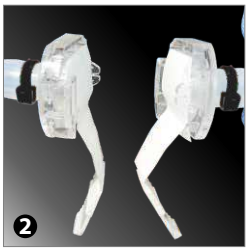
- Two gamma sterile single use systems
- Gamma sterilized single use system and autoclavable stainless steel hardware

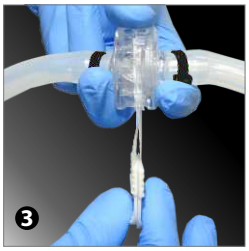
Validated for

The *AseptiLink SC* is designed and validated to meet all regulatory as well as functional requirements such as:

- Absolute resistance to microbial ingress
- Sterilization by autoclaving
- Bioburden
- Bacterial endotoxins
- Biosfaety
- No leakages
- Burst strength

Simple 3 Step Connection





Unique Performance Advantages

- Reliable aseptic connection even in non sterile areas
- Fast and easy 3 step connection
- Minimum inventory: Genderless design
- Carefully selected materials of construction for minimum extractables

Materials of construction

Fluid Contact Parts	Polypropylene
Seal Material	Silicone
Protective Cap	Polypropylene

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 ANSI/AAMI/ISO 11737-1 : 1995

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>.

Burst Pressure
> 4 bar (60 psi)

Operating Temperature
4 - 40 °C

Sterilization
Autoclavable for 1 cycle at 125°C for 30 minutes. Do not steam in place.
Gamma sterilizable upto 50 kGy.

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

Packaging Integrity

AseptiLink SC connectors are packed in double polythene bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room assembly or process areas.

Ordering Information

Type		X	X	End Connection		XXX	XX	Sterility		Pack Size	
	Code				Code				Code		Code
AseptiLink SC Sterile Connector	ASCX			Single Step ½" Hose Barb	Q			Non Sterile	1	10	02
				¼" Hose Barb	B						
				⅜" Hose Barb	I						

Example

ASCX	X	X	I	XXX	XX	1	02

ADVANCED MICRODEVICES PVT. LTD. 20-21, Industrial Area, Ambala Cantt- 133 006, India
Tel: +91 - 171-2699290, 2699471, E-mail: info@mdimembrane.com, Website: www.mdimembrane.com