



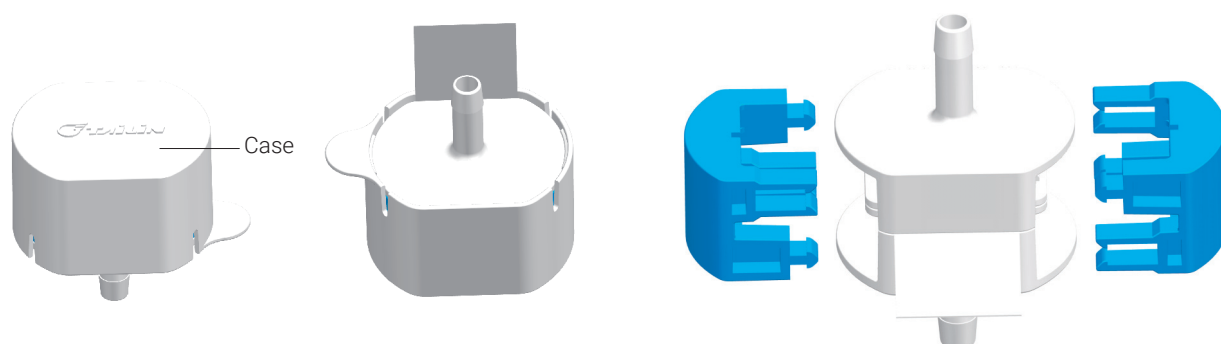
Sterile Connector

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SteriSafe Sterile Connectors are the next generation of disposable fluid handling and management devices. This new universal connector can achieve a permanent sterile connection between two fluids.

It is widely used in the field of biopharmaceuticals. This sterile connector is intuitive to operate, with only 3 simple steps. It will not affect the operation even in a non-sterile environment.

Sterilization of this fluid path. Key designs such as anti-priming buckles and tamper-resistant protective covers give end users greater confidence in operation and greater confidence in process safety.



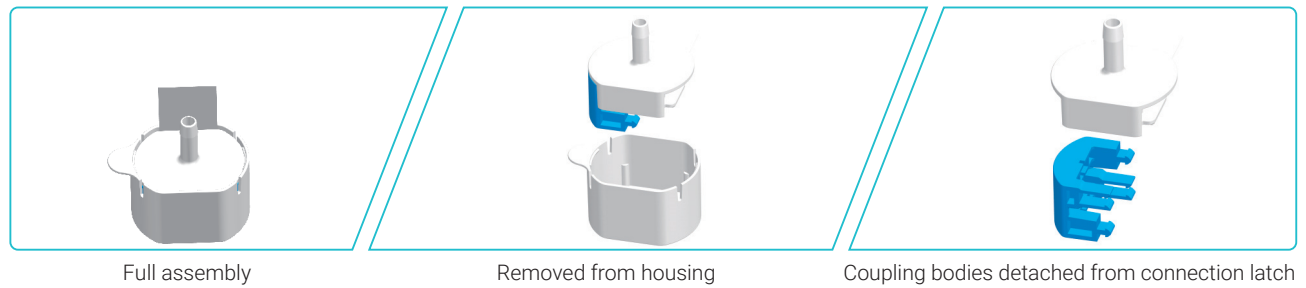
Features

Gender-less design	Simplify SUS specifications with one part number covering both halves.
Allow aseptic connection of two fluid channels in non-sterile environment	No need for laminar flow hood or glove box for aseptic connection.
Audible "click"	Safe assembly confirmed by audible sound.
Pipeline is designed with straight-through and consistent inner diameter	No air bubbles generated during medium transfer.
Four-way interlock structure ensures equipment can only be connected once	100% anti-disassembly after completion of connection, ensuring safe and reliable use with stronger pressure resistance.
Two-step connection	Ensure easy removal of membranes and prevent re-contamination during assembly.
High sterility assurance	Reduce the risk of cross-contamination risk and quality nonconformity.
Pressure	Up to 0.6Mpa/48hr
Temp	1°C-45°C
Sterilization	Gammairradiation: Max. 50 kGy perdose; 25kGy recommended. Autoclave: Max. 130 °C/75 min; 121 °C/20 minrecommended.
Hose barb diameter	6.35mm(1/4") / 9.53mm(3/8")ID Hose Barb

Applications

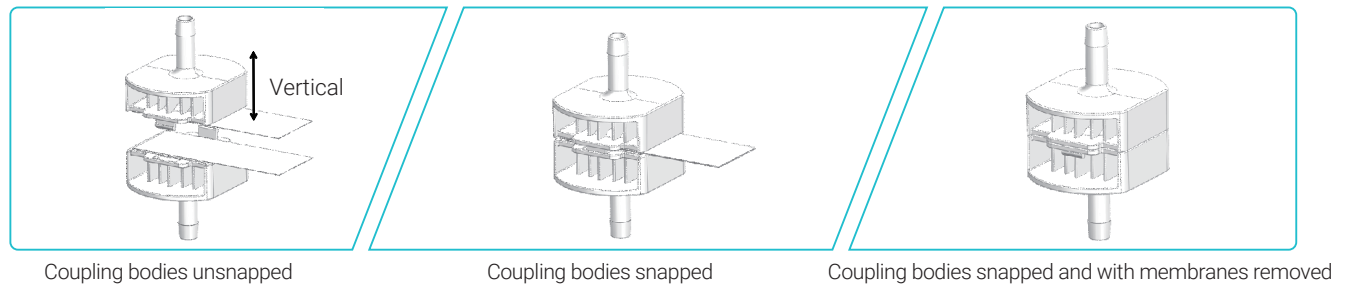
- ▶ Culture medium preparation and transfer
- ▶ Buffer preparation and transfer
- ▶ Inoculation into bio-reactors
- ▶ Sampling during fermentation/culturing processes
- ▶ Harvesting from bio-reactors
- ▶ Aseptic transfer between unit operations
- ▶ Aseptic bulk processing in uncontrolled environment
- ▶ Connection of sterile electrode/probe with bio-reactors, dispensing systems and 3D bio-containers
- ▶ Connection with sterilizing filtration system
- ▶ Aseptic connection for stainless steel-based system and SUS
- ▶ Aseptic transfer of intermediates to filling system
- ▶ Removal of sterile wastes from process materials

Assembly Procedures



Step 1:

Remove the protective housing, pull and detach the connection latch from the connector body.



Step 2:

Align the two coupling bodies and press them together until hearing a "click" sound, and pull the membranes from the connector.



Step 3:

Insert both latches into the snapped connector body and press together until hearing a "click" sound.

Mechanical requirement testing

- Integrity test
- Burst test
- Stress rupture test
- Tensile test

Functional requirement testing

- Leak test under work-case conditions
- Flow test
- Microbial ingress test
- Autoclave test
- Gamma irradiation test
- E&L test

Construction materials

Product contact parts

Coupling body	Polycarbonate, FDA certified
O-ring	Silicone (transparent), Platinum(II) sulfide

Non-product contact parts

Connection latch	Polycarbonate, FDA certified
Protective housing	Polycarbonate, FDA certified
Filter membrane	Hydrophobic PES (heat-compatible)

Performance

Pressure	Up to 0.6Mpa/48hr
Temp	1°C-45°C
Sterilization	<p>Gammairradiation: Max. 50 kGy perdose; 25kGy recommended.</p> <p>Autoclave: Max. 130 °C/75 min; 121 °C/20 minrecommended.</p>

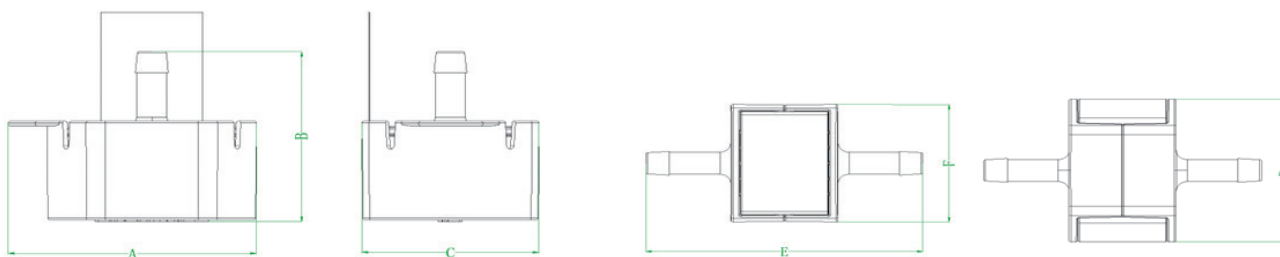
Validation Method

E&L test (NVR)		Time		
		0(≤30min)	24hour	7day
Test Seq.	Reagent	Ambient Temp(25°C)	40°C	40°C
1	50%Alcohol	√	√	√
2	0.5NNaOH	√	√	√
3	0.1MH ₃ PO ₄	√	√	√
4	1%PS-80	√	√	√
5	5MNaCl	√	√	√
6	WFI or DI Water	√	√	√

Specifications

Nominal Size A/B/C: Connector OD; D/E/F: Adapter OD.

Type	A	B	C	D	E	F	
1/4"Hose Barb	61MM	52MM	43MM	48MM	75MM	39MM	10PCs/Pack
3/8"Hose Barb	61MM	52MM	43MM	48MM	75MM	39MM	10PCs/Pack
Hose barb diameter	6.35mm(1/4")/9.53mm(3/8")ID Hose Barb						



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