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Datasheet

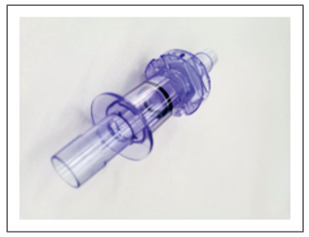
LeCouple® products for Sterile connection

Aseptic connection products can quickly and effectively help users of biopharmaceutical enterprises to ensure the sterility and operational reliability in the process of liquid transmission, customized one-time solutions and other requirements. LePure's LeCouple® series of disposable aseptic connection products provide a safe and reliable aseptic connection solution for users of biopharmaceutical enterprises.

LeCouple® sterile connection series include LeCouple® LSC sterile connector and LeCouple® LPS pH/DO electrode sleeve assembly.

LeCouple® LSC Sterile Connectors

- Allows the dry connection of two separate fluid pathways, while maintaining the sterile integrity.
- The connector is disposable, and can be Gamma or autoclaved sterilized.
- The connector consists of a male and a female connector. Once assembled, the two components cannot be disassembled to reduce the risk of sterility breach.



Typical applications

It is widely used in aseptic connection of liquid pipelines in biological processes such as antibodies, vaccines and cell gene therapy, and connection of pH/DO interface of single use reactor bag in cell culture process.

- Preparation of medium/buffer solution
- Inoculation of fermenter
- Sampling during fermentation or cell culture
- Connection from tank to filling line
- The separation of culture-medium/buffer solution and stock solution

Advantages

- Secure, fast and convenient connection
- Maintain the sterile integrity of fluid pathways
- Single-use reduces the risk of sterility breach
- The connector can be Gamma or autoclaved sterilized
- Locking device design, reduce the risk of leakage and installation failure caused by operation error
- Reliable supply chain. Self-production ensures stable delivery

Quality Standards

The factory has passed SGS ISO 9001:2015 and ISO13485:2016 quality management system certification.

Validation tests include:

- ☑ Burst test
- ☑ Integrity test
- ☑ Bacterial spore challenge test
- ☑ Extractable test
- ☑ Insoluble particle
- ☑ Shelf-life

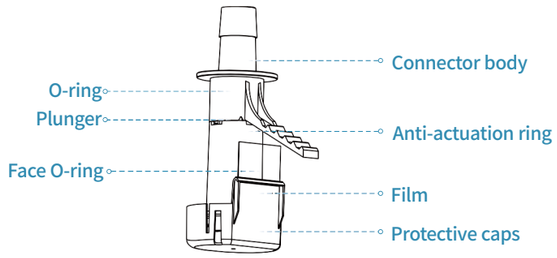
The materials of fluid path meet regulatory requirements:

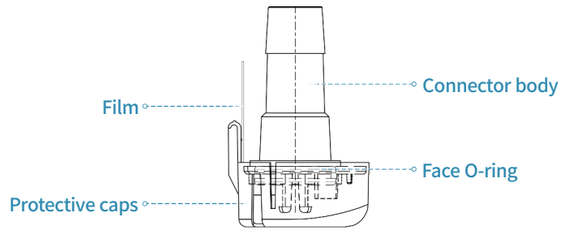
Endotoxin	< 0.25 EU/mL
Biocompatibility	Biological Reactivity Tests in vivo for Class VI Plastics, USP <87> and USP <88>

Sterility Assurance

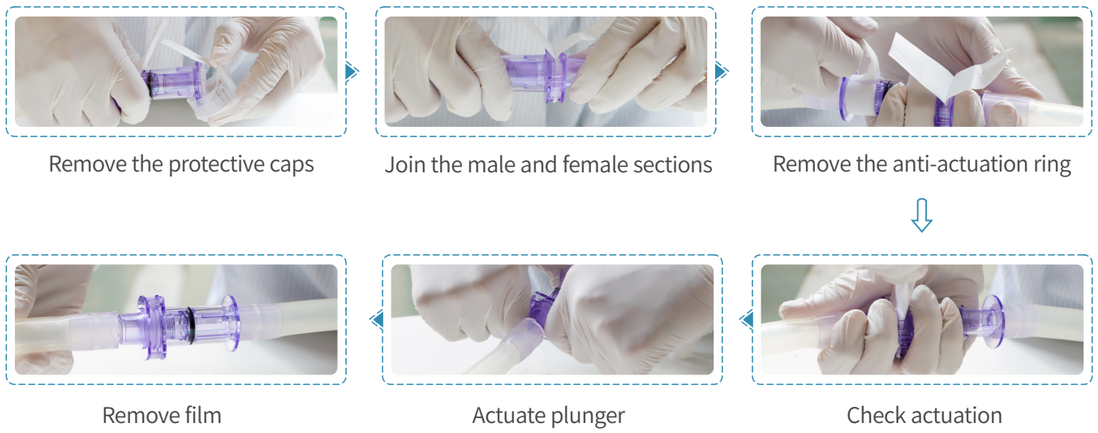
Connector sets were taken the bacterial spore challenge test with 10^6 Colony Forming Units (cfu) of B. diminuta. Connector sets were assembled in 10^6 cfu of B. diminuta environment and proved that the connection is sterile after 7 days sterile medium culture. Assuring a sterile connection can be made in non-classified areas.

Structure chart





Operation procedure



Materials

Component	Material
Connector body	Polycarbonate
Plunger	Polycarbonate
O-ring	Ethylene-Propylene-Diene Monomer
Anti-actuation ring	Silicone
Face O-ring	Silicone
membrane	PTFE/ Polyester resin
Protective cap	Polypropylene

Relevant Tests

Test standard	Test item	Test result
USP <788>	Insoluble particle	⩾10μm：⩽10 PCS/mL
		⩾25μm：⩽1 PCS/mL
ISO 4548-6	Burst test	Pass
USP <665>	Extractable test	Pass
ISO 11607	Sterilize test	Pass
ASTM F1980-2016	Shelf-life	2 years

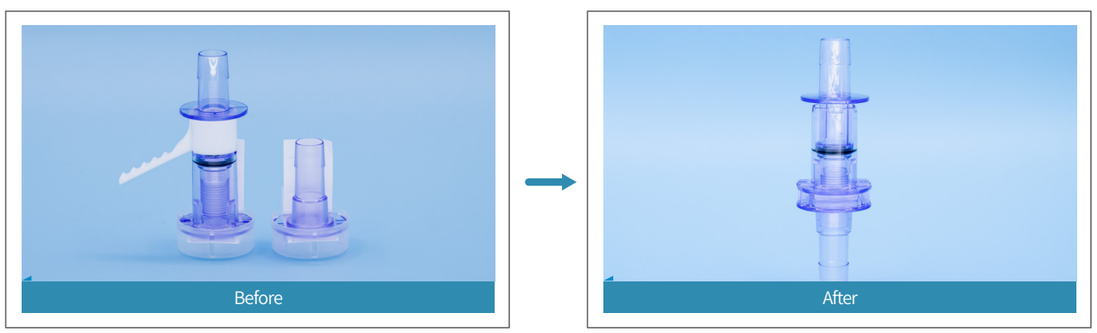
Specifications

Size	1/2 inch hose barb
Sterilization Methods	Gamma irradiation: 25-40 kGy Autoclave: 30minutes at 121°C
Operating Conditions	Maximum operating pressure: 3bar
Shelf-life	2 years

Order Information

Cat. No.	Description
LSC1M01	LeCouple® LSC 1/2"Hose Barb, male connector
LSC1F01	LeCouple® LSC 1/2"Hose Barb, female connector

Note: This product is not sold after sterilization.



LeCouple® LPS pH/DO Sensor Sleeve Assembling

The cell culture process, as one of the key links in different biopharmaceutical fields, like antibodies, vaccines, cell and gene therapy, can directly affect the yield and quality of the products. In order to ensure the performance indicators, such as cell density, cell viability and specific productivity, it is essential to monitor pH and DO during the cell culture process. The LeCouple® pH/DO Sensor Sleeve Assembling can fully meet the aseptic monitoring for pH and DO; meanwhile, the separate pH and DO threaded plugs can ensure good air impermeability.

There are two types of Sterile connector for LeCouple® LPS pH/DO sensor sleeve assemblies: CPC G Series sterile connectors and LeCouple® LSC series sterile connectors.

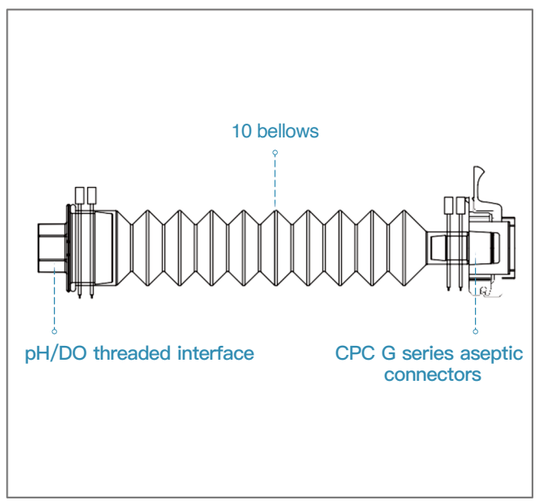
Applications

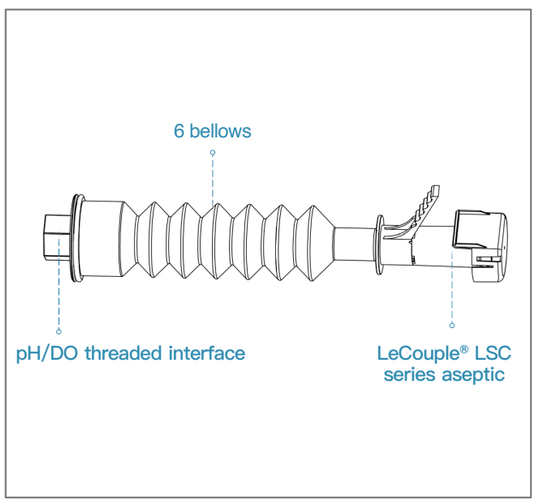
Realize the aseptic connection of pH/DO Sensor and ensure the online monitoring during the cell culture process.

Advantages

- Different threaded plugs at pH/DO to adequately ensure gas impermeability
- Easy to operate and can be installed in conventional environment
- Adequate inventory of raw materials and related components, stable supply chain

Structure chart





Materials of Construction

Component		Main Materials
CPC G Series Sterile Connectors 	Body Portion	Polycarbonate
	Slides	Polycarbonate
	Seal	Silicone
	Film	Hydrophobic polysulfone
LeCouple®LSCSeries Sterile Connectors 	Connector body	Polycarbonate
	O-ring	Ethylene-Propylene-Diene Monomer
	Anti-actuation ring	Silicone
	Face O-ring	Silicone
	Film	PTFE/ Polyester resin
	Protective caps	Polypropylene
Bellows		Silicone
pH/DO threaded plug		Polycarbonate

Relevant Tests

Test standard	Test item	Test result
ISO 10993-4	Hemolysis	Pass
ISO 10993-5	Cytotoxicity	Pass
ISO 10993-6	Implantation tests	Pass
ISO 10993-10	Irritation and Sensitization tests	Pass
ISO 10993-11	Acute Systemic Toxicity tests	Pass

Order Information

Cat. No.	Description
CDCG10P	CPC ASEPTIQUIK® G + 10 Bellows + pH Sensor Insertion Port (Non-Sterilized + Autoclave)
CDCG10O	CPC ASEPTIQUIK® G + 10 Bellows + DO Sensor Insertion Port (Non-Sterilized + Autoclave
CDLP06P	LeCouple® LSC + 6 Bellows + pH Sensor Insertion Port (Non-Sterilized + Autoclave
CDLP06O	LeCouple® LSC + 6 Bellows + DO Sensor Insertion Port (Non-Sterilized + Autoclave

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