Membrane Technologies

AseptiProbe™ Bellow Assembly

for Single Use Mixer and Bioreactor Systems

DATASHEET

Single use mixer systems and bioreactors require real time monitoring of various critical process parameters (CPP) such as pH, conductivity, dissolved oxygen etc. These systems are also available with pre installed single use sensors, these disposable sensors have multiple challenges of in terms of accuracy, reliability, on site calibration etc. Such disposable sensors also reduce the overall residual shelf life of high value Single Use Mixers/ Bioreactors.

This makes reusable sensors the preferred choice, which can be calibrated and autoclaved before use for real time monitoring of CPPs in mixing (mixer systems) and cell culture expression systems (bioreactor).

mdi *AseptiProbe*™ Bellow Assembly provides easy to use aseptic connection systems for reusable sensors to Single use mixers and bioreactors.

Materials of construction

Body

Silicone

Port Connector

Polycarbonate

Sterile Connector

AseptiProbe™ Bellow Assemblies are available with different sterile connectors as required by the user.

Applications

Facilitates in monitoring of critical process parameters in single use mixer bags and bioreactors while maintaining the sterility.

Specifications

Autoclaving

Autoclavable at 125°C for 30 minutes

for Microbial Ingress

Exhibit absolute resistance to microbial ingress against a challenge of 10^7 org/mL of *B. diminuta*.

Bioburden Levels

Bioburden level is < 1000 cfu/device as per ISO 11737-1:2018.

Bacterial Endotoxin Levels

Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amoebocyte Lysate (LAL) test as per USP <85>.

Particle Release

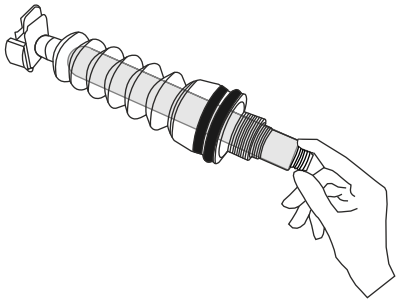
Complies with USP <788> test for particulate matter in injections

Fiber Release

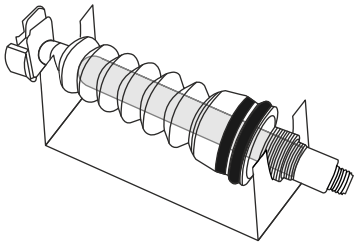
Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release

Installation

1. Insert sensor probe into the bellows assembly. Do not push the sensor end too far during installation in the bellows, as this may cause damage to the sterile connector peel strip.

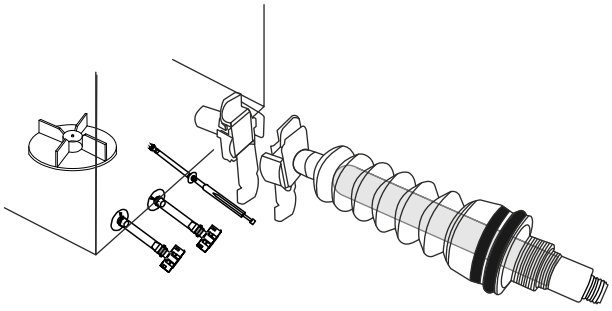


2. Autoclave the assembly before use, using bellow support system.



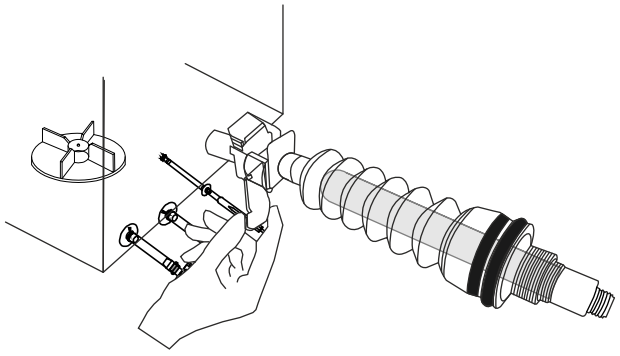
3. Open the cover of both the connectors by pulling extended part of cover against connector i.e from bellow assembly and mixer bag.

Align two connector facing each other. Make sure that the pull tabs are facing downwards.

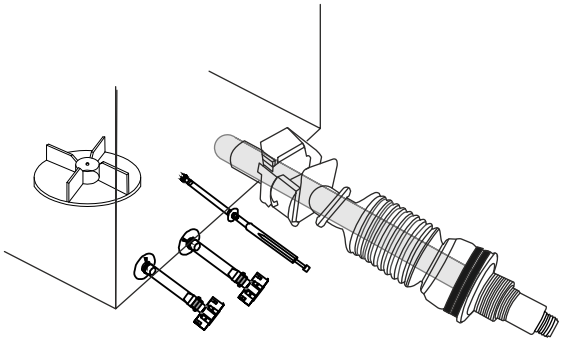


4. Press on one side till you hear a click. Now press on the other side to hear a second click. Press again to ensure that the connectors have mated properly.

Hold the two pull tabs together and pull the film downward to make a sterile pathway.



5. Push the sensor into the single use mixer bag or bioreactor, collapsing the bellows.



Note: Sensors must be installed in the *AseptiMix™ MI* mixer bag system before fluid is added.

Ordering Information

Type		Length of Shaft		Sensor Diameter		Sterile Connector Vendor		Size		XX	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
AseptiProbe Bellow Assembly	APBA	225 mm	225	12 mm	A	mdi	A	1/2" HB	Q		Non Sterile	1	1	01
						CPC	K							
						Millipore	E							
						Cytiva	H							

Example

ABPA	225	A	A	Q	XX	1	01

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