

# BIO BAG ASSEMBLIES

When a single drop of fluid can make the difference in someone's health, you need smart fluid handling solutions that get the job done safely. Manufacturers worldwide rely on connector products that improve yield, cut costs and reduce time to market.

PART NUMBERS:  
(SEE PAGE 3 FOR FULL DETAILS)

- ◆ F-2DBA-(XXX)ML-SIL
- ◆ F-2DBA-(XXX)L-SIL
- ◆ F-2DBA-(XXX)ML-TPE
- ◆ F-2DBA-(XXX)L-TPE

## DESCRIPTION:

FlowLinX 2D bio bag assemblies are designed for aseptic fluid handling in upstream and downstream processing, such as sampling, buffer and media storage, and chromatography. The bag chamber design allows for easy product recovery with minimal product hold up. Made from USP Class VI components, FlowLinX 2D bio bag assemblies are available from 50mL to 100L volumes in 3-port and 4-port configurations with silicone and TPE tubing. Choose from standard configurations or customize to your requirements.



## SPECIFICATIONS:

- ☑ Manufactured in an ISO 7 Cleanroom
- ☑ ISO 9001:2015 Certified Facility
- ♥ USP <88> Class VI & Animal Component Free
- ✂ Aseptically connect using AseptiQuik® or TPE tube welder
- ✂ Aseptically disconnect using TPE tube sealer
- ☑ Double bagged and ready to use
- 🌀 Sterility assurance level  $10^{-6}$  per ISO 11137



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Figure 1

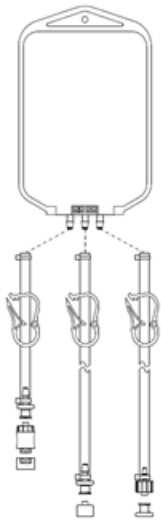


Figure 2

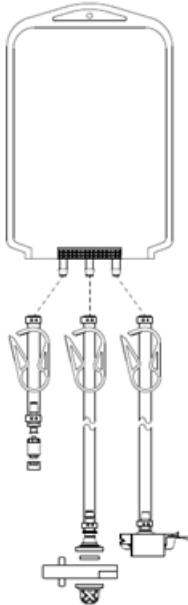


Figure 3

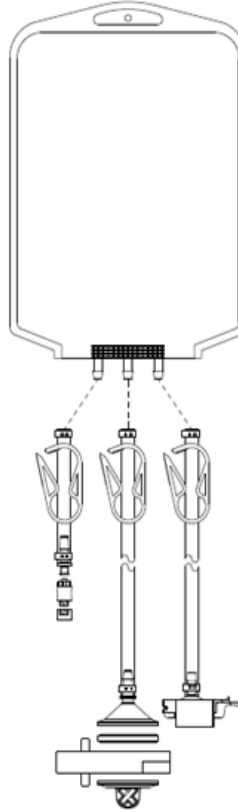
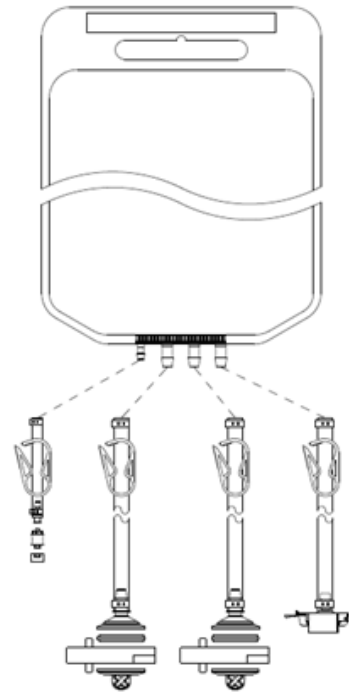


Figure 4



## BAG FILM REGULATORY OVERVIEW:

### Material of Construction

ULDPE Fluid Contact Layer

### Biocompatibility

USP <85>, Bacterial Endotoxin

USP <88>, Biological Ractivity Tests, Class VI, In Vivo

USP <87>, Biological Teactivity Test, In Vitro

ISO 10993-4, Hemolysis

ISO 10993-5, Cytotoxicity

ISO 10993-6, Implantation

ISO 10993-10, Irritation and Sensitization

ISO 10993-11, Systemic Toxicity

### Physiochemical

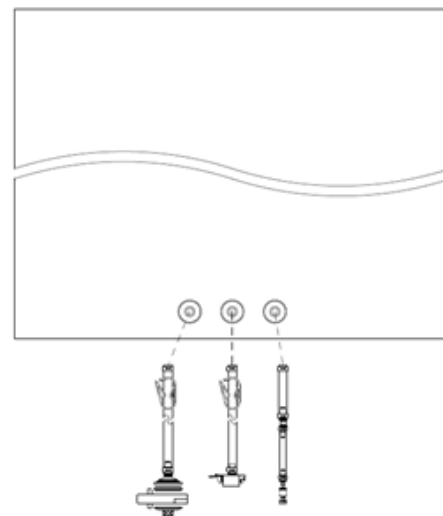
USP <661>, Plastic Packaging Systems

EP 3.2.2.1, Plastic Containers for Aqueous Solutions for Infusion

### Extractables

Per BPOG Protocol

Figure 5



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PART NUMBER	VOLUME	TUBING	CONFIGURATION	QTY	FIGURE DETAILS
F-2DBA-050ML-SIL	50 mL	Platinum Cured Silicone	Line 1: 1/8" x 1/4", 12" OAL with male luer	Each	Figure 1
F-2DBA-100ML-SIL	100 mL		Line 2: 1/8" x 1/4" 12" OAL with female luer		
F-2DBA-250ML-SIL	250 mL		Line 3: 1/8" x 1/4", 4" OAL with needle-free luer sampling valve		
F-2DBA-500ML-SIL	500 mL	Platinum Cured Silicone	Line 1: 1/4" x 1/2", 12" OAL with AseptiQuik® G Line 2: 1/4" x 1/2", 12" OAL with mini TC Line 3: 1/4" x 1/2", 4" OAL with needle-free luer sampling valve	Each	Figure 2
F-2DBA-001L-SIL	1 L	Platinum Cured Silicone	Line 1: 1/4" x 1/2", 12" OAL with AseptiQuik® G	Each	Figure 3
F-2DBA-002L-SIL	2 L		Line 2: 1/4" x 1/2", 12" OAL with maxi TC		
F-2DBA-003L-SIL	3 L		Line 3: 1/4" x 1/2", 4" OAL with needle-free luer sampling valve		
F-2DBA-005L-SIL	5 L	Platinum Cured Silicone	Line 1: 3/8" x 5/8", 12" OAL with AseptiQuik® G	Each	Figure 4
F-2DBA-010L-SIL	10 L		Line 2: 3/8" x 5/8", 12" OAL with maxi TC		
F-2DBA-020L-SIL	20 L		Line 3: 3/8" x 5/8", 12" OAL with maxi TC		
F-2DBA-030L-SIL	30 L		Line 4: 1/4" x 1/2", 4" OAL with needle-free luer sampling valve		
F-2DBA-050L-SIL	50 L				
F-2DBA-100L-SIL	100 mL	Platinum Cured Silicone	Line 1: 3/8" x 5/8", 12" OAL with maxi TC Line 2: 3/8" x 5/8", 12" OAL with AseptiQuik® G Line 3: 1/4" x 1/2", 8" OAL with needle-free luer sampling valve	Each	Figure 5
F-2DBA-050ML-TPE	50 mL	TPE	Line 1: 1/8" x 1/4", 12" OAL with male luer	Each	Figure 1
F-2DBA-100ML-TPE	100 mL		Line 2: 1/8" x 1/4" 12" OAL with female luer		
F-2DBA-250ML-TPE	250 mL		Line 3: 1/8" x 1/4", 4" OAL with needle-free luer sampling valve		
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