PRODUCT SPECIFICATIONS - 3D BIO BAG ASSEMBLIES

3D 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-3DBA-(XXX)L-SIL
- F-3DBA-(XXX)L-TPE

DESCRIPTION:

FlowLinX 3D bio bag assemblies are designed for aseptic fluid handling in upstream and downstream processing, such as buffers and media, chromatography feed and collection, and bulk drug product storage and transport. The bag chamber design allows for easy product recovery with minimal product hold up. Made from USP Class VI components, FlowLinX 3D bio bag assemblies are available from 50 L to 3000 L volumes in 3-port configurations with silicone and TPE tubing. Choose from standard configurations or customize to your requirements.

v	Manufactured in an ISO 7 cleanroom
Ø	ISO 9001:2015 certified facility
\bigcirc	Fluid path components meet USP <88> Class VI & animal component free
8	Superb physical strength and excellent biocompatibility
	Standard bags with needle free sampling port
۲Ľ	Aseptically connect using AseptiQuik® or TPE tube welder
\ge	Aseptically disconnect using TPE tube sealer
Ō	Each bag assembly is double bagged and ready to use
æ	Sterility assurance level 10-6 per ISO 11137

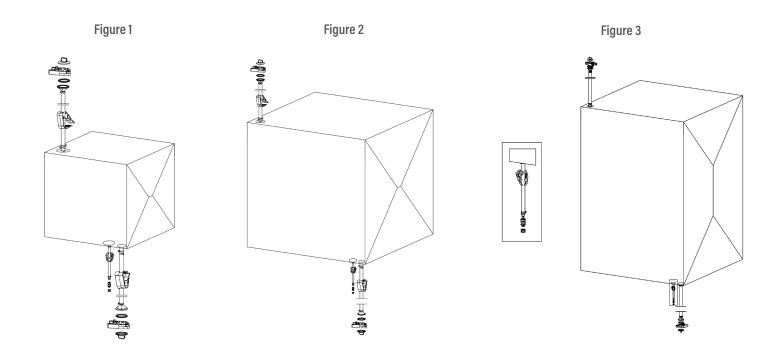








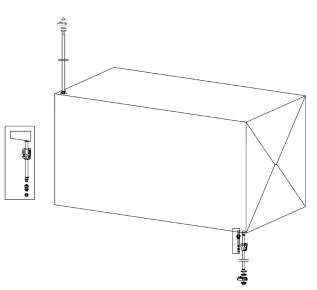
product specifications - 3d bio bag assemblies **3D BIO BAG ASSEMBLIES**



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 4





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PART NUMBER	VOLUME	TUBING	CONFIGURATION	QTY	FIGURE DETAILS
F-3DBA-0050L-SIL F-3DBA-0100L-SIL F-3DBA-0200L-SIL	50 L 100 L 200 L	Platinum Cured Silicone	Upper Inlet: 3/8" x 5/8", 60" OAL with 1.5" sanitary connector and clamp Bottom Outlet: 3/8" x 5/8", 60" OAL with 1.5" sanitary connector and clamp Sampling: 1/4" x 3/8", 6" OAL with needle-free luer sampling valve	Each	Figure 1
F-3DBA-0500L-SIL	500 L	Platinum Cured Silicone	Upper Inlet: 1/2" x 3/4", 80" OAL with 1.5" sanitary connector and clamp Bottom Outlet: 1/2" x 3/4", 80" OAL with 1.5" sanitary connector and clamp Sampling: 1/4" x 3/8", 6" OAL with needle-free luer sampling valve	Each	Figure 2
F-3DBA-1000L-SIL F-3DBA-1500L-SIL	1000 L 1500 L	Platinum Cured Silicone	Upper Inlet: 3/4" x 1", 96" OAL with 1.5" sanitary connector and clamp Bottom Outlet: 3/4" x 1", 96" OAL with 1.5" sanitary connector and clamp Sampling: 1/4" x 3/8", 6" OAL with needle-free luer sampling valve	Each	Figure 3
F-3DBA-2000L-SIL	2000 L		Upper Inlet: 3/4" x 1", 120" OAL with 1.5" sanitary connector and clamp Bottom Outlet: 3/4" x 1", 120" OAL with 1.5" sanitary connector and clamp Sampling: 1/4" x 3/8", 6" OAL with needle-free luer sampling valve	Each	Figure 4
F-3DBA-2500L-SIL	2500 L	Platinum Cured Silicone			
F-3DBA-3000L-SIL	3000 L				
F-3DBA-0050L-TPE	50 L		Upper Inlet: 3/8" x 5/8", 60" OAL with 1.5" sanitary connector and clamp		
F-3DBA-0100L-TPE	100 L	TPE Bottom Outlet: 3/8" x 5/8", 60" OAL with 1.5" sanitary connector and clamp	Each	Figure 1	
F-3DBA-0200L-TPE	200 L		Sampling: 1/4" x 3/8", 6" OAL with needle-free luer sampling valve		
F-3DBA-0500L-TPE	500 L	TPE	Upper Inlet: 1/2" x 3/4", 80" OAL with 1.5" sanitary connector and clamp Bottom Outlet: 1/2" x 3/4", 80" OAL with 1.5" sanitary connector and clamp Sampling: 1/4" x 3/8", 6" OAL with needle-free luer sampling valve	Each	Figure 2
F-3DBA-1000L-TPE	1000 L	TPF	Upper Inlet: 3/4" x 1", 96" OAL with 1.5" sanitary connector and clamp Bottom Outlet: 3/4" x 1", 96" OAL with 1.5" sanitary connector and clamp Sampling: 1/4" x 3/8", 6" OAL with needle-free luer sampling valve	Each	Figure 3
F-3DBA-1500L-TPE	1500 L				
F-3DBA-2000L-TPE 2000 L F-3DBA-2500L-TPE 2500 L		TPE	Upper Inlet: 3/4" x 1", 120" OAL with 1.5" sanitary connector and clamp	Each	
			Bottom Outlet: 3/4" x 1", 120" OAL with 1.5" sanitary connector and clamp		Figure 4
F-3DBA-3000L-TPE	3000 L		Sampling: 1/4" x 3/8", 6" OAL with needle-free luer sampling valve		

