3D Bioprocess Assemblies

Quality assembly solutions that provide ultimate customization, quick-turn design, and fast delivery

Bringing the benefits of ultimate customization, fast design, and delivery to fluid handling, Entegris offers customizable 3D multilayer bioprocess assemblies with a broad range of capabilities that can be integrated into a variety of medium to large single-use biopharmaceutical processes. Applying decades of experience and materials expertise, we provide complete solutions for upstream and downstream applications.

Whether you need a small volume, large volume, or manifold configuration, we can customize sterilized assemblies to meet your needs in:

- Storage
- Mixing
- Purification

- · Chemical processing
- Large-volume processing
- Inter- and intra-facility transport

Standard Features

- 3D bioprocess assemblies and associated components are sterilized using gamma irradiation between 25 – 40 kGy
- Comprehensive validation guide available
- Extractables and leachables (E&L) data available upon request
- Full traceability for all materials
- · Certificates of analysis provided for each lot
- Include Flex 100/150, a multilayer film designed to provide strength and low gas permeability for a wide variety of applications
- Manufactured under a quality system designed to be compliant to 21 CFR Part 820: Quality System Regulation



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All 3D assemblies are custom tailored to your application, designed with tubing and accessories that meet your specific processing needs, and provide a complete large-volume solution. With multi-ply strength in a single ply thickness, our 3D assembly solutions eliminate 70% of common seams adding robust security to your system.

Outer Containment Solutions

<u>Rigid bioprocess support containers</u> are available for mixing, processing, storing, and transporting large volumes of solutions.

Made of high quality, durable materials, our vessels are an efficient and more economical option than stainless-steel tanks, and when combined with liners, require virtually no cycle time between batches.

We also offer alternative outer containment options for a variety of applications and volumes to interface with your current technology. Please contact Entegris for additional information.



APPLICATIONS

- Secure handling and storage of bioprocess liquids
- Bulk sterile shipping
- Media and buffer storage
- Drug substance and excipients
- Fluid management solutions for purification
- Bioreactor harvest
- Waste collection
- Solution transfers

FEATURES & BENEFITS

Process driven design and engineering	Allows personalized, timely, and knowledgeable attention throughout the collection, design, and ordering process				
Customized system design	Provides design flexibility and allows the system to fit the process rather than the process adapt to the system				
Standard design library	Enables quick access to standard products, providing consistently fast development and delivery while minimizing the risk of production delays				

SPECIFICATIONS

Product Specifications

Configurations	1 to 4 ports*					
Sizes	50 L, 100 L, 200 L, 500 L, 1000 L, 2500 L					
Ports	Male and female Luer locks, quick connect inserts and couplers, bottom drain					
Tubing	1/8" to 3/4" inside diameter					
	36" to 48" standard length					
Dip tubes	Available for multiple mixing applications. Contact Entegris with your requirements.					
Materials of construction	Flex 100/150**					
	This design provides strength and low gas permeability. The two-layer, multi-ply design helps reduce stress, preventing container leak through under harsh conditions.					
	Total 8 mil thickness					
	 Inner product contact barrier: Flex 100 LDPE (low density polyethylene) 					
	Outer barrier: Flex 150 (PE/nylon/EVOH/nylon/PE)					

^{*}Entegris has high capability of design configuration. Please contact your sales representative for additional ports or customizations.

^{**}An additional layer can be added to create a Flex 100/100/150 film.

Standard Products

						Connectors	
Part number	Volume	Chamber geometry 22.9" Ø, 24" H	Dispense port options		Tubing length*	MPC MPX	
FSB04564.01	50 L		Тор	2x ³ /8", 2x ¹ /2" ports	30" per line	1 male, 1 female	1 male, 1 femal
FSB04564.02	100 L	22.9" Ø, 30" H	Тор	2x ³ /8", 2x ¹ /2" ports	30" per line	1 male, 1 female	1 male, 1 femal
FSB04564.03	200 L	22.9" Ø, 38" H	Тор	2x ³ /8", 2x ¹ /2" ports	30" per line	1 male, 1 female	1 male, 1 femal
FSB04565.01	500 L	44" L × 44" W × 34" H	Тор	4x ½" ports	30" per line	_	2 male, 2 femal
FSB04565.02	1000 L	44" L × 44" W × 38" H	Тор	4x ½" ports	30" per line	1 male, 1 female	1 male, 1 femal
FSB04566.01 50 L	22.9" Ø, 18" H	Тор	2x ³ /8", 2x ¹ / ₂ " ports	30" per line on top ports	1 male, 1 female	1 male, 1 femal	
		Bottom	³ / ₄ " port	48" on bottom port	_	1 femal	
FSB04566.02 100 L	22.9" Ø, 18" H	Тор	2x ³ /8", 2x ¹ /2" ports	30" per line on top ports	1 male, 1 female	1 male, 1 femal	
		Bottom	³ / ₄ " port	48" on bottom port	_	1 femal	
FSB04566.03 200 L	22.9" Ø, 18" H	Тор	2x ³ /8", 2x ¹ /2" ports	30" per line on top ports	1 male, 1 female	1 male, 1 femal	
	-	Bottom	³ / ₄ " port	48" on bottom port	_	1 femal	
FSB04567.01 500 L	44" L × 44" W × 32" H	Тор	4x ½" ports	30" per line on top ports	_	2 male, 2 femal	
	-	Bottom	1" port	48" on bottom port	_	1 femal	
FSB04567.02 1000 L	44" L × 44" W × 32" H	Тор	4x ½" ports	30" per line on top ports	1 male, 1 female	1 male, 1 femal	
	-	Bottom	1" port	48" on bottom port	-	1 femal	

^{*}TPE tubing is standard. For custom tubing options, additional ports, filters, dip tubes, or other customizations specific for your process please contact Entegris.

ORDERING INFORMATION

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FOR MORE INFORMATION

Please call your Regional Customer Service Center today to learn what Entegris can do for you. Visit <u>entegris.com</u> and select the <u>Contact Us</u> link to find the customer service center nearest you.

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