ADVANCED MATERIALS HANDLING

# Aramus<sup>™</sup> Single-Use 2D Bag Assemblies

High-grade, gamma-stable fluoropolymer film provides higher purity and greater reliability

The utilization of single-use (SU) systems continues to grow, and so do the purity concerns of the SU components and their potential impact on high-value final products. From the high cost of product loss due to assembly failures, to the challenges of maintaining compliance in an evolving global regulatory landscape, every angle requires protective measures.

Entegris brings a new level of assurance to your process. Our Aramus<sup>™</sup> single-use assembly product design incorporates high purity, integrity, and performance standards of the microelectronics industry with the regulatory and quality requirements for life sciences. Entegris allows you to protect and store your high-value process solutions with reduced risk of product loss, contamination, and compromised quality.

Aramus single-use 2D bags are made of a high-grade, gammastable fluoropolymer, and provide high purity, exceptional compatibility, and increased safety for critical process fluids and final products. The innovative single-layer technology does not contain curing agents, antioxidants, plasticizers, or adhesives, so the potential for process fluid contamination is greatly reduced. These subassemblies withstand a wide operating temperature range (-196° to 121°C [-321° to 250°F] or lower), without negatively affecting the film; making them extremely durable in frozen applications.

Aramus single-use assemblies are manufactured in an ISO<sup>®</sup> Class 5 cleanroom and provide high purity, performance, quality, and safety for your process.



Provides a new level of assurance for your frozen product.

### APPLICATIONS

- Frozen product storage and shipment
- Cell culture freezing and storage
- Bulk product fill
- Critical buffer and media storage
- Process sampling and archiving
- Downstream bioprocessing



Custom manifolding enables process efficiency in any application.

## **FEATURES & BENEFITS**

Wide temperature	Maintains mechanical properties across a wide range of process temperatures.
operating range	Reduces bag breakage and can be used in cold temperature applications to -196°C (-321°F) or lower without negatively affecting bag or boat fitment.
Single-layer, fluoropolymer construction	Single-layer design does not delaminate, reducing the risk of material failures and product loss caused by delamination.
construction	Exhibits chemical compatibility with a wide range of process chemicals including strong acids, strong bases, oils, lipids, and organic solves, without affecting the material or product.
Gamma-stable fluoropolymer film	Withstands market-standard gamma sterilization, from 25 to 40 kGy.
High-purity fluoropolymer materials	Reduces the number of potential contaminants (adhesives, binders, etc.) introduced to final product.
materials	The high hydrophobicity of the fluoropolymer film has low potential to absorb active pharmaceutical ingredients and critical formulation excipients, reducing yield loss.
	Have low particulates, low bioburden, and low endotoxin, increasing purity.
Manufactured in an ISO Class 5 certified	Operators properly trained on gowning and handling procedures increases contamination control.
cleanroom	Mitigates contamination and maintains components low bioburden levels.
Multiple connectivity options	Provides greater flexibility when incorporating into an already validated process.



Multiple connectivity options enable process flexibility.

# SPECIFICATIONS

Sterilization	Gamma irradiatio	Gamma irradiation: 25 to 40 kGy		
Dimensions		LENGTH	WIDTH	
	20 mL	100 mm (3.9")	80 mm (3.1")	
	50 mL	120 mm (4.7")	100 mm (3.9")	
	100 mL	160 mm (6.3")	100 mm (3.9")	
	250 mL	240 mm (9.4")	100 mm (3.9")	
	500 mL	210 mm (8.3")	158 mm (6.2")	
	1 L	285 mm (11.2")	178 mm (7.0")	
	2 L	354 mm (13.9")	254 mm (10.0")	
	5 L	470 mm (18.5")	323 mm (12.7")	
	10 L	570 mm (22.4")	383 mm (15.1")	
	20 L	718 mm (28.3")	483 mm (19.0")	
	50 L	970 mm (38.2")	820 mm (32.3")	
Compliance	Biological	USP <87>	Pass	
		USP <88>	Pass	
		USP Class VI	Pass	
		USP <85> and EP 2.6.14	<0.125 EU/mL (based on 40 mL rinse)	
		ISO 10993-4	Non-hemolytic	
	Particulates	USP <788> and EP 2.9.19	Pass	
	Extractables	USP <661>	Pass	
	Animal origin	TSE/BSE	Compliant	

#### **CONFIGURATIONS**

Full Aramus Assembly Configuration Options

2-port: 20 mL, 50 mL, 100 mL, 250 mL



3-port: 500 mL, 1 L	3-port: 2 L , 50 L* (no rod), 5 L, 10 L, 20 L, 50 L* (with rod)
	9
4	

ITEM	DESCRIPTION	ITEM	DESCRIPTION
1	Aramus fluoropolymer film with hole for hanging	1	Aramus fluoropolymer film with slot for hanging
2	Fluoropolymer "boat" fitment with 2 hose barb ports	2	Fluoropolymer "boat" fitment with 3 hose barb ports
3	Tubing connection (BarbLock® clamp, Oetiker Stepless® clamp, or zip ties*)	3	Tubing connection (BarbLock clamp, Oetiker Stepless clamp, or zip ties*)
4	Tubing ¼" ID × ¼" OD (AdvantaFlex® thermoplastic elastomer [TPE], AdvantaSil® silicone, Tygon® silicone, or C-Flex® 374 elastomer)	4	Tubing for 500 mL, 1 L, and 2 L is $\frac{1}{4}$ " ID $\times \frac{3}{8}$ " OD Tubing for 5 L, 10 L, 20 L, and 50 L* is $\frac{3}{8}$ " ID $\times \frac{5}{8}$ " OD (AdvantaFlex TPE, AdvantaSil silicone, Tygon silicone, or C-Flex 374 elastomer)
5	Pinch clamps	5	Tubing for 500 mL, 1 L, and 2 L is $\frac{1}{6}$ " ID $\times$ $\frac{1}{4}$ " OD Tubing for 5 L, 10 L, 20 L, and 50 L* is $\frac{1}{4}$ " ID $\times$ $\frac{3}{8}$ "
6	Tubing fittings ¼" ID (Luer male/female with plugs)		OD (AdvantaFlex TPE, AdvantaSil silicone, Tygon silicone, or C-Flex 374 elastomer)
		6	Pinch clamps
		7	Tubing fittings (Colder Product Company MPC male/female with plugs)

<ul> <li>6 Pinch clamps</li> <li>7 Tubing fittings (Colder Product Company MPC male/female with plugs)</li> <li>8 Tubing fittings (Luer male/female with plugs)</li> </ul>		
(Colder Product Company MPC male/female with plugs) 8 Tubing fittings	6	Pinch clamps
5 5	7	(Colder Product Company MPC male/female
	8	5 5

#### 9 Rod (5 L, 10 L, 20 L, and 50 L\*)

Note: See Ordering Information for the standard part numbers available; customization available upon request. \*Not a standard product, but is available upon request.

#### **ORDERING INFORMATION**

Aramus Assemblies (2-port): part number



Notes: Assemblies sold sterilized and are individually double bagged. \*Not a standard product, but is available upon request.

#### **ORDERING INFORMATION (CONTINUED)**

#### Aramus Assemblies (3-port): part number



Notes: Assemblies sold sterilized and are individually double bagged. \*Not a standard product, but is available upon request.

#### **ORDERING INFORMATION (CONTINUED)**

#### Aramus Subassemblies (2-port): part number

<u>SU-2D-</u>	-U	
······ <b>Product fam</b> SU = Single		Volume 0.020 = 20 mL 0.050 = 50 mL 0.100 = 100 mL 0.250 = 250 mL

Note: Subassemblies sold unsterilized.

#### Aramus Subassemblies (3-port): part number

<u>SU-2D-</u> -U		
······ Product family SU = Single-use	<b>Product type</b> 2D = 2D bag	• Volume 00.5 = 500 mL 0001 = 1 L 0002 = 2 L 0005 = 5 L
Note: Subassemblies sold unsterilized. *Not a standard product, but is available upon request.		0010 = 10 L 0020 = 20 L 0050 = 50 L*

FOR MORE INFORMATION

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