

Aramus™ Single-Use 2D Bag Assemblies

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

The utilization of single-use systems continues to grow, and so does the concern about the purity levels of the SU components and their potential impact on high-value final products. From the high cost of losing product due to assembly failures at fill/finish, to the ever-increasing scrutiny from regulatory bodies, every angle requires protective measures.

Now, Entegris brings a new level of assurance to your process. With product design that incorporates the 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 or compromised quality and efficacy.

The Aramus™ single-use 2D bags are made of a high-grade, gamma-stable fluoropolymer, providing higher purity, greater compatibility and increased safety for critical process fluids and final products. With a new single-layer technology that contains no curing agents, antioxidants, plasticizers or adhesives, the number of potential contaminants is greatly reduced. These assemblies offer the widest operating temperature range, making them more durable in frozen applications (to -85°C [-121°F] or lower) without negatively affecting the film.



Additionally, the fluoropolymer film offers universal material compatibility, reducing the risk of material and assembly failure. Aramus single-use assemblies are manufactured in an ISO® Class 5 cleanroom using methodologies that go beyond the standard. These assemblies allow for easier validation and provide high purity, performance, quality and safety for your process.

APPLICATIONS

- Frozen product storage and shipment
- Downstream bioprocessing
- Stem cell freezing and storage
- Final fill
- Storage of critical buffers and media
- Process sampling and archiving

FEATURES & BENEFITS

FEATURES	BENEFITS
Widest temperature operating range	More durable in frozen applications including cryogenics, whereas current solutions will not withstand those conditions.
	Maintains mechanical properties across a wide range of process temperatures.
	Reduces assembly breakage and can be used in cold temperature applications to -85°C (-121°F) or lower without negative affect to bag or boat.
Chemical compatibility	Outperforms other polymers as very few chemicals have an effect on fluoropolymers.
	Reduces the risk of material failure – no delamination.
	Increases the number of applications in which the product can be used.
	Reduces risk of assembly failure and can be used with a wider range of process chemicals without negative affect to the material or product.
Gamma-stable fluoropolymer film	Provides lower bioburden by utilizing market-standard gamma sterilization.
Single-layer technology	Reduces the number of potential contaminants introduced to final product (because no adhesives, binders, etc.).
	No delamination.
	No additives to base resin results in extremely low extractable profile.
High-purity materials	Reduces contamination of final product.
	The nature of the fluoropolymer used makes it more durable in frozen applications.
	Improved process yield and higher security of frozen drug product.
	Reduces risk of assembly failure or breakage; reduces product loss.
Manufactured in an ISO Class 5 certified cleanroom	Low particulates.
	Low bioburden.
	Low endotoxin.
Multiple connectivity options	Greater flexibility when incorporating into an already validated process.
	Eliminates the need for process requalification and speeds time to market.

SPECIFICATIONS

	500 mL	1 L	2 L
Length	210 mm (8.3")	285 mm (11.2")	345 mm (13.6")
Width	158 mm (6.2")	178 mm (7.0")	248 mm (9.8")

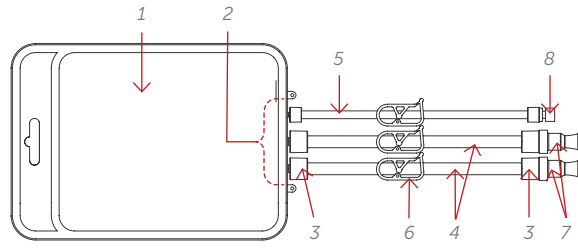
Sterilization Gamma irradiation

Note: Bag body dimensions listed.

Compliance

Biological	USP <87>	Pass
	USP <88>	Pass
	USP Class VI	Pass
	USP <85> and EP 2.6.14	<0.125 EU/mL
	ISO 10993-4	Non-hemolytic
Particulates	USP <788> and EP 2.9.19	Pass
Extractables	USP <661>	Pass
Animal origin	TSE/BSE	Compliant

CONFIGURATION



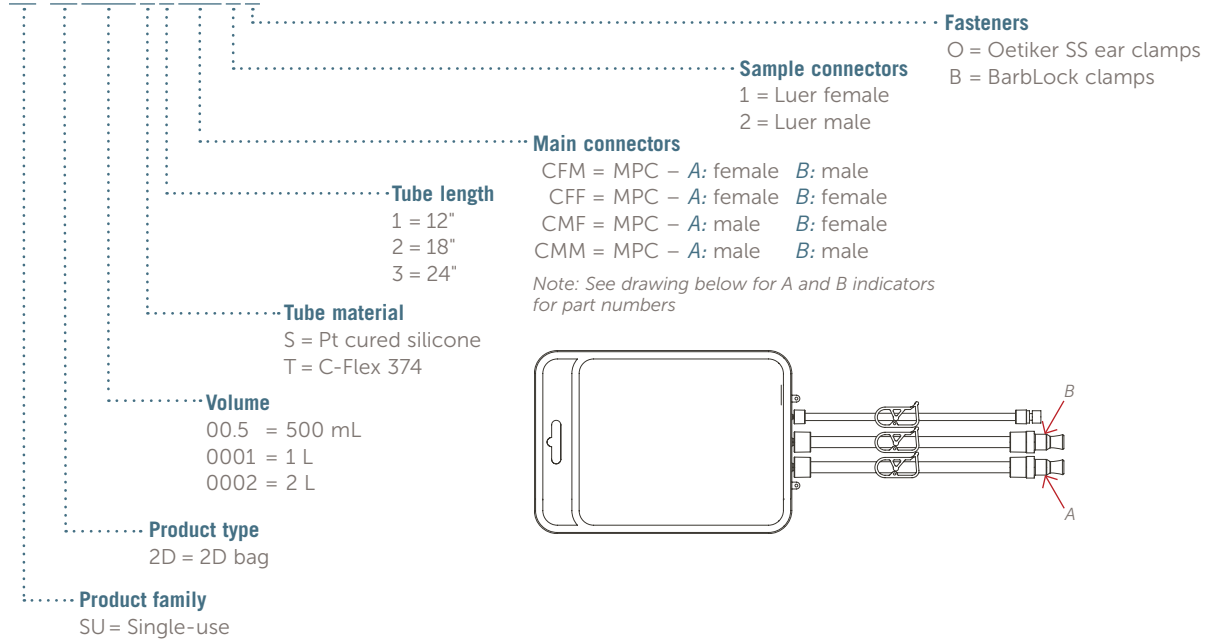
ITEM	DESCRIPTION
1	Aramus fluoropolymer film with slot for hanging
2	Fluoropolymer "boat" fitment with 3 hose barb ports
3	Tubing connection (BarbLock® or Oetiker Stepless® clamp)
4	Tubing 1/4" ID X 3/8" OD (platinum cured silicone or C-Flex® 374)
5	Tubing 1/8" ID X 1/4" OD (platinum cured silicone or C-Flex 374)
6	Pinch clamps
7	Tubing fittings 1/4" ID (CPC MPC male/female with plugs)
8	Tubing fittings 1/8" ID (Luer male/female with plugs)

Note: See Ordering Information for the standard part numbers available; customization available upon request.

ORDERING INFORMATION

Aramus Assemblies: part number

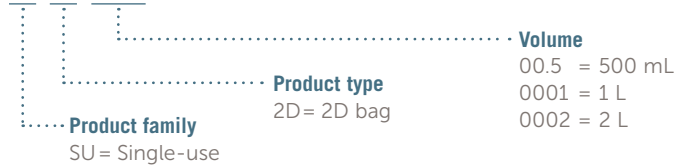
SU-2D



Note: Assemblies sold sterilized

Aramus Subassemblies: part number

SU-2D- -U



Note: Subassemblies sold unsterilized

FOR MORE INFORMATION

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

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Patent pending.

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