Aramus™ Standard Bag Assemblies

User manual

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INTRODUCTION

Standard Aramus™ single-use 2D bag assemblies 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 -196°C [-321°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 a minimum ISO® Class 7 clean-room using methodologies that go beyond the standard. These assemblies allow for easier validation and provide high purity, performance, quality, and safety for your process.

This user manual describes the instructions for use for the Aramus bag and assemblies.

SAFETY

Before using any Aramus single-use assembly or subassembly, you should read, understand, and follow the instructions in this manual. Save these instructions and make them available to users of this product.

To prevent injury, follow these safety procedures:

- Do not hang bags on anything that cannot support the weight; doing so can cause injury and/or equipment damage from tipping over.
- Do not use the tubing to handle or carry the bags.
- Do not use this product in a manner inconsistent with its intended use.
- Follow all appropriate chemical safety and disposal regulations.
- Wear appropriate personal protective equipment when handling components containing chemicals.
- Over pressurizing this product may cause injury from flying debris and/or exposure to chemicals.
- **DO NOT** overfill this product. Overfilling may lead to a spill and chemical exposure.
- Regularly inspect the product for leaks or other damage.
- Please note that the user shall be solely responsible and liable for validation and use of Aramus bags beyond the range of our specifications for unit operations, applications, and process parameters.

ARAMUS SUBASSEMBLIES

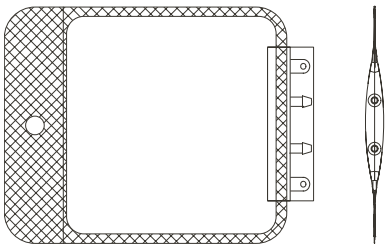
If you ordered the full assembly, skip to *Aramus Standard Bag Assemblies* on page 4.

Entegris offers the Aramus bag assembly in a sub-assembly configuration; meaning without tubing, connectors, or sterilization.

BAG DESCRIPTION

Aramus subassemblies are offered in 2D configurations in various sizes with a 2- or 3-port boat fitment. See Figure 1 for Aramus subassembly bag configuration. See *Ordering Information* on page 9 for the standard part numbers available; customization is available upon request.

2-port Subassembly



3-port Subassembly

Figure 1. Aramus subassembly bag configurations

REMOVING THE ARAMUS SUBASSEMBLY FROM ITS PACKAGING

⚠ **CAUTION: DO NOT use anything sharp to remove the Aramus subassembly from its packaging.**

1. The Aramus subassemblies will arrive in a corrugated box. **DO NOT** use anything sharp to open the box. Remove packing tape with caution to avoid damaging the contents.
2. There are two sealed bags protecting the Aramus subassembly. To open the outer bag, grip the side of the protective packaging bag and use the "easy tear" notches, Figure 2, to pull in opposite directions, allowing the top section and main body of the packaging to separate and subsequently open the bag. Repeat this procedure to open the inner protective package.

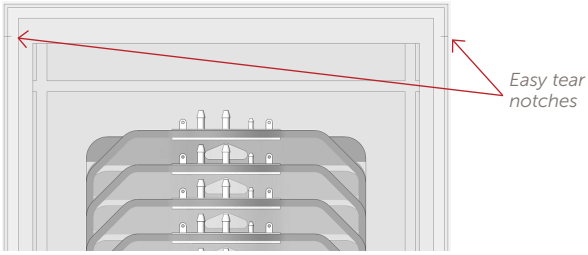


Figure 2. Easy tear notches

CONNECTING BAGS

Attach appropriately sized tubing to the hose barb connections found on the boat fitment. The tubing can then be combined with your desired connecting piece or method.

FILLING AND FREEZING BAGS

The specified Aramus bag volume is the actual fill volume the bag is capable of holding. The bags are rated to 110% of the nominal volume to avoid overfilling. For best freezing, it is recommended that the Aramus bag be laid flat or in a horizontal position and should be filled to no more than the maximum rated volume.

STORAGE, HANDLING, AND SHIPPING

The Aramus subassembly has a recommended storage temperature of 18° to 30°C (64° to 86°F), but due to its material of construction, has a performance temperature rating of -196° to 121°C (-321° to 250°F). Handle with care to avoid dropping and when hanging the bag vertically, ensure that it is hung securely. To reduce the risk of damage, filled bags should be stored, handled, and shipped in a secondary protective container. **DO NOT** use bubble wrap around filled and frozen bags for shipping.

ARAMUS STANDARD BAG ASSEMBLIES

Entegris offers the Aramus bag in a full assembly with your desired configuration of tubing and connectors, delivered sterilized with a Sterility Assurance Level (SAL) of 10^{-6}.

REMOVING THE FULL ARAMUS ASSEMBLY FROM ITS PACKAGING

⚠ **CAUTION: DO NOT use anything sharp to remove the Aramus assembly from its packaging.**

1. The Aramus assembly will arrive in a corrugated box. **DO NOT** use anything sharp to open the box. Remove packing tape with caution to avoid damaging the contents.
2. There are two sealed bags protecting the Aramus assembly. To open the outer bag, grip the side of the protective packaging bag and use the "easy tear" notches, Figure 3, to pull in opposite directions, allowing the top section and main body of the packaging to separate and subsequently open the bag. Repeat this procedure to open the inner protective package.

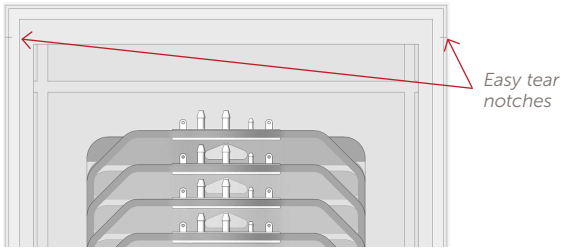


Figure 3. Easy tear notches

HANGING THE FULL ARAMUS ASSEMBLY

The Aramus assembly has a convenient and durable hanging slot, as shown in Figure 4.

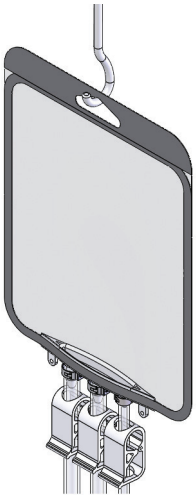


Figure 4. Convenient hanging slot

CONNECTING BAGS

The standard mating hardware offered are Luer connections and MPC connections. Please follow the manufacturer's guidelines when connecting to these components. The pinch clamp must be in the released position to ensure flow within the bag.

FILLING AND FREEZING BAGS

The specified Aramus bag volume is the actual fill volume the bag is capable of holding. The bags are rated to 110% of the nominal volume to avoid overfilling.

For best freezing, it is recommended that the Aramus bag be laid flat or in a horizontal position and should be filled to no more than the maximum rated volume.

STORAGE, HANDLING, AND SHIPPING

The components on the full Aramus assembly are commonly used in the market and have various temperature claims. Entegris has tested the Aramus bag assemblies while using these components.

The Aramus assembly has a recommended storage temperature of 18° to 30°C (64° to 86°F), but due to its material of construction, has a performance temperature rating of -196° to 121°C (-321° to 250°F). Handle with care to avoid dropping and when hanging the bag vertically, ensure that it is hung securely. To reduce the risk of damage, filled bags should be stored, handled, and shipped in a secondary protective container. **DO NOT** use bubble wrap around filled and frozen bags for shipping.

SPECIFICATIONS FOR ARAMUS ASSEMBLY STANDARD COMPONENTS

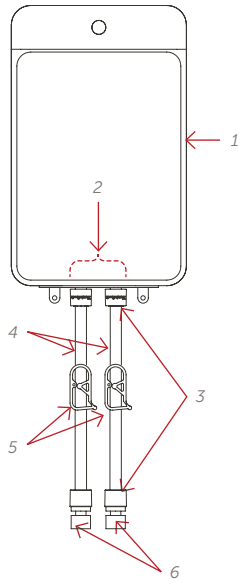
Specifications for the components found on full Aramus assemblies can be located on the supplier websites:

Component supplier	Website
Colder Product Company MPC connections	https://www.cpcworldwide.com/
Saint-Gobain C-Flex® tubing, platinum-cured silicone tubing, BarbLock®, and pinch clamps	https://www.saint-gobain-northamerica.com/business/markets/life-sciences
Oetiker Stepless® clamps	http://www.oetiker.com/
Nordson Medical Luer connections	http://www.nordsonmedical.com/
AdvantaPure AdvantaFlex® and AdvantaSil® tubing	http://www.advantapure.com/

CONFIGURATIONS

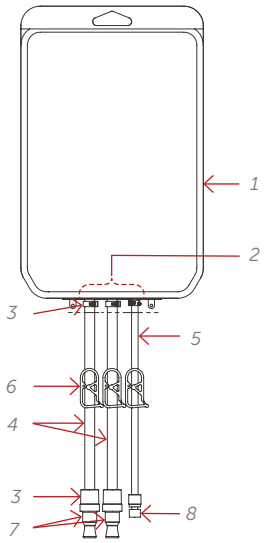
Full Aramus bag assemblies are offered in 2D configurations in various sizes with a 2- or 3-port boat fitment and the selected configuration of tubing and connectors. See *Ordering Information* on page 7 for the standard part numbers available; customization is available upon request.

Full Aramus Assembly
Configuration Options
2-port: 4 mL, 20 mL, 50 mL, 100 mL, 250 mL

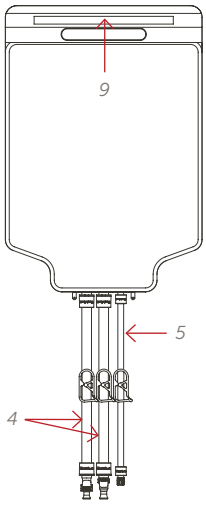


ITEM	DESCRIPTION
1	Aramus fluoropolymer film with slot for hanging
2	Fluoropolymer "boat" fitment with 2 hose barb ports
3	Tubing connection (BarbLock clamp, Oetiker Stepless clamp, or zip ties*)
4	Tubing ⅛" ID × ¼" OD (AdvantaFlex thermoplastic elastomer [TPE], AdvantaSil silicone, Tygon® silicone, or C-Flex 374 elastomer)
5	Pinch clamps
6	Tubing fittings ⅛" ID (Luer male/female with plugs)

Full Aramus Assembly
Configuration Options
3-port: 500 mL, 1 L



Full Aramus Assembly
Configuration Options
3-port: 2 L (no rod),
5 L, 10 L, 20 L, 50 L* (with rod)



ITEM	DESCRIPTION
1	Aramus fluoropolymer film with slot for hanging
2	Fluoropolymer "boat" fitment with 3 hose barb ports
3	Tubing connection (BarbLock clamp, Oetiker Stepless clamp, or zip ties*)
4	Tubing for 500 mL, 1 L, and 2 L is ¼" ID × ⅜" OD Tubing for 5 L, 10 L, 20 L, and 50 L* is ⅜" ID × ⅝" OD (AdvantaFlex TPE, AdvantaSil silicone, Tygon silicone, or C-Flex 374 elastomer)
5	Tubing for 500 mL, 1 L, and 2 L is ⅛" ID × ¼" OD Tubing for 5 L, 10 L, 20 L, and 50 L* is ¼" ID × ⅜" OD (AdvantaFlex TPE, AdvantaSil silicone, Tygon silicone, or C-Flex 374 elastomer)
6	Pinch clamps
7	Tubing fittings (CPC MPC male/female with plugs)
8	Tubing fittings (Luer male/female with plugs)
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 Standard Bag Assemblies (2-port): part number

SU - 2D - _____ __ __ - __ __

Fasteners
O = Oetiker SS ear clamps
B = BarbLock clamps
Z = Zip ties*

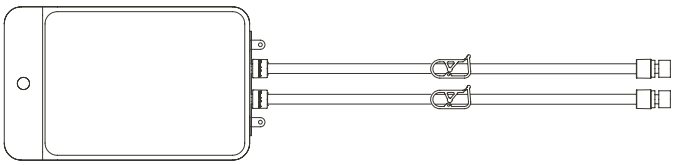
Main connectors

L11 = Luer –	1: female	1: female
L12 = Luer –	1: female	2: male
L22 = Luer –	2: male	2: male

Tube length
0 = 6"
1 = 12"
2 = 18"
3 = 24"

Tube material
F = AdvantaFlex thermoplastic elastomer
P = AdvantaSil silicone
S = Tygon silicone
T = C-Flex 374 elastomer

Volume
0.004 = 4 mL
0.020 = 20 mL
0.050 = 50 mL
0.100 = 100 mL
0.250 = 250 mL



Product type
2D = 2D bag

Product family
SU = Single-use

Notes: Assemblies sold sterilized. Assembly temperature performance is component-dependent. Assemblies are individually double-bagged.
**Not a standard product, but is available upon request.*

ORDERING INFORMATION (CONTINUED)

Aramus Standard Bag Assemblies (3-port): part number

SU - 2D - _____ __ __ - _____ __ __

Fasteners
O = Oetiker SS ear clamps
B = BarbLock clamps
Z = Zip ties*

Sample connectors
1 = Luer female
2 = Luer male

Main connectors
CFM = MPC – *A:* female *B:* male
CFF = MPC – *A:* female *B:* female
CMF = MPC – *A:* male *B:* female
CMM = MPC – *A:* male *B:* male

Note: See drawing below for A and B indicators for part numbers

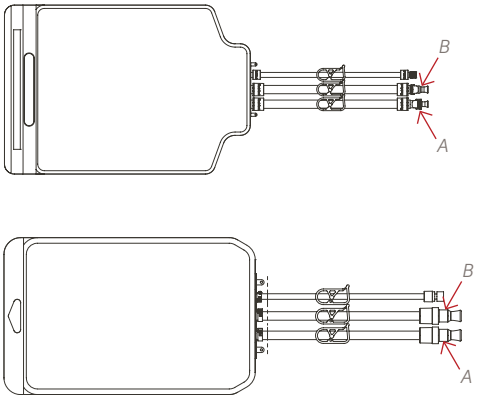
Tube length
0 = 6"
1 = 12"
2 = 18"
3 = 24"

Tube material
F = AdvantaFlex thermoplastic elastomer
P = AdvantaSil silicone
S = Tygon silicone
T = C-Flex 374 elastomer

Volume
00.5 = 500 mL
0001 = 1 L
0002 = 2 L
0005 = 5 L
0010 = 10 L
0020 = 20 L
0050 = 50 L*

Product type
2D = 2D bag

Product family
SU = Single-use



Notes: Assemblies sold sterilized. Assembly temperature performance is component-dependent. Assemblies are individually double-bagged.
**Not a standard product, but is available upon request.*

ORDERING INFORMATION (CONTINUED)

Aramus Subassemblies (2-port): part number

SU - 2D - _____ -U

Volume
0.004 = 4 mL
0.010 = 10 mL
0.020 = 20 mL
0.050 = 50 mL
0.100 = 100 mL
0.250 = 250 mL

Product type
2D = 2D bag

Product family
SU = Single-use

Note: Subassemblies sold unsterilized.

Aramus Subassemblies (3-port): part number

SU - 2D - _____ -U

Volume
00.5 = 500 mL
0001 = 1 L
0002 = 2 L
0005 = 5 L
0010 = 10 L
0020 = 20 L
0050 = 50 L*

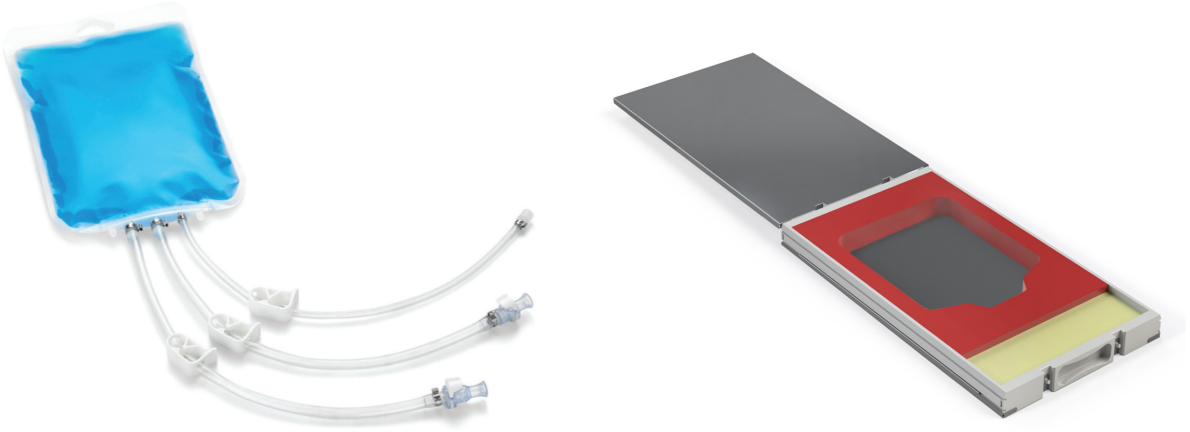
Product type
2D = 2D bag

Product family
SU = Single-use

Note: Subassemblies sold unsterilized.
**Not a standard product, but is available upon request.*

ARAMUS STANDARD BAG ASSEMBLY WITH ROSS® SHELL

Aramus single-use bag assembly, combined with the RoSS (Robust Storage and Shipping) shell, provide greater protection during handling, more consistent freezing/thawing, and reduced storage density. The following instructions explain how to most effectively use the two together for filling, freezing, handling, and thawing applications.



Aramus bag assembly and RoSS shell

Please use the correct Aramus bag size and RoSS shell combination. If filling to maximum volume, remove excess air from bag to prevent the bag from over expanding within the RoSS shell. Fill the bags to greater than 30% of their maximum fill volume stated in the specification table, page 11. For example, 30% of a 10 L bag's maximum fill volume is 2.3 L (7.6 x 0.3). To prevent adverse freezing conditions, do NOT fill bags above their maximum fill volume, or below 30% of this volume. This information is for guidance purposes only. Optimal fill volumes and ranges should be determined by the customer for each individual product, freezing method, freezer type, and profile.

⚠ **CAUTION: Failure to confirm fit for use under the customer's requirements may result in product failure.**

NOTE: Additional accessories such as foam inserts may be necessary to ensure consistent freezing at different fill volumes.

SPECIFICATIONS

Aramus bag size	1 L	2 L	5 L	10 L	20 L
Maximum fill volume	0.9 L	1.7 L	3.5 L	6.5 L	11.0 L
RoSS shell part number	SU-FS-0001-01	SU-FS-0002-01	SU-FS-0005-01	SU-FS-0010-01	SU-FS-0020-01
RoSS shell weight	1.96 kg (4.31 lbs)	2.83 kg (6.23 lbs)	4.45 kg (9.79 lbs)	6.13 kg (13.49 lbs)	8.73 kg (19.21 lbs)
RoSS shell dimensions	208 mm × 483 mm × 37 mm (8.2" × 13.7" × 1.5")	288 mm × 533 mm × 37 mm (11.3" × 21" × 1.5")	358 mm × 643 mm × 52 mm (14.1" × 25.3" × 2.0")	408 mm × 703 mm × 70 mm (16" × 27.7" × 2.0")	503 mm x 883 mm × 70 mm (19.8" × 34.8" × 2.0")

Contact Entegris technical support if you have questions regarding this information, and to confirm you have the most up-to-date version.

⚠ WARNINGS

Aramus Bag Assembly

- Do not handle or carry the bags by the tubing
- Do not overfill or over pressurize the bag
- Regularly inspect for leaks and other damage
- Always ensure that all bag assembly components are secure within the RoSS shell before use
- Do not use this product in a manner inconsistent with its intended use

NOTE: User shall be solely responsible and liable for validation and use of the Aramus bag assemblies beyond the range of our specifications.

SHIPPING

Based on currently available information, the RoSS shells may give user the best chance for successfully shipping your product in an Aramus bag assembly. However, since each company's product likely has unique freezing characteristics, the combined use of RoSS shells and Aramus bag assemblies should be fully validated by the customer.

As always, the customer is responsible for verifying fit for use in combination with their product and in their specific application.

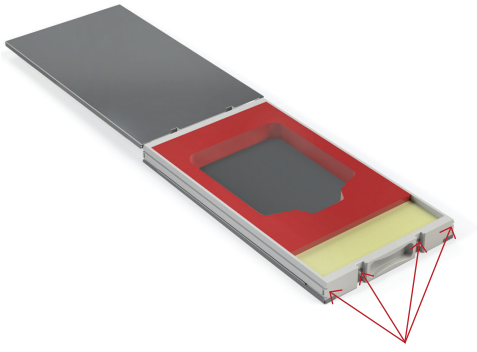
INSPECTION

When unpacking the RoSS shell, be sure not to scratch the stainless-steel shell cover when removing the plastic overwrap. If a knife is used, keep the blade point away from the stainless-steel shell cover.

Place the RoSS shell horizontally on a table making sure the product label is oriented correctly.

ASSEMBLY INSTRUCTIONS

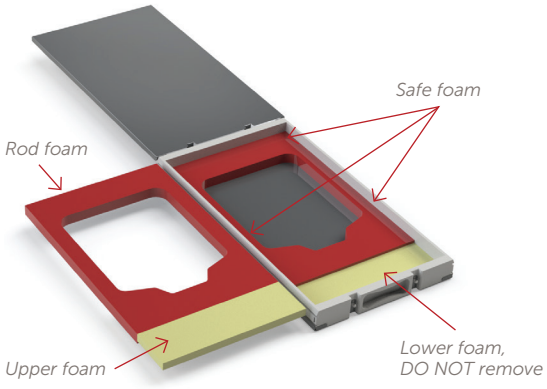
Step 1: Open RoSS Shell



Pull open the four, stainless-steel upper tabs; two on the sides and two in the middle near the recessed handle. Slide open the stainless-steel top lid until completely removed.

Keep the lid fully removed and stored in a horizontal position until step 5.

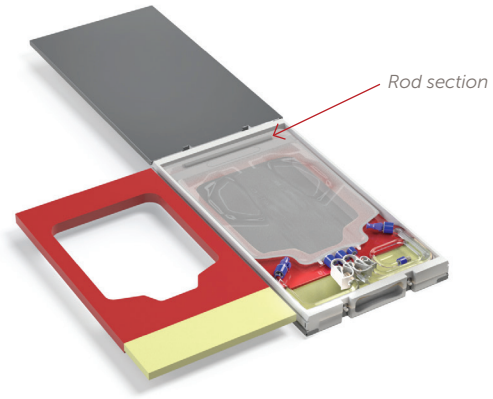
Step 2: Remove Foam Layers



Remove only the upper tubing foam and the rod foam before placing the bag inside.

⚠ **CAUTION! Safe foam pads along the sides are attached to the RoSS shell and will be damaged if they are removed.**

Step 3: Fill and Insert Aramus Bag



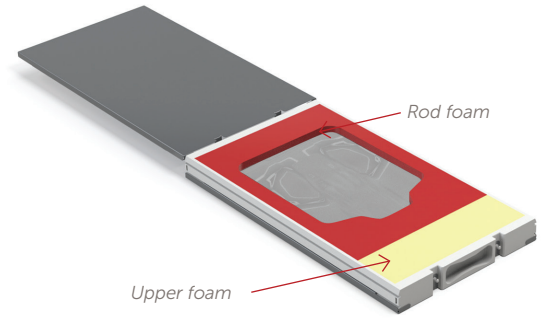
Fill the Aramus bag to correct fill volume (see Specifications, page 11). It is suggested to fill to maximum volume. If the bag is 10 L or greater, fill the bag while it is inside the RoSS shell.

NOTE: The RoSS system will not work correctly if the Aramus bag is positioned improperly.

Place the Aramus bag in the middle with the bag chamber on the stainless-steel base, between the side foam pads. The rod section needs to be placed to the very back of the shell.

Wrap the tubing in a loose coil and place on top of the lower tubing foam. Ensure the clamps on the tubing are placed in a horizontal orientation to fit in the shell and that the tubing and bag do not overlap.

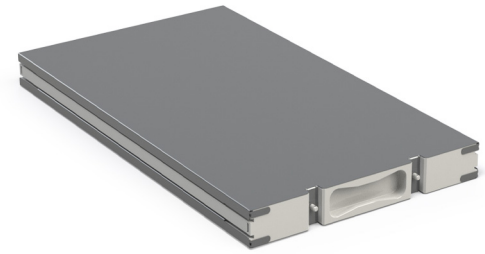
Step 4: Secure Tubing



Place the upper foam and rod foam pads back in their initial positions while making sure there are no overhanging parts.

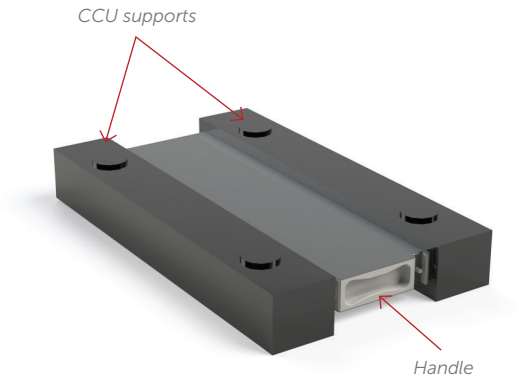
⚠ **CAUTION! If the tubing and/or foam pads are not placed in a snug, correct manner, they can be damaged when closing the RoSS shell.**

Step 5: Close the Shell



Insert and slide stainless-steel lid back onto the shell. You may need to push down on the foam while sliding the lid. Close the upper stainless-steel tabs to secure the system.

Step 6: Insert Cryo Control Unit (CCU) Supports



CCUs are used to facilitate controlled freezing. When freezing in standard static or blast freezers, insert CCU onto the long sides of the RoSS shell, one at a time. The CCU should fit snuggly with the shell.

NOTE: If using a plate freezer, CCUs are not needed with the RoSS shell. Please refer to plate freezer manufacturers' recommended procedures.

Step 7: Lift and Place in Freezer (Static and Blast Freezing Only)

Lift by the recessed handles on each end and place horizontally in a freezer. For consistent freezing, ensure the RoSS shell bottom plate is not in direct contact with the freezer shelf.

Always use the recessed handles for carrying the RoSS shell and use a cart for the 20 L size.

Step 8: Thawing

Inspect the RoSS system to ensure no damage or significant bulging occurred during freezing. The stainless-steel tabs should all be secure, and neither the bag nor tubing should be visible.

To thaw, store the RoSS system at ambient temperature on a bench or table. Thawing can be accelerated using a fan.

Thawing can also be done in a plate freezer, refer to manufacturer's recommended procedures.

ORDERING INFORMATION

To order RoSS shells and CCUs for filling, freezing, handling, and thawing applications, refer to the following:

RoSS Shell

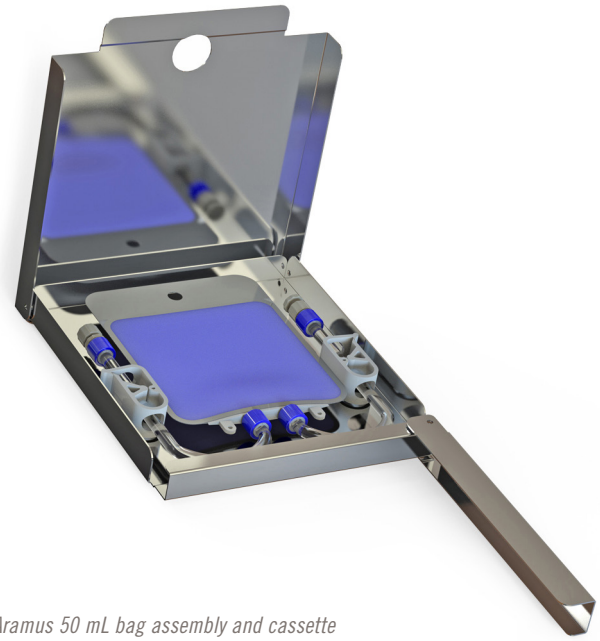
Part number	Compatible Aramus bag assembly
SU-FS-0001-01	1 L
SU-FS-0002-01	2 L
SU-FS-0005-01	5 L
SU-FS-0010-01	10 L
SU-FS-0020-01	20 L

Cryo Control Unit (CCU)

Part number	Compatible Aramus bag assembly
SU-CC-0001-01	1 L
SU-CC-0002-01	2 L
SU-CC-0005-01	5 L
SU-CC-0010-01	10 L
SU-CC-0020-01	20 L

ARAMUS STANDARD BAG ASSEMBLY WITH CASSETTES

At lower volumes, the Aramus single-use bag assemblies can be combined with cassettes to provide greater protection during freezing and handling. The following instructions explain how to most effectively utilize the two together for filling, freezing, handling, and thawing applications.



Aramus 50 mL bag assembly and cassette

Please use the correct Aramus bag size and cassette combination. These cassettes are designed to be used with standard pinch clamps allowing for sterile connections. In general, do not use tubing lengths longer than 12", which can be difficult to fit into the cassette.

Fill the bags to greater than 25% of their maximum fill volume stated in the specification table, page 16. For example, 25% of a 250 mL bag's maximum fill volume is 50 mL (200 x 0.25). To prevent adverse freezing conditions, do NOT fill bags above their maximum fill volume, or below 25% of this volume. This information is for guidance purposes only. Optimal fill volumes and ranges should be determined by the customer for each individual product, freezing method, freezer type, and profile.

⚠ **CAUTION: Failure to confirm fit for use under the customer's requirements may result in product failure.**

SPECIFICATIONS

Aramus bag size	20 mL	50 mL	100 mL	250 mL	500 mL
Maximum fill volume	20 mL	50 mL	100 mL	200 mL	350 mL
Cassette part number	SU-FS-0.05-C2	SU-FS-0.05-C2	SU-FS-0.10-C2	SU-FS-0.25-C2	SU-FS-0.50-C2
Cassette dimensions	203 mm x 160 mm x 21 mm (8.0" x 6.3" x 0.8")	203 mm x 160 mm x 21 mm (8.0" x 6.3" x 0.8")	213 mm x 161 mm x 21 mm (8.4" x 6.3" x 0.8")	302 mm x 157 mm x 22 mm (11.9" x 6.2" x 0.9")	305 mm x 190 mm x 23 mm (12.0" x 7.5" x 0.91")

Contact Entegris technical support if you have questions regarding this information, and to confirm you have the most up-to-date version.

⚠ WARNINGS

Aramus Bag Assembly

- Do not handle or carry the bags by the tubing
- Do not overfill or over pressurize the bag
- Regularly inspect for leaks and other damage
- Always ensure that all bag assembly components are secure within the cassette before usage
- Do not use this product in a manner inconsistent with its intended use

NOTE: User shall be solely responsible and liable for validation and use of the Aramus bag assemblies beyond the range of our specifications.

Cassette

- Always wear appropriate personal protective equipment including gloves when handling cassette
- Use two hands when transporting frozen cassettes
- Do not disassemble cassette before use
- Though reusable, inspect cassette prior to each use
- To prevent damage to the product, do not mishandle the cassette

Note: User shall be solely responsible and liable for validation and use of the Aramus bag assemblies and cassettes beyond the range of our specifications.

SHIPPING

Based on currently available information, the cassettes may give user the best chance for successfully shipping your product in an Aramus bag assembly. However, since each company's product likely has unique freezing characteristics, the combined use of cassettes and Aramus bag assemblies should be fully validated by the customer.

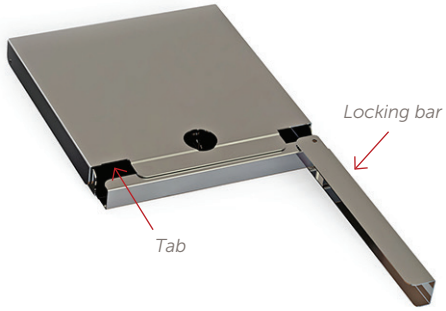
As always, the customer is responsible for verifying fit for use in combination with their product and in their specific application.

INSPECTION

When unpacking the cassette, be sure to check for damage such as dents or missing components. Also, open and close the cassette to ensure functionality.

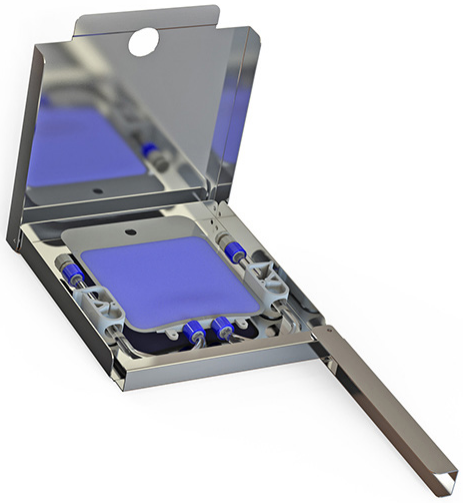
ASSEMBLY INSTRUCTIONS

Step 1: Open Cassette



Swivel open the locking bar and then lift the tab vertically.

Step 2: Fill and Insert Aramus Bag Assembly



Place filled, Aramus bag into cassette. Orient any connected tubing, clamps, and connectors as shown to fit into the cassette. Ensure no components are raised above the cassette's side walls.

Step 3: Close Cassette

Close tab and then swivel locking bar into a closed position. There should be little to no resistance from the bag when closing. Ensure the cassette does not bulge once closed.

NOTE: If the cassette bulges when closed, go back to step 2 and reposition the components.

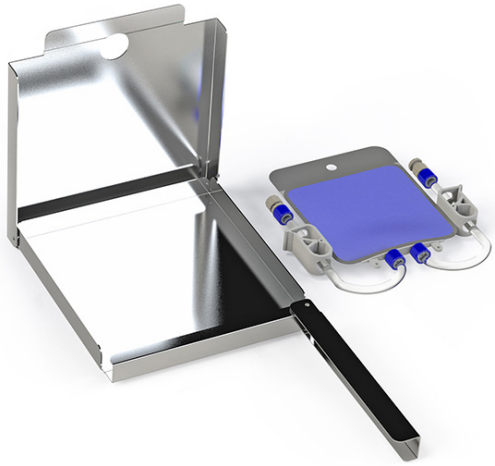
Step 4: Freezing and Storage

For ultra-low temperatures, the cassette assembly can be placed directly into static and blast freezers in a horizontal orientation (flat on shelf).

For freezing in a liquid nitrogen Dewar, a rack is recommended. Be sure to slide the cassette completely inside the rack, and lock if applicable, before immersing in liquid nitrogen vapor.

⚠ **CAUTION! Always use cryogenic gloves when handling cassettes or racks in low temperatures.**

Step 5: Thawing



Inspect the cassette assembly to ensure no damage or significant bulging occurred during freezing. The locking bar and tab should be secure.

To thaw, remove the bag from the cassette assembly and store at ambient temperature on a bench or table. Other methods are available to accelerate thawing such as using a fan or immersing the bag in a water bath.

ORDERING INFORMATION

To order cassettes for filling, freezing, handling, and thawing applications, refer to the following:

Cassette

Part number	Compatible Aramus bag assembly
SU-FS-0.05-C2	20 mL, 50 mL
SU-FS-0.10-C2	100 mL
SU-FS-0.25-C2	250 mL
SU-FS-0.50-C2	500 mL

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