

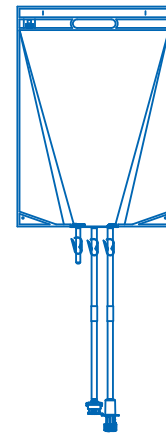
Mobius® 2D Freeze Assembly for Frozen Liquid Transportation and Storage

Protect and Freeze Your Bulk Drug Substance

The Mobius® 2D Freeze single-use assembly offers a robust freeze and thaw solution that allows safe storage and transportation of your valuable product at a very low temperature. Combined with the RoSS® (Robust Storage and Shipping) shell, this solution enables easy and safe bulk drug substance and product transfers between multiple sites providing flexibility and security to your processes.

Available in 1 L, 5 L, 10 L, and 20 L sizes, the standard Mobius® 2D Freeze assembly is made with our PureFlex™ film and is helium integrity tested to assure integrity will be maintained at temperatures down to -80 °C during freezing, storage, transportation, and thawing*.

* Testing performed in RoSS® (Robust Storage and Shipping) Shells by Single Use Support GmbH.



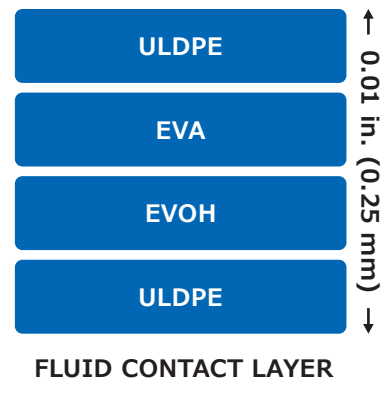
Mobius® 5 L Freeze assembly with Lynx® S2S sterile connectors

PureFlex™ Film

PureFlex™ film is a high-purity, medical-grade, coextruded film that can be used at every step in the drug manufacturing process, including media and buffer preparation, cell culture, purification, product intermediate storage and mixing, sterile sampling, and drug product filling. This versatility enables use of a single film for the full process, limiting validation and implementation effort.

For more information on our PureFlex™ film, please refer to the PureFlex™ Single-Use Process Container Films specification sheet SP1005EN00.

PureFlex™ Film



Helium Integrity Test

Assuring the integrity of single-use assemblies used for freezing, thawing, transportation and storage is critical to prevent valuable product loss. The Helium Integrity Test is a sensitive manufacturing release test that detects defects down to 2 µm in size. This method provides an extra level of integrity assurance by testing the entire assembly, including tubing and connection points.

Testing Performed with Mobius® 2D Freeze Assemblies and Single Use Support RoSS® Shells*

The purpose of this testing was to demonstrate that the Mobius® 2D Freeze assemblies were protected during freezing, storage, transportation and thawing processes when secured with RoSS® shells.

During testing, the Mobius® bags were placed into their compatible RoSS® shell and filled with water. The 3D Foam inlays the RoSS® shell covers the tubing section, the shoulders, and the back end of the bag. Freezing and thawing were performed with plate freezer technology. During this process, the liquid expands, the bag gets pressed against the foam, and the foam becomes hard at sub-zero (<0 °C). The bag, therefore, is fully immobilized at frozen state.



Mobius® 2D Freeze Assemblies are compatible with RoSS® (Robust Storage and Shipping) Shells from Single Use Support GmbH.

Testing Package	Summary	Result
Freeze Studies	<p>The Mobius® 2D Freeze assembly was filled, placed into RoSS® shell using Cryo Control Units (CCU) and then frozen in a static lab freezer to -85 °C.</p> <p>Acceptance Criteria:</p> <ul style="list-style-type: none"> • Immobilization of assembly within foam when checked at frozen state • Assembly not damaged after freeze and thaw • Contact with lids acceptable • No warping of lid <p>All acceptance criteria for the executed tests were met.</p>	Passed
Operator Handling	<p>During the qualification filling and freezing test, rough handling testing was performed for the RoSS® shell together with the Mobius® 2D Freeze assembly. While the Mobius® 2D Freeze assembly frozen within the RoSS® shell, the shell was roughly taken out of the static freezer and carelessly placed on a laboratory table. The CCU was then removed.</p> <p>Acceptance Criteria:</p> <ul style="list-style-type: none"> • No assembly damage detected <p>All acceptance criteria for the executed tests were met.</p>	Passed
Shipping and Thawing	<p>Mobius® 2D Freeze assemblies were filled to the recommended maximum filling volume and placed into RoSS® shells. RoSS® shells were then frozen and stored at -85 °C in static freezer. RoSS® shells were loaded into a RoSS.SHIP_1020 multi-use shipper along with dry ice and shipped twice via truck then air. Post transportation, bags were thawed, drained, and pressure tested for damages.</p> <p>Acceptance Criteria:</p> <ul style="list-style-type: none"> • No assembly damage detected post transport and thaw • Shippers must remain below -50 °C for duration of testing <p>All acceptance criteria for the executed tests were met.</p>	Passed
ASTM Shipping Test	<p>ASTM D4169-16 DC4 was performed on the RoSS.SHIP_1020 multi-use shipper. The dry ice pallet shipper was filled with 12 RoSS_1022 shells and 150 kg of dry ice.</p> <ul style="list-style-type: none"> • Mechanical handling (ASTM D6179-07R14) tested prior to and post vibration of shipping containers • Vibration testing of shipping containers (ASTM D4728-17) <p>Acceptance Criteria:</p> <ul style="list-style-type: none"> • No damages or abnormalities detected from the outside. The shipping unit was not opened. <p>All acceptance criteria for the executed tests were met.</p>	Passed

*Testing completed by Single Use Support GmbH

Testing Package	Summary	Result
Freeze and Thaw Study on Scalability	Single Use Support offers a plate-based freeze and thaw scalable platform to be used with RoSS® shells. Mobius® 2D Freeze assemblies, with the protection of their compatible RoSS® shell, were tested on the Lab- and Large-Scale RoSS.pFTU. Proven scalability was confirmed for Mobius® bags from 1 L to 20 L. The implementation and qualification are product specific.	Passed
Particles and Microbiology Contamination Study	A particle study was conducted to determine if the RoSS® shell and foam technology had an impact on particle count in a clean room environment. A second study assessed if the use of foam had an impact on microbial growth. Result: Particle limitations were not exceeded with the introduction of the RoSS® shell. The microbiological contamination concluded that there was not impact to bioburden.	Passed

Specifications

Mobius® 2D Freeze Assembly

Mobius® Bag Size	1 L	5 L	10 L	20 L
Maximum Filling Volume*	0.9 - 1.0 L	3.7 - 4.0 L	7.2 - 7.4 L	11.7 - 12.2 L
Bag Dimensions	6 in. W x 12.3 in. H	12.5 in. W x 12 in. H	11.5 in. W x 21.75 in. H	16.5 in. W x 23 in. H
Operating Temperature inside RoSS® shell	-112-140 °F (-80-60 °C)			
Certification Level	Gold Certification with Helium Integrity Testing			
Shelf Life	2 Year Shelf Life			
Integrity Testing	100% assembly integrity tested using Helium as a tracer gas			
Sterility	Sterilized using a validated gamma irradiation level of 25-40 kGy			
USP<85> Endotoxins, USP <788> Subvisible Particulates	1 assembly per lot tested, post-gamma irradiation			
USP<88> Biological Reactivity <i>in vivo</i> (Class VI), USP <661> Physicochemical Tests	Post-gamma irradiation			
Bioburden	Post-gamma irradiation			
Bacteriastasis/Fungistasis	Post-gamma irradiation			
Materials of Construction				
Film	PureFlex™ film with hanger	PureFlex™ film with hanger and support rod		
Tube	Pharma 65 (3mm ID x 6mm OD)	C-Flex® 374 (1/4 in. ID X 1/2 in. OD)	C-Flex® 374 (1/4 in. ID X 1/2 in. OD)	C-Flex® 374 (1/4 in. ID X 1/2 in. OD)
		C-Flex® 374 (3/8 in. ID X 5/8 in. OD)	C-Flex® 374 (3/8 in. ID X 5/8 in. OD)	C-Flex® 374 (3/8 in. ID X 5/8 in. OD)
Port	End ported with 2 ports	Boat ported with 3 ports	Boat ported with 3 ports	Boat ported with 3 ports
Connector	AseptiQuik® S connector 1/8 in. HB	Lynx® S2S male and female connector 3/8 in. HB or AseptiQuik® G connector 3/8 in. HB	Lynx® S2S male and female connector 3/8 in. HB or AseptiQuik® G connector 3/8 in. HB	Lynx S2S® male and female connector 3/8 in. HB or AseptiQuik® G connector 3/8 in. HB
Disconnect	NovaSeal™ pinch pipe for 3mm ID X 6 mm OD tubing	NovaSeal™ pinch pipe for 3/8 in. ID X 5/8 in. OD tubing	NovaSeal™ pinch pipe for 3/8 in. ID X 5/8 in. OD tubing	NovaSeal™ pinch pipe for 3/8 in. ID X 5/8 in. OD tubing
Compatible RoSS® Shell from Single Use Support**				
RoSS® Part Number	RoSS_1043	RoSS_1042	RoSS_1022	RoSS_1040
RoSS® Shell Dimensions	183 x 462.6 x 41.6 mm 7.2 x 18.2 x 1.6 in.	333 x 490 x 70 mm 13.1 x 19.3 x 2.8 in.	303 x 712 x 70 mm 11.9 x 28 x 2.8 in.	460 x 823.6 x 69.6 mm 18.1 x 32.4 x 2.7 in.

* Do not overfill maximum fill volume

**RoSS® shells are to be ordered directly from Single Use Support GmbH. To order RoSS® shells, please refer to the compatible RoSS® shell part number.

Ordering Information

Mobius® 2D Freeze Assemblies

Mobius® Bag Size	Catalogue Number	Description	Pack Size
1 L	FRZ0001L001P5	Mobius® bag, Gold w/Helium IT, 1 L STD PureFlex™ film with AseptiQuik® S connectors	5
5 L	FRZ0005L001P5	Mobius® bag, Gold w/Helium IT, 5 L STD PureFlex™ film with AseptiQuik® G connectors	5
	FRZ0005L002P5	Mobius® bag, Gold w/Helium IT, 5 L STD PureFlex™ film with Lynx® S2S connectors	5
10 L	FRZ0010L001P5	Mobius® bag, Gold w/Helium IT, 10 L STD PureFlex™ film with AseptiQuik® G connectors	5
	FRZ0010L002P5	Mobius® bag, Gold w/Helium IT, 10 L STD PureFlex™ film with Lynx® S2S connectors	5
20 L	FRZ0020L001P5	Mobius® bag, Gold w/Helium IT, 20 L STD PureFlex™ film with AseptiQuik® G connectors	5
	FRZ0020L002P5	Mobius® bag, Gold w/Helium IT, 20 L STD PureFlex™ film with Lynx® S2S connectors	5

Note:

- Mobius® 2D Freeze Assemblies are intended to be used solely with Single Use Support RoSS® shells.
- User shall be solely responsible and liable for validation and use of the Mobius® bag assemblies beyond the range of our specifications.
- Carefully handle the Mobius® assembly at all times.
- Do not handle the Mobius® assembly until completely thawed.

For training on RoSS® shells, contact Single Use Support GmbH directly.
Reference Single Use Support literature at www.susupport.com

- RoSS® Product Brochure
- RoSS® Instruction for Use

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

To place an order or learn more, please visit
SigmaAldrich.com/singleuseassemblies

To receive technical assistance, please visit
SigmaAldrich.com/offices

