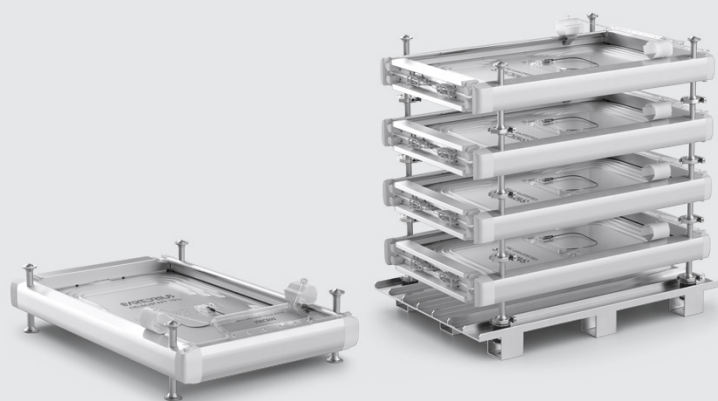


Celsius® FFT 75 L with Safecore™ Technology and Accessories

Benefit From Safecore™ Technology
to Protect Your Large-Volume Frozen
Drug Substance



Product Information

Celsius® FFT 75 L with Safecore™ Technology is an essential part of the Celsius® FFT Platform. The container has an innovative bag-in-place design (cassette) and is single-use, sterile, and ready-to-use. The Celsius® FFT 75 L with Safecore™ Technology is used in combination with Celsius® FFT Pallet and Celsius® FFT Platform equipment to easily manage large-volume biopharmaceutical products with exceptional drug substance protection during frozen storage, handling, and shipping.

Benefits

- Exceptional drug substance protection throughout the product lifecycle thanks to superior container design qualified according to stringent ASTM D4169 standard
- High throughput with limited batch processing time and optimal productivity
- Simple daily bulk processing of large volumes with minimal employee resources. Manage up to 75 L per container and 300 L per pallet with maximum robustness down to -80 °C
- Inspection and cleaning capabilities, simple use, configurable with various tubing and aseptic connectors

Applications

Celsius® FFT 75 L with Safecore™ Technology is designed in combination with Celsius® FFT 75 L | Pallet, to allow reliable and easy handling of large volumes of biopharmaceuticals up to 300 L per pallet. Combined with the Celsius® FFT Platform equipment for filling, freezing, thawing, mixing and draining, it constitutes a fully integrated solution to ensure successful management of frozen bulk drug substance (BDS) in large volume for commercial manufacturing.

Key Benefits

- Celsius® FFT 75 L is a single-use ready to fill container featuring Safecore™ Technology for exceptional robustness. It is designed to be used in combination with Celsius® FFT Platform equipment for fully integrated BDS cold chain management.
- Combined with the Celsius® FFT Pallet, containers are user configurable and stackable (up to four containers) allowing a maximum of 300 L.
- Celsius® FFT Pallet with stacked frozen containers meets ASTM D4169 transportation test standard for both truck and air shipping
- Smaller Celsius® FFT containers are available with the same film (S71*) and the same Safecore™ Technology-based robustness, supporting full scalability.
- Material of construction and all design attributes allow for maximum recyclability

Safecore™ Technology for Maximum Robustness Down to -80 °C

The Safecore™ Technology concept relies on protecting the bag and tubes from their environment by encapsulating them into a semi-rigid casing and a surrounding rigid structure. The semi-rigid casing is composed of two polyester plates which secure the bag by adding impact resistance, suppressing wrinkles, and restricting degrees of freedom. Furthermore, all materials used in Celsius® FFT 75 L with Safecore™ Technology have been characterized across a wide temperature range. The container robustness has been validated and qualified according to the most rigorous international standards with performance down to -80°C.

Simplified Operations

Celsius® FFT 75 L with Safecore™ Technology is designed to secure tubing, pinch-clamp, connector, and disconnecter stowage. The polyester plates are transparent allowing bag chamber and product visibility during all process steps. It can be configurable with various aseptic connectors, disconnectors, and tubing and can be easily wiped down for entry into production area after shipment.

Celsius® FFT 75 L containers are designed to be securely stacked onto the Celsius® FFT 75 L | Pallet for handling with Celsius® FFT Lift for easy transfer between equipment for filling, freezing, thawing, mixing, and draining.

Simplified Frozen Transfer

Frozen transfers are simplified with various shipping solutions. Celsius® FFT 75 L | Pallet is designed according to standard European pallet dimensions. It maximizes storage and shipping densities and reduces associated risks during handling. Up to four Celsius® FFT 75 L containers with Safecore™ Technology can be loaded on Celsius® FFT 75 L | Pallet. It is compatible with any transportation modes and can be shipped directly into a refrigerated container or truck. It will fit most thermal insulated shippers with suitable dimensions for air transportation (cargo and passenger aircraft). Celsius® FFT 75 L | Pallet with loaded Celsius® FFT 75 L have been qualified according to regulations for shipping containers: ASTM D4169 and ISTA 7D extreme summer/winter temperature profiles.

Validation

Celsius® FFT 75 L with Safecore™ Technology have been qualified applying biological, chemical, and physical tests combined with extensive extractable testing to provide users with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO 11137 allows sterility assurance level validation of 10^{-6} throughout the product's life cycle.

* S71: multi-layer EVA-based film with 360 µm thickness, high gas and water barrier properties, excellent biocompatibility, and low extractable profile

Security of Supply

Sartorius' expertise in supplying single-use solutions is based on collaborative supplier management and customer demand planning, assuring a state-of-the-art and robust supply chain that can cope with strong market growth.

Optional Accessories

Celsius® FFT 75 L | Sample Bag Cover: for placing and attaching a sample bag to remain with the main container throughout lifecycle, allowing the end-user to position an ID sample bag with the drug substance container that can be stored and shipped together.

Celsius® FFT 75 L | Thermal Sensor: measures the product temperature during freezing and thawing process inside the Celsius® FFT Freezer. Sensor is attached to the Celsius® FFT 75 L container surface and temperatures are recorded and reported on Celsius® FFT Freezer HMI

Celsius® FFT | Sample Storage Pod: Semi rigid transparent plastic pouch allowing the storage of small bags in a frozen state for long term stability testing post-freezing into benchtop Celsius® S3 system.

Celsius® FFT | Probe Holder: Holds a temperature sensor (PT100 type) and allow its insertion into Celsius® FFT 75 L container for customer testing|process characterization purposes.

Quality Assurance

Relevant ISO and FDA regulations are applied. Design, manufacture and sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements. A type III drug master file (DMF) has been recorded (applicable for all S71* single-use bags).



Figure 1: Celsius® FFT 75 L | Sample Bag Cover

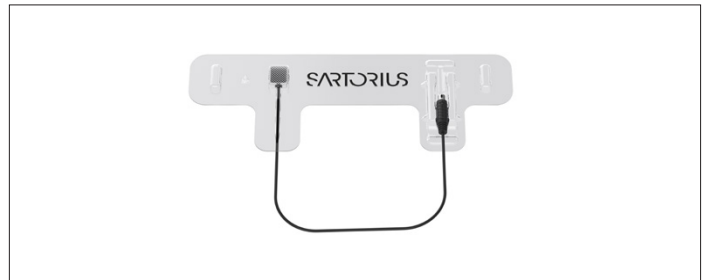


Figure 2: Celsius® FFT 75 L | Thermal Sensor

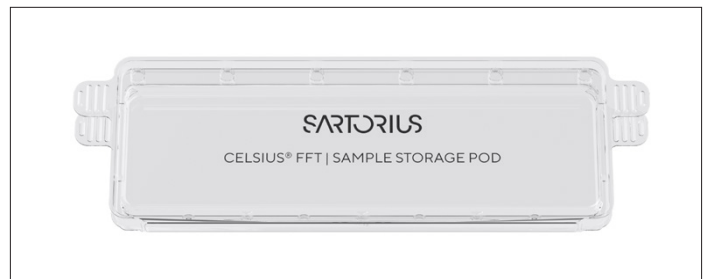


Figure 3: Celsius® FFT | Sample Storage Pod

Technical Specifications

Celsius® FFT 75 L with Safecore™ Technology

Min Max working volumes	18.75 L 75 L
Dimensions L × W × H	1140 × 740 × 260 mm 44.9" × 29.1" × 10.2"
Weight (empty)	20 kg
Sterilization	Gamma Irradiation (25–45 kGy) according to ISO 11737
Packaging	1 unit / box
Packaging dimensions L × W × H	1194 × 794 × 320 mm 47" × 31.2" × 12.6"
Packaging weight with product	26 kg

Materials

Film	S71, 360 µm thickness
Product contact layer	EVA*
Gas barrier layer	EVOH*
Bag ports**	HDPE*
Tubes available for filling, draining and sampling lines	<ul style="list-style-type: none"> Tuflux® Silicone Tuflux® TPE* Pharma-50 Silicone C-Flex® TPE*
Connectors available for filling, draining and sampling lines	<ul style="list-style-type: none"> Opta® Aseptic Connector: PC*, EPDM*, PP*, PES* MPC Quick Coupling: PC*, Si* Plug: PP* (not available on sampling line) Kleenpak™ HT Sterile Connector: PC*, PES*, PP, PSU*, TPE* Kleenpak® Presto Sterile Connector: PBT*, PES* AseptiQuick® Sterile Connector: PC*, PES*, PTFE*, SI*
Corner caps, connector holders	HDPE*
Transparent plates	Polyester
Lateral frames and feet	Aluminum

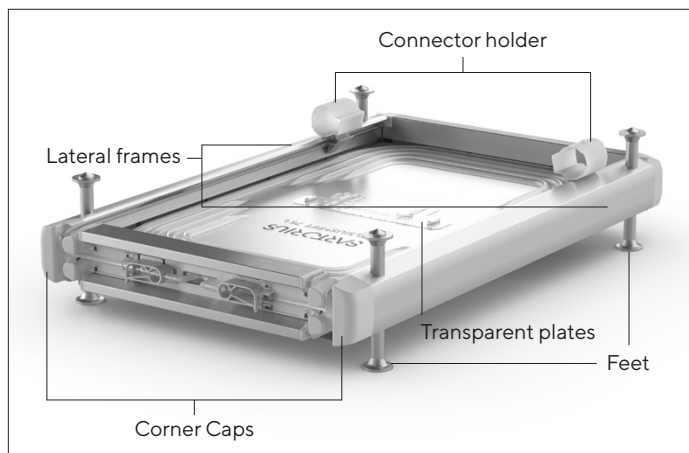


Figure 4: Celsius® FFT 75 L

* EPDM: Ethylene Propylene Diene Monomer; EVA: Ethylene Vinyl Acetate Copolymer; EVOH: Ethylene Vinyl Alcohol; HDPE: High-Density Polyethylene; Si: Silicone; PBT: Poly Butylene Terephthalate; PC: Polycarbonate; PE: Polyethylene; PES: polyethersulfone; PP: Polypropylene; PTFE: Poly Tetra Fluoro Ethylene; TPE: Thermo Plastic Elastomer

**Port welded onto the bag chamber to allow connection of tubing lines

Celsius® FFT 75 L | Pallet

Celsius® FFT 75 L | Pallet has two main components:

- Celsius® FFT 75 L | Pallet Base: Single-use aluminium pallet with integrated shock absorbers to support up to four Celsius® FFT 75 L containers throughout the cold chain from initial container stacking, filling, freezing, shipping, and thawing to final container draining
- Celsius® FFT 75 L | Pallet Cover: Single-use corrugated plastic sleeve and stainless steel bars to cover containers when stacked onto the Celsius® FFT Pallet base to protect them against shock and environment during storage and shipment.

Celsius® FFT 75 L | Pallet and Celsius® FFT 75 L Cover have to be ordered separately.

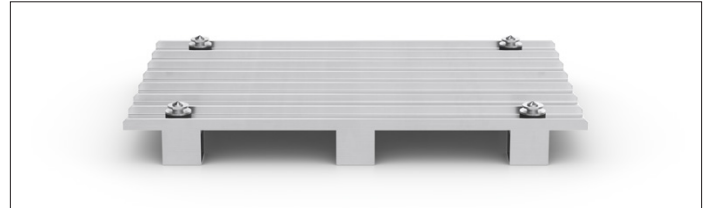


Figure 5: Celsius® FFT 75 L | Pallet Base



Figure 6: 4x Celsius® FFT 75L Containers on Celsius® FFT 75 L | Pallet Base



Figure 7: Assembled Celsius® FFT 75 L | Pallet (assembly of Celsius® FFT 75 L | Pallet Base and Celsius® FFT 75 L | Pallet Cover)

Shipping of Celsius® FFT 75 L Pallet:

Celsius® FFT 75 L | Pallet is not temperature controlled, a refrigerated truck or thermal shipper should be used to maintain low temperature.

- Celsius® FFT 75 L | Pallet is compatible with any transportation mode and can be shipped directly into refrigerated container (e.g. refrigerated truck). It will fit many types of thermal insulated shippers with suitable dimensions for air transportation (cargo and passenger air-craft).
- Sartorius, in collaboration with va-Q-tec, has characterized and qualified the shipping of Celsius® FFT 75 L | Pallet into va-Q-tainer USx shipper from a thermal (ISTA 7D) and robustness (ASTM D4169) perspective.

Temporary Thermal Protection of Celsius® FFT 75 L | Pallet:

- To help protect frozen containers from exposure to ambient temperature during your process, Celsius® FFT 75 L | Pallet can be covered with a thermal jacket.
- Sartorius has identified a thermal jacket model from the market (Silverskin from CSafe) which has been characterized for thermal performances.



Figure 8: Celsius® FFT 75 L | Pallet into va-Q-tainer USx from va-Q-tec

Specifications

	Celsius® FFT 75 L Pallet Base	Celsius® FFT 75 L Pallet Cover	Celsius® FFT 75 L Pallet*
Dimensions L × W × H	1200 × 800 × 187 mm 47.2" × 31.5" × 7.4"	1200 × 814 × 1085 mm 47.2" × 32" × 42.7"	1200 × 814 × 1189 mm 47.2" × 32" × 46.8"
Weight without containers	31.6 kg	30.4 kg	62 kg
Shipping box dimensions L × W × H	1240 × 838 × 215 mm 48.7" × 33" × 8.5"	1240 × 840 × 300 mm 48.8" × 33.1" × 11.8"	N A
Shipping box weight	34.6	38.9	N A
Quantity per shipping box	1	1	N A
Shipping box stackability	yes	yes	No
Max quantity per stack	6	4	N A

* Assembly of Celsius® FFT 75 L | Pallet Base and Celsius® FFT 75 L | Pallet Cover

Materials

Celsius® FFT 75 L | Pallet Base

Pallet Structure	Aluminium
Isolators	Silicone
Bolt Washers	Stainless Steel

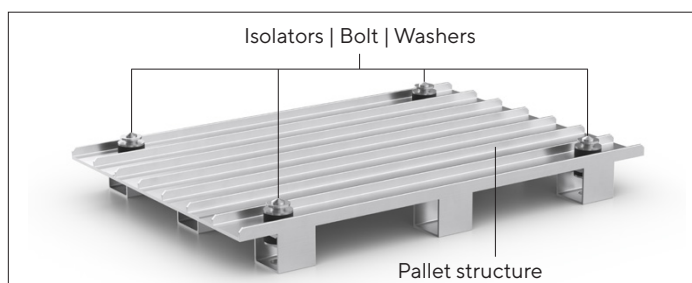


Figure 9: Celsius® FFT 75 L | Pallet Base

Celsius® FFT 75 L | Pallet Cover

Sleeve	PP PVC HDPE
Bars	Stainless Steel



Figure 10: Celsius® FFT 75 L | Pallet Cover on Celsius® FFT 75 L | Pallet Base

Recommended Shipper and Thermal Cover

Thermal shipper	
Supplier	va-Q-tec
Model	va-Q-tainer USx with dunnage system Multi-use container which consists of four layers. From the outside to the inside there is the outer protective shell, an insulation layer made of 30 mm thick vacuum insulation panels, and an inner protective shell.
Outer dimensions (mm)	1426 × 1490 × 1580 mm 56.1" × 58.7" × 62.2"
Inner dimensions (mm)	1200 × 1250 × 1170 mm 47.2" × 49.2" × 46.1"
Weight	420 kg
Thermal cover	
Supplier	CSafe
Model	Silverskin QLT 40 mm thick cover made of 19 layers compressible multilayer insulation
Reference	370F126106120T

Celsius® FFT 75 L | Sample Bag Cover and Celsius® FFT | Sample Storage Pod (Optional)

To hold 30 or 100 mL Celsius® Pak bag for sampling or stability testing purposes.



Figure 11: Celsius® FFT 75 L | Sample Bag Cover



Figure 12: Celsius® FFT | Sample Storage Pod

Specifications

	Celsius® FFT 75 L Sample Bag Cover	Celsius® FFT Sample Storage Pod
Dimensions L × W × H	708.5 × 265 × 13.7 mm 27.9" × 10.4" × 0.5"	406 × 265 × 13.7 mm 16" × 10.4" × 0.5"
Weight	70.8 g	63.5 g
Material	Polyester	Polyester
Shipping box dimensions L × W × H	750 × 300 × 150 mm 29.5" × 11.8" × 5.9"	750 × 300 × 150 mm 29.5" × 11.8" × 5.9"
Quantity per shipping box	20	20

Compliant Celsius® Pak Bags

Bag Volume	Tubing	Connector	Thermowell ⁽¹⁾ (Y/N)	Part Number	Units per Box
30 mL	EVA ⁽²⁾	LL ⁽⁶⁾	Y	FZB114804	10
	EVA + Si ⁽³⁾	LL ⁽⁶⁾	Y	FZB129264	10
	EVA + TPE ⁽⁴⁾	LL ⁽⁶⁾	Y	FZB114866	10
	EVA + Si ⁽³⁾	MPC + Cap	N	FZB129265	10
	EVA + TPE ⁽⁵⁾	MPC + Cap	N	FZB129266	10
100 mL	EVA ⁽²⁾	LL ⁽⁶⁾	Y	FZB114839	10
	EVA + Si ⁽³⁾	LL ⁽⁶⁾	Y	FZB129261	10
	EVA + TPE ⁽⁴⁾	LL ⁽⁶⁾	Y	FZB114908	10
	EVA + Si ⁽³⁾	MPC + Cap	N	FZB129262	10
	EVA + TPE ⁽⁵⁾	MPC + Cap	N	FZB129263	10

- (1): Pre-install blind internal tubing for Thermowell insertion and non-invasive temperature measurement
(2): From bag to end line: 1/4" ID 5/16" OD EVA 0.1 m (4")
(3): From bag to end line: 1/4" ID 5/16" OD EVA 0.1 m (4") + 1/4" ID 3/8" OD Dow Corning® Pharma-50 Silicone 0.15 m (6")
(4): From bag to end line: 1/4" ID 5/16" OD EVA 0.1 m (4") + 1/8" ID 1/4" OD Clear C-Flex® 0.15 m (6")
(5): From bag to end line: 1/4" ID 5/16" OD EVA 0.1 m (4") + 1/4" ID 3/8" OD Clear C-Flex® 0.15 m (6")
(6): 1/4" Luer Lock Female + Luer Lock plug
EVA: Ethylene Vinyl Acetate
TPE: Thermo Plastic Elastomer

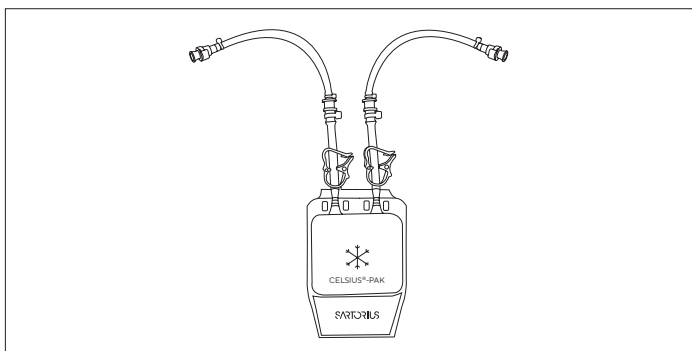


Figure 13: Celsius® Pak Bag

Celsius® FFT 75 L | Thermal Sensor (Optional)

Specifications

Dimensions L × W × H	360 × 200 × 12.5 mm 14.2" × 7.9" × 0.5"
Weight	70 g
Material	Polyester / FEP* / Aluminium
Shipping box dimensions	400 × 300 × 200 mm 15.7" × 11.8" × 7.9"
Shipping box weight	1.8 kg
Quantity per shipping box	8
Shipping box stackability	Yes

*: FEP: fluorinated ethylene propylene

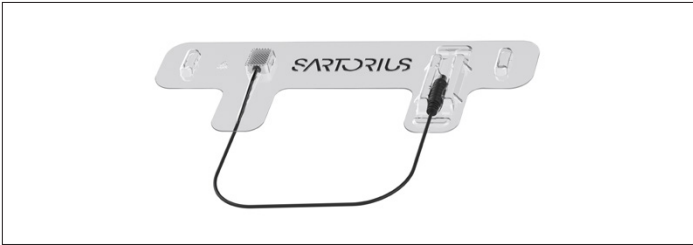


Figure 14: Celsius® FFT 75 L | Thermal Sensor



Figure 15: Thermal Sensor mounted on Celsius® FFT 75 L container

Ordering Information

Celsius® FFT 75 L with Safecore™ Technology

Part Number	Tubing Material	Connector	Tubing Size ID × OD × L (in)
FZB314931	Tuflux® Sil	Opta male 3/8"	3/8" × 5/8" × 47.2"
FZB314932	Tuflux® TPE		
FZB314933	Dow Corning Sil		
FZB314934	C-Flex® TPE		
FZB314935	Tuflux® Sil	MPC male 3/8"	
FZB314936	Tuflux® TPE		
FZB314937	Dow Corning Sil		
FZB314938	C-Flex® TPE		
FZB314939	Tuflux® Sil	Plug 3/8"	
FZB314940	Tuflux® TPE		
FZB314941	Dow Corning Sil		
FZB314942	C-Flex® TPE		

Other configurations available under request

Accessories

Designation	Part Number
Celsius® FFT 75 L Pallet Base	FTH-SM00101-0087
Celsius® FFT 75 L Pallet Cover	FTH-SM00101-0088
Celsius® FFT 75 L Sample Bag Cover	FZA311640
Celsius® FFT 75 L Sample Storage Pod	FZA311642
Celsius® FFT 75 L Thermal Sensor	FZA311641
Celsius® FFT 75 L Probe Holder	FZA311643

Celsius® FFT Platform Equipment

Celsius® FFT 75 L container, pallet, and accessories are designed to be used with the following Sartorius equipment to ensure efficient cold chain management of BDS in large volume. Contact your Sartorius Sales representative for further information.

Equipment	Description
Celsius® FFT Freezer	Blast freezer to freeze and thaw palletized Celsius® FFT containers
Celsius® FFT Mixer	To homogenise palletized Celsius® FFT containers
Celsius® FFT Lift	Electric semi-automatic lift to handle move palletized Celsius® FFT containers and load unload Celsius® FFT Platform other equipment and AliquoT® Pallet
AliquoT® Pallet	Automatic filling draining station to fill and drain palletized Celsius® FFT containers



Figure 16: Celsius® FFT Freezer



Figure 17: AliquoT® Pallet



Figure 18: Celsius® FFT Lift



Figure 19: Celsius® FFT Mixer

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