

Celsius® FFT|FFTp with Safecore™ Technology

Protect your frozen drug substances
with the Safecore™
bag-in-plate technology



Product Information

Celsius® FFT|FFTp with Safecore™ Technology is a single-use sterile and pre-assembled container with an innovative bag-in-plate design (cassette) for exceptional protection during frozen storage, handling and shipping of biopharmaceutical products.

Benefits

- Exceptional protection throughout lifecycle
- Maximum robustness down to -80 °C
- Inspection and cleaning capabilities, simple manipulation, configurable with various aseptic connectors
- Flexible and consistent freeze and thaw compatible with a wide variety of methods, scalable
- Bulk processing (storage | shipping)

Applications

Celsius® FFT|FFTp with Safecore™ Technology is designed to fit with any type of freezing and thawing methods for the frozen storage and shipping of biopharmaceuticals (FFT: conventional freezers; FFTp: horizontal plate freezers). It can be used throughout all processes, from harvest to downstream process intermediates and bulk drug substances. Leveraging the existing equipment infrastructure, these containers can be easily deployed in clinical drug development as well as in commercial manufacturing.

Safecore™ Technology

The Safecore™ Technology concept relies on protecting the bag from its environment with encapsulating it into a semi-rigid casing and a surrounding shell. The semi-rigid casing is composed of two polyester plates which secure bag and lines by adding impact resistance, suppressing wrinkles and restricting degrees of freedom. The excellent bag-to-plate contact ensures high efficiency energy transfer for quick and uniform freeze and thaw and provides higher robustness and more uniform freeze and thaw.

Validation

Celsius® FFT|FFTp with Safecore™ Technology bags have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing 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 over product entire shelf life.

Maximum robustness down to -80 °C

All materials used in Celsius® FFT|FFTp with Safecore™ Technology have been characterized across a wide temperature range. The container robustness has been then confirmed through innovative methods and extensive handling and shipping lifecycle tests for performances down to -80 °C. To ensure consistent robustness in routine, quality controls have been implemented such as leak testing and integrity testing during the manufacturing of the single-use assemblies. The standard Celsius® FFT|FFTp with Safecore™ Technology can be tested at 100% Supplier Integrity test (SIT) with Helium Technology with 2µm sensitivity for the bag and direct lines.

Simple operations

Celsius® FFT|FFTp with Safecore™ Technology is designed with an integrated line management system for secured tubing, pinch-clamp and connector stowage. The polyester plates are transparent with the bag chamber fully visible for product inspection during all process steps. The container can be configurable with various aseptic connectors |

disconnectors and can be easily wiped down with access to all surfaces for entry into production area after shipment to thaw sites. The containers have been designed to allow secured stackability during freezing and storage operations.

Frozen Transfers

Frozen transfers are simplified with various shipping solutions

- Celsius® FFT|FFTp Box Shipper allows reliable shipment of individual container to remote locations. This is an insulated corrugated single-use shipper refrigerated with dry-ice pellets designed for one-way logistics transportation.
- Celsius® FFT|FFTp Bulk Shipper* is designed according to standard European pallet dimensions. It maximizes storage and shipping densities and reduces associated risks during handling. Up to 10 containers Celsius® FFT 12 L with Safecore™ Technology can be loaded per bulk shipper. The bulk shipper is compatible with any transportation modes and can be shipped directly into refrigerated container (e.g. refrigerated truck). It will fit any type of thermal insulated shipper with suitable dimensions for air transportation (cargo and passenger air-craft).

Both shipping solutions have been qualified according to regulations for shipping containers: ASTM D4169 at Assurance Level 1 and ISTA 7D extreme summer|winter temperature profiles.

Optional Accessories

- a sample bag cover to place and attach a sample bag to remain with the main container throughout lifecycle, this allows the end-user to position an ID sample bag with the drug substance container that can be stored and shipped together
- a label placard offering a dedicated labelling space to provide end-user with a specific location to quickly and easily identify each container, the label placard can remain with the drug substance container throughout its lifecycle

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing single-use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

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).

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

Technical Data

Celsius® FFT | FFTp with Safecore™ Technology

Specifications

	Celsius® FFT 2 L	Celsius® FFT 4 L	Celsius® FFT 6 L	Celsius® FFT 12 L (2.1)	Celsius® FFTp 12 L
Min Max working volumes	0.5 L 2 L	1.0 L 4 L	1.5 L 6 L	3 L 12 L	9.6 L 11 L
Inlet & outlet ports	Standard: MPC Quick Coupling or Opta® connector Configurable: Aseptiquick® G or KPC Others upon request				
Sterilization	Gamma Irradiation (25 – 45 kGy)				
Dimensions (L × W × H) ± 5 mm ± 0.2 inch	42.0 × 34.2 × 12.9 cm 16.5" × 13.4" × 5.1"	44.0 × 45.6 × 12.9 cm 17.3" × 18.0" × 5.1"	61.4 × 45.2 × 12.9 cm 24.2" × 17.8" × 5.1"	71.4 × 56.0 × 12.8 cm 28.1" × 22.0" × 5.0"	70.5 × 56.0 × 7.1 cm 27.7" × 22.0" × 2.8"
Weight (empty)	0.9 kg	1.2 kg	1.4 kg	2.5 kg	2.3 kg

Materials

Film	S71, 360 µm thickness
Product contact layer	EVA*
Gas barrier layer	EVOH*
Fill and drain ports	EVA*
Fill and drain tubing	C-Flex® 374
Connection	MPC Quick Coupling: PC*, Si* Opta® Aseptic Connector: PC*, EPDM*, PP*, PES*
Plates	Polyester
Shell	HDPE*
Screw	PUR*
Nut	PA*

Accessories

Specifications

Sample bag cover	Designed to hold 30 mL Celsius® Pak
Label placard	Dedicated labeling space

Materials

Sample bag cover	Polyester
Label placard	HDPE*

* EPDM: Ethylene Propylene Diene Monomer ; EVA: Ethylene Vinyl Acetate Copolymer ; EVOH: Ethylene Vinyl Alcohol ; HDPE: High-Density Polyethylene ; Si: Silicone ; PA: Polyamide ; PC: Polycarbonate ; PE: Polyethylene ; PES: polyethersulfone ; PP: Polypropylène ; PUR: polyurethane ; PS: Polystyrene

Celsius® FFT | FFTp Box Shipper

Specifications

1-Unit Box Shipper

Load capacity	1x Celsius® FFT 2 L	1x Celsius® FFT 4 L	1x Celsius® FFT 6 L	1x Celsius® FFT 12 L	1x Celsius® FFTp 12 L
Maximum number of Box Shippers per pallet	6	6	6	3	3
Dimensions (L x W x H)	64.7 x 53.7 x 58.7 cm 25.5" x 21.2" x 23.1"	61.2 x 59.2 x 52.4 cm 24.1" x 23.3" x 20.6"	73.9 x 58.9 x 43.9 cm 29.1" x 23.2" x 17.3"	90.6 x 75.4 x 52.3 cm 35.7" x 29.7" x 20.6"	90.6 x 75.4 x 52.3 cm 36.7" x 29.7" x 20.6"
Refrigeration mode	Dry-ice pellets				

4-Unit Box Shipper

Load capacity	4x Celsius® FFT 2 L	4x Celsius® FFT 4 L	4x Celsius® FFT 6 L
Maximum number of Box Shippers per pallet	2	2	2
Dimensions (L x W x H)	85.2 x 60.2 x 74.7 cm 33.5" x 23.7" x 29.4"	112.2 x 64.7 x 77.1 cm 44.2" x 25.5" x 30.4"	111.4 x 77.8 x 72.3 cm 43.9" x 30.6" x 28.5"
Refrigeration mode	Dry-ice pellets		

Materials

Product box and dry-ice bunker	Corrugated cardboard
Top insulation	PUR*
Top crush zone	PS*
Outer box	Corrugated cardboard, PUR*, PS*

Celsius® FFT | FFTp Bulk Shipper**

Specifications

Load capacity	Up to 10 x Celsius® FFT 12 L with Safecore™ Technology
Dimensions (L x W x H)	120 x 80 x 117 cm 47.2" x 31.5" x 46.1"
Refrigeration mode	N A : must be loaded inside thermal insulated system. Robustness (ASTM) and thermal (ISTA 7D) performances tested within va-Q-tainer® offered by va-Q-tec.

Materials

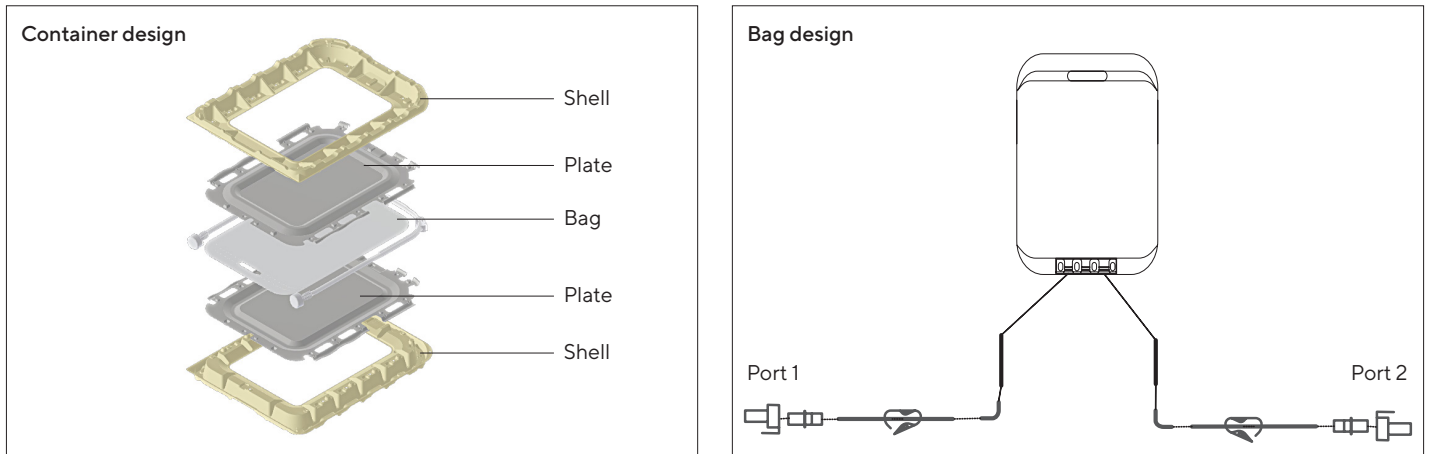
Bottom pad	HDPE*, PE*
Straps	PA*
Top pads	HDPE*
Spacers	HDPE*

* EPDM: Ethylene Propylene Diene Monomer; EVA: Ethylene Vinyl Acetate Copolymer; EVOH: Ethylene Vinyl Alcohol; HDPE: High-Density Polyethylene; Si: Silicone; PA: Polyamide; PC: Polycarbonate; PE: Polyethylene; PES: polyethersulfone; PP: Polypropylene; PUR: polyurethane; PS: Polystyrene

** Only available for Celsius® FFT 12 L with Safecore™ Technology

Ordering Information

Celsius® FFT with Safecore™ Technology

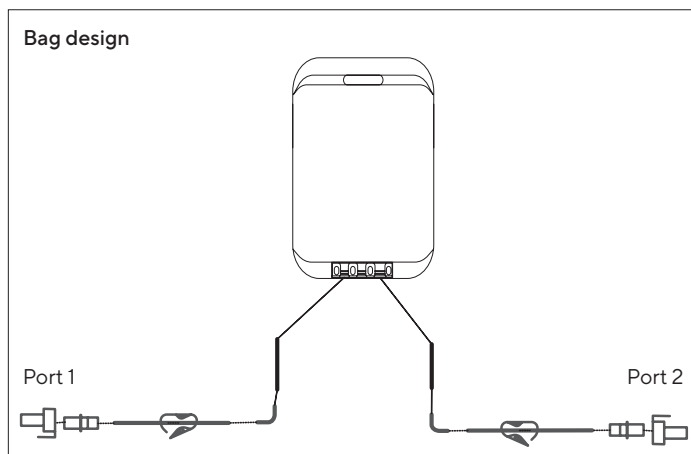
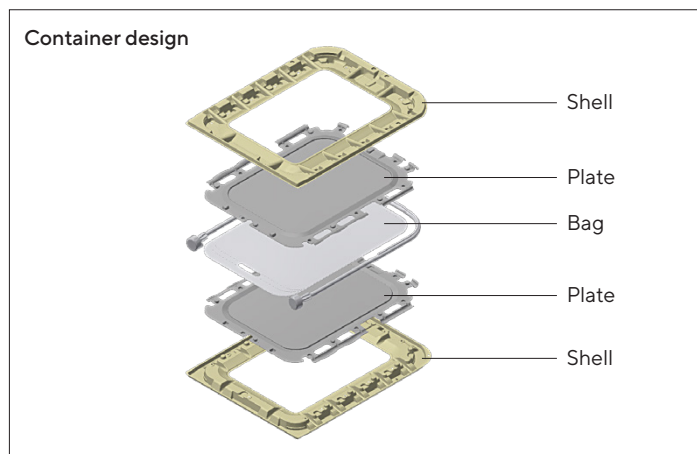


Part Number	Description	Tubing	Port 1*	Port 2*	Qty./Box
FZB310530	Celsius® FFT 2 L with Safecore™ Technology (2T, MPC, TPE) - SIT** tested	TPE Clear C-Flex® 374	3/8" x 5/8" x 380 mm (15") + male MPC + sealing cap	3/8" x 5/8" x 380 mm (15") + male MPC + sealing cap	4
FZB313489	Celsius® FFT 2 L with Safecore™ Technology (2T, MPC, TPE)				
FZB310532	Celsius® FFT 2 L with Safecore™ Technology (2T, Opta®, TPE) - SIT** tested	TPE Clear C-Flex® 374	3/8" x 5/8" x 380 mm (15") + Opta® male	3/8" x 5/8" x 380 mm (15") + Opta® male	4
FZB313491	Celsius® FFT 2 L with Safecore™ Technology (2T, Opta®, TPE)				
FZB302498	Celsius® FFT 4 L with Safecore™ Technology (2T, MPC, TPE) - SIT** tested	TPE Clear C-Flex® 374	3/8" x 5/8" x 430 mm (16.9") + male MPC + sealing cap	3/8" x 5/8" x 430 mm (16.9") + male MPC + sealing cap	2
FZB313492	Celsius® FFT 4 L with Safecore™ Technology (2T, MPC, TPE)				
FZB302499	Celsius® FFT 4 L with Safecore™ Technology (2T, Opta®, TPE) - SIT** tested	TPE Clear C-Flex® 374	3/8" x 5/8" x 430 mm (16.9") + Opta® male	3/8" x 5/8" x 430mm (16.9") + Opta® male	2
FZB313493	Celsius® FFT 4 L with Safecore™ Technology (2T, Opta®, TPE)				
FZB302502	Celsius® FFT 6 L with Safecore™ Technology (2T, MPC, TPE) - SIT** tested	TPE Clear C-Flex® 374	3/8" x 5/8" x 610 mm (24") + male MPC + sealing cap	3/8" x 5/8" x 610 mm (24") + male MPC + sealing cap	2
FZB313494	Celsius® FFT 6 L with Safecore™ Technology (2T, MPC, TPE)				
FZB302501	Celsius® FFT 6 L with Safecore™ Technology (2T, Opta®, TPE) - SIT** tested	TPE Clear C-Flex® 374	3/8" x 5/8" x 610 mm (24") + Opta® male	3/8" x 5/8" x 610 mm (24") + Opta® male	2
FZB313496	Celsius® FFT 6 L with Safecore™ Technology (2T, Opta®, TPE)				
FZB302503	Celsius® FFT 12 L with Safecore™ Technology (2T, MPC, TPE) - SIT** tested	TPE Clear C-Flex® 374	3/8" x 5/8" x 750 mm (30") + male MPC + sealing cap	3/8" x 5/8" x 750 mm (30") + male MPC + sealing cap	2
FZB313762	Celsius® FFT 12 L with Safecore™ Technology (2T, MPC, TPE)				
FZB302504	Celsius® FFT 12 L with Safecore™ Technology (2T, Opta®, TPE) - SIT** tested	TPE Clear C-Flex® 374	3/8" x 5/8" x 750 mm (30") + Opta® male	3/8" x 5/8" x 750 mm (30") + Opta® male	2
FZB313763	Celsius® FFT 12 L with Safecore™ Technology (2T, Opta®, TPE)				

* Tube inner diameter x Tube outer diameter x Tube length + Connector

** SIT: Supplier Integrity Test at 2 µm sensitivity

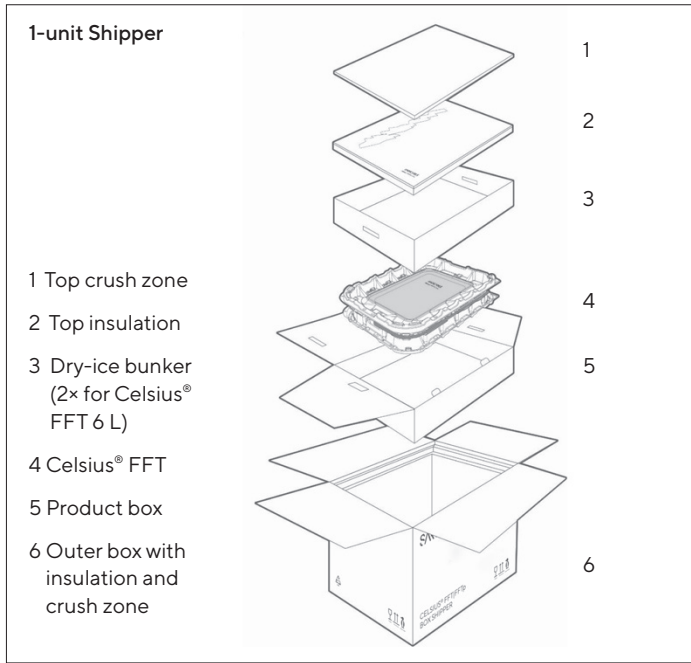
Celsius® FFTp with Safecore™ Technology



Part Number	Description	Tubing	Port 1*	Port 2*	Qty./Box
FZB302505	Celsius® FFTp 12 L with Safecore™ Technology (2T, MPC, TPE)	TPE Clear C-Flex® 374	3/8" x 5/8" x 750 mm (30") + male MPC + sealing cap	3/8" x 5/8" x 750 mm (30") + male MPC + sealing cap	2
FZB302500	Celsius® FFTp 12 L with Safecore™ Technology (2T, Opta®, TPE)	TPE Clear C-Flex® 374	3/8" x 5/8" x 750 mm (30") + Opta® male	3/8" x 5/8" x 750 mm (30") + Opta® male	2

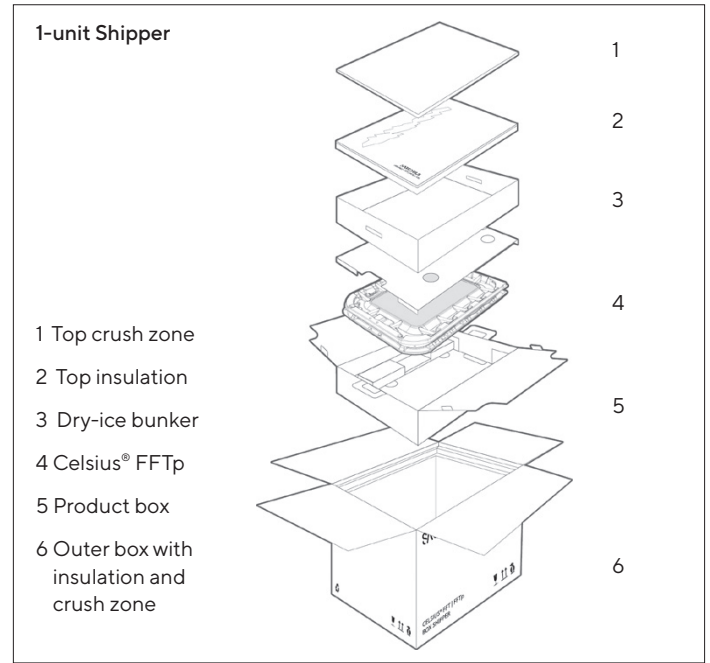
*Tube inner diameter x Tube outer diameter x Tube length + Connector

Celsius® FFT Box Shipper

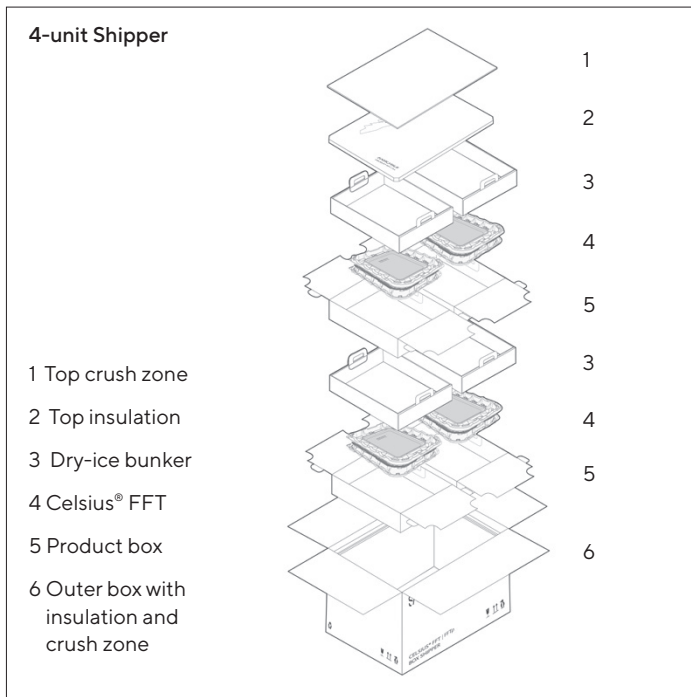


Part Number	Description
FTH-SM00103-0019	Celsius® FFT 2 L 1-Unit Shipper
FTH-SM00103-0017	Celsius® FFT 4 L 1-Unit Shipper
FTH-SM00103-0013	Celsius® FFT 6 L 1-unit Shipper
FTH-SM00103-0012	Celsius® FFT 12 L (2.1) 1-unit Shipper

Celsius® FFTp Box Shipper



Part Number	Description
FTH-SM00103-0010	Celsius® FFTp 12 L 1-unit Shipper



Part Number	Description
FTH-SM00103-0020	Celsius® FFT 2 L 4-Unit Shipper
FTH-SM00103-0018	Celsius® FFT 4 L 4-Unit Shipper
FTH-SM00103-0014	Celsius® FFT 6 L 4-unit Shipper



Celsius® FFT|FFTp Bulk Shipper*



Collapsed at reception



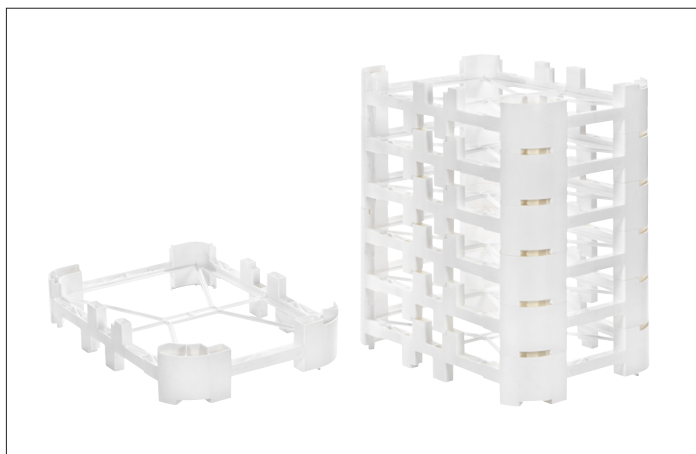
Celsius® FFT 12 L containers stacking with spacers



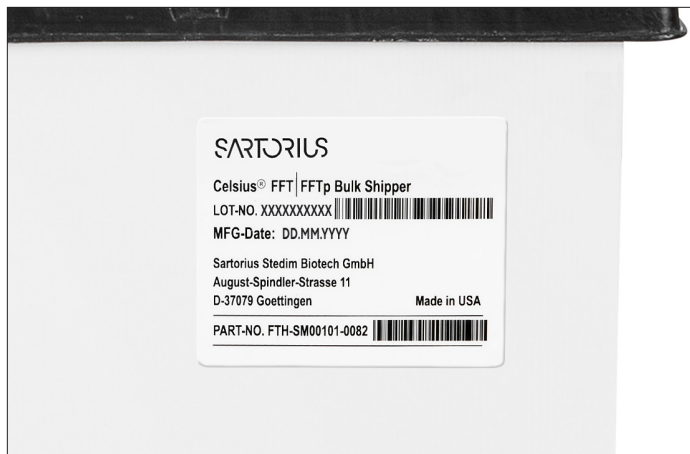
Celsius® FFT 12 L securely held



Fully assembled



Spacers



Labelling

Part Number	Description	Qty Box
FTH-SM00101-0082	Celsius® FFT FFTp Bulk shipper	1
FTH-SM00101-0089	Spacers for Celsius® FFT 12 L (2.1)	1 set of 12

* Only available for Celsius® FFT 12 L with Safecore™ Technology

Accessories

Sample Bag Cover



Part Number	Description	Qty Box
FZA307269	Sample Bag Cover Celsius® FFT 2 L	1 set of 20
FZA307270	Sample Bag Cover Celsius® FFT 4 L 6 L	1 set of 20
FZA307266	Sample Bag Cover Celsius® FFT FFTp 12 L	1 set of 20

Label Placard



Part Number	Description	Qty Box
FZA307272	Label Placard Celsius® FFT	1 set of 40

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