

Celsius® FFT with Safecore™ Technology

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

Product Information

Celsius® FFT 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 with Safecore™ Technology is designed to fit with any type of conventional freezing and thawing methods for the frozen storage and shipping of biopharmaceuticals. 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 cassette concept is a semi-rigid bag composed of 2 polyester plates and a bag assembly protected with a surrounding shell. The plates secure the bag and lines by adding impact resistance, suppressing wrinkles and restricting degrees of freedom. The excellent bag-to-plate contact provides higher robustness and more uniform freeze and thaw.

Validation

Celsius® FFT 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 with Safecore™ Technology have been characterized across 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.

Simple operations

Celsius® FFT 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 wipedown 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 Box Shipper allows safe 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 Bulk Shipper is designed according to standard European pallet dimensions. It maximizes storage and shipping density and reduces associated risks during handling. Up to 10 frozen 12L Celsius® FFT 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 (eg. refrigerated truck). It will fit any type of thermal insulated shipper with the 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 for medical devices 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).

Technical Data

Celsius® FFT with Safecore™ Technology

Specifications

Min Max working volumes	3 L 12 L
Inlet & outlet ports	MPC Quick Coupling or OPTA connector
Sterilization	Gamma Irradiation (25 – 45 kGy)
Dimensions (L × W × H)	69.8 × 55.4 × 12.8 cm 27.5" × 21.8" × 5.0"

Materials

Film	S71, 360 µm
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
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Materials

Sample bag cover	Polyester
Label placard	HDPE*

Celsius® FFT Box Shipper

Specifications

Load capacity	1 × 12 L Celsius® FFT
Maximum number of Shippers per pallet	3
Temperature control	Dry-ice pellets
Dimensions (L × W × H)	90.7 × 74.9 × 51.6 cm 35.7" × 29.5" × 20.3"

Materials

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

Celsius® FFT Bulk Shipper

Specifications

Load capacity	Up to 10 × 12L Celsius® FFT with Safecore™ Technology
Dimensions (L × W × H)	120 × 80 × 117 cm 47.2" × 31.5" × 46.1"

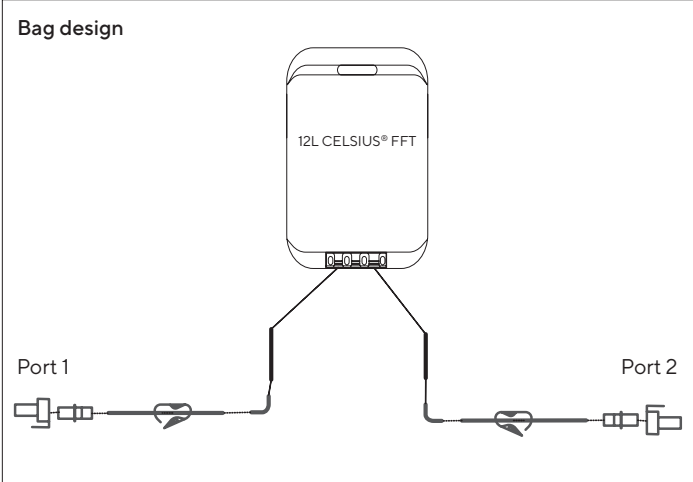
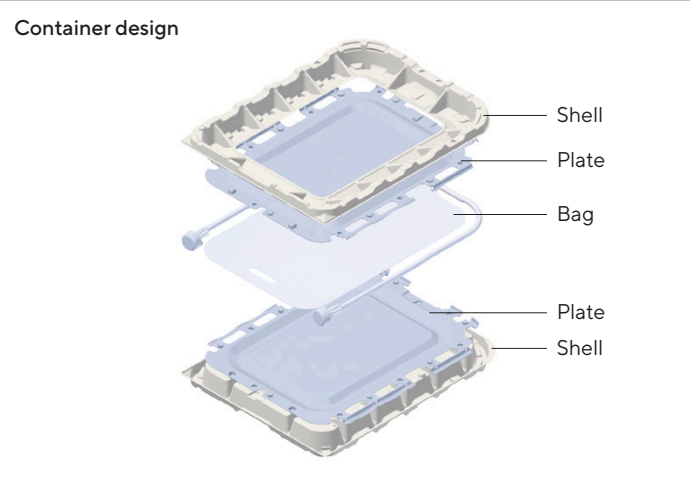
Materials

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

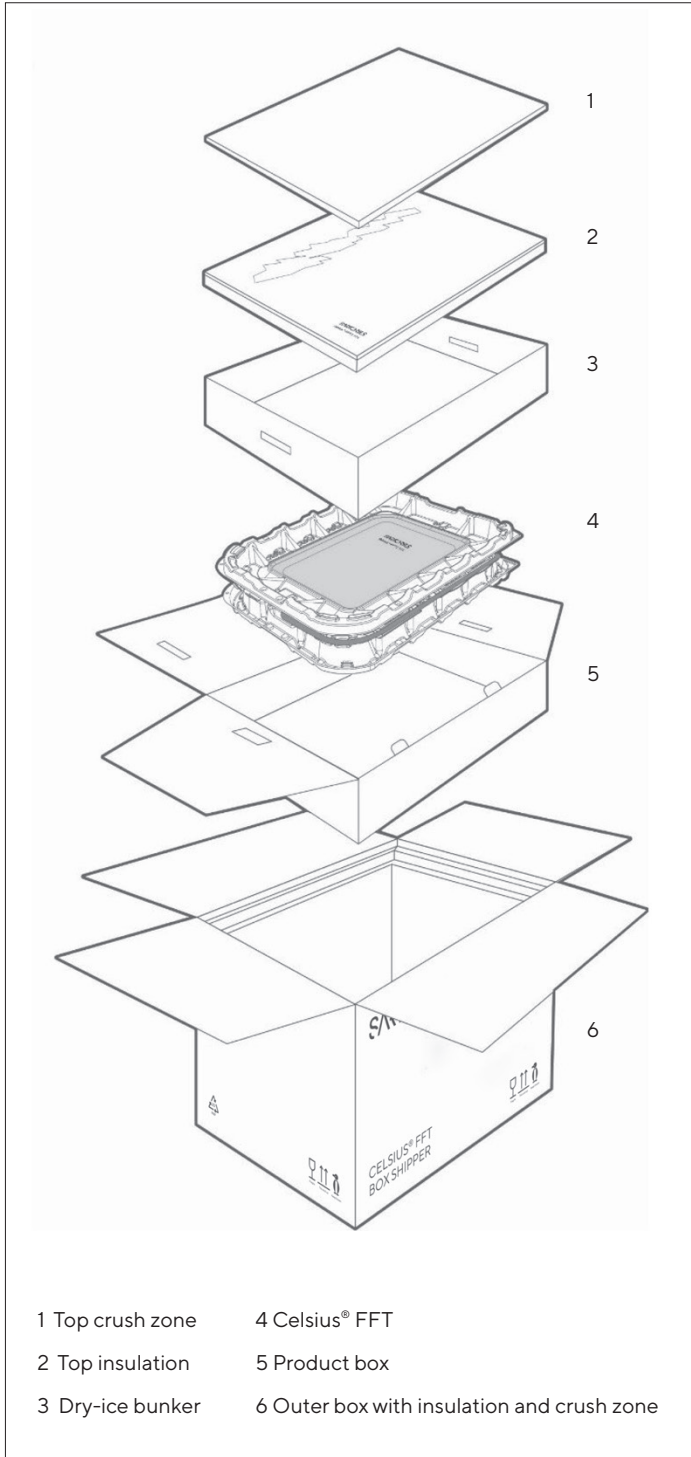
Ordering Information

Celsius® FFT with Safecore™ Technology (Bag + Shell)



Part Number	Description	Tubing	Port 1	Port 2	Qty./Box
FZB302503	12L Celsius® FFT with Safecore™ Technology (2T, MPC, TPE)	TPE Clear C-Flex® 374	3/8" x 5/8" x 75 cm (30") + male MPC + sealing cap	3/8" x 5/8" x 75 cm (30") + male MPC + sealing cap	2
FZB302504	12L Celsius® FFT with Safecore™ Technology (2T, OPTA, TPE)	TPE Clear C-Flex® 374	3/8" x 5/8" x 75 cm (30") + OPTA male	3/8" x 5/8" x 75 cm (30") + OPTA male	2

Celsius® FFT Box Shipper



Part Number	Description
FTH-SM00103-0005	12L Celsius® FFT 1-unit Shipper

Celsius® FFT Bulk Shipper



Collapsed at reception



Containers stacking with spacers



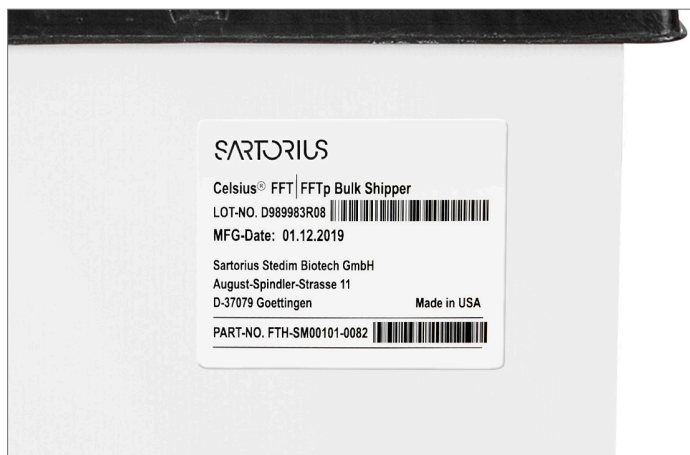
Containers securely held



Fully assembled



Spacers



Labelling

Part Number	Description	Qty/Box
FTH-SM00101-0082	Celsius® FFT FFTp Bulk shipper	1
FTH-SM00101-0083	Spacers for 12L Celsius® FFT	1 set of 12

Accessories

Sample Bag Cover



Label Placard




Part Number	Description	Qty/Box
FZA307266	Sample Bag Cover 12L Celsius® FFT	1 set of 20
FZA307267	Label Placard Celsius® FFT	1 set of 40

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