

Celsius® FFT

Single-Use Container
for Flexible Freeze-
Thaw Processes



Product Information

Celsius® FFT is a “ready-to-use” sterile container, for freezing and thawing biopharmaceutical solutions in commercially available equipment such as laboratory (walk-in) freezer, cold room, temperature controlled cabinet or water bath.

Benefits

- Single-use
- Proven robustness at low temperature
- Ease-of-use
- Facilitated implementation
- Pre-qualified shippers
- Pre-sterilized, ready-to-use and 100% integrity testing of bag and immediate connection

Description

Celsius® FFT combines a unique design of a flexible bag with an integral protective shell. The robustness of this single-use assembly ensures protection, support and ease of handling.

Applications

Celsius® FFT is specifically designed for freezing, thawing and long term frozen storage of biopharmaceuticals such as

- Process intermediates
- Bulk drug substances
- Product in clinical phases (pre, I, II +)
- Vaccines
- Monoclonal antibodies
- Other recombinant proteins

Single-Use System for Freeze-Thaw Operation

Celsius® FFT is constructed from S71 film, a multi-layer co-extruded high gas barrier film containing EVAM (ethylene vinyl acetate copolymer, monomaterial) as fluid contact layer and EVOH (ethylene vinyl alcohol) as gas barrier layer. The shell provides protection to the contents during all processes, proven during extensive characterization under freeze and thaw real process conditions. It makes the assembly robust, reliable, simplifying the handling, storage and shipping of the single-use containers.

Celsius® FFTp for Plate Freezer

Celsius® FFTp has been especially designed to be used with plate freezers. It also combines the flexible bag with an integral protective shell design. The design is compact and flat to offer a good contact with heat exchange freezer plates.

Celsius® FFT Shippers

The Celsius® FFT Shippers is a robust solution allowing safe shipment of individual or multiple Celsius® FFT to remote locations. The Celsius® FFT shipper has been qualified according to the most restrictive regulations for shipping containers such as ASTM-D4169 Level 1 and ISTA 7D. The shipper provides adequate insulation and refrigeration to maintain the Celsius® FFT below -40°C for at least 96 h.

Technical Data

Specifications

Nominal Volume	2 L, 4 L, 6 L and 12 L
Sampling Port	Luer® lock
Inlet & Outlet Port	MPC Quick Coupling or OPTA connector
Sterilization	Gamma Irradiation (25 – 45 kGy)

Materials

Film	S71, 360 µm
Product Contact Layer	EVA (ethylene vinyl acetate copolymer)
Gas Barrier Layer	EVOH (Ethylene Vinyl Alcohol)
Fill and Drain Ports	EVA (Ethylene Vinyl acetate copolymer)
Fill, Drain and Sampling	C-Flex® 374
MPC Quick Coupling	PC (Polycarbonate) with Silicone O-ring
Shell	HDPE (High-Density Polyethylene)
Screw	Isoplast 101 40% LGF, natural
Nut	Nylon 6/6, natural
Shippers	<ul style="list-style-type: none">▪ Corrugate product box and dry-ice bunker▪ Molded Pur▪ EPS Crush Zone▪ DBL Wall Corrugate

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.

Validation

Celsius® FFT bags have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Celsius® with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows sterility assurance level validation of 10⁻⁶ for each Single-use System over its entire shelf life.

Quality Assurance

Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. 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).

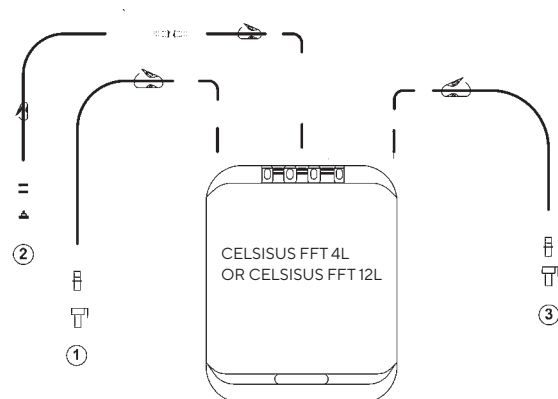
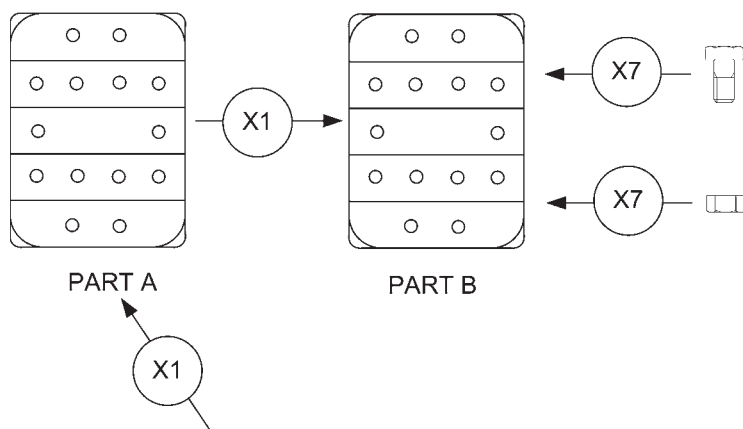
Dimensions L × W × H

Celsius® FFT 2L	38.6 × 32.8 × 12.4 cm 15.2" × 12.9" × 4.9"
Celsius® FFT 4L	43.4 × 42.4 × 12.6 cm 17.1" × 16.7" × 5.0"
Celsius® FFT 6L	57.8 × 42.6 × 11.7 cm 22.8" × 16.8" × 4.6"
Celsius® FFT 12L	69.8 × 53.4 × 13.1 cm 27.5" × 21.0" × 5.23"
Celsius® FFTp 6L	56.6 × 40.4 × 5.1 cm 22.3" × 15.9" × 2.00"
Celsius® FFTp 12L	67.8 × 51.3 × 6.9 cm 26.7" × 21.0" × 2.72"
Shipper; Celsius® FFT 2L 1-unit Shipper	63.5 × 52.8 × 60.4 cm 25.0" × 20.8" × 23.8"
Shipper; Celsius® FFT 2L 4-unit Shipper	87.0 × 60.0 × 74.3 cm 34.3" × 23.6" × 29.3"
Shipper; Celsius® FFT 4L 1-unit Shipper	61.5 × 58.9 × 52.8 cm 24.2" × 23.2" × 20.8"
Shipper; Celsius® FFT 4L 4-unit Shipper	110.5 × 64.3 × 79.2 cm 43.5" × 25.3" × 31.2"
Shipper; Celsius® FFT 6L 1-unit Shipper	74.4 × 59.2 × 42.7 cm 29.3" × 23.3" × 16.8"
Shipper; Celsius® FFT 6L 4-unit Shipper	112.1 × 78.3 × 72.5 cm 44.1" × 30.8" × 28.6"
Shipper; Celsius® FFT 12L 1-unit Shipper	90.7 × 74.9 × 51.6 cm 35.7" × 29.5" × 20.3"



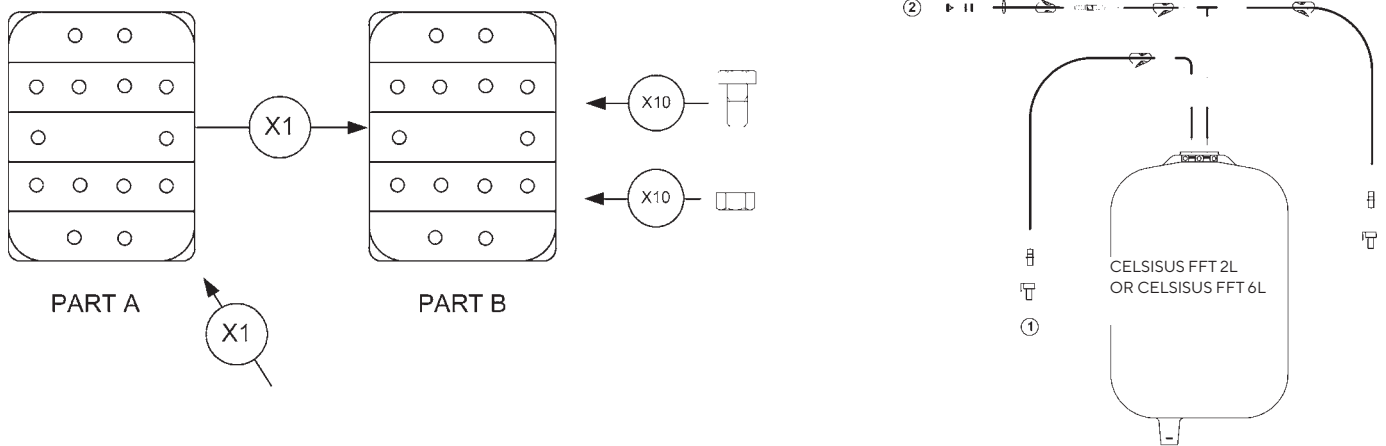
Ordering Information

Celsius® FFT (Bag + Shell)



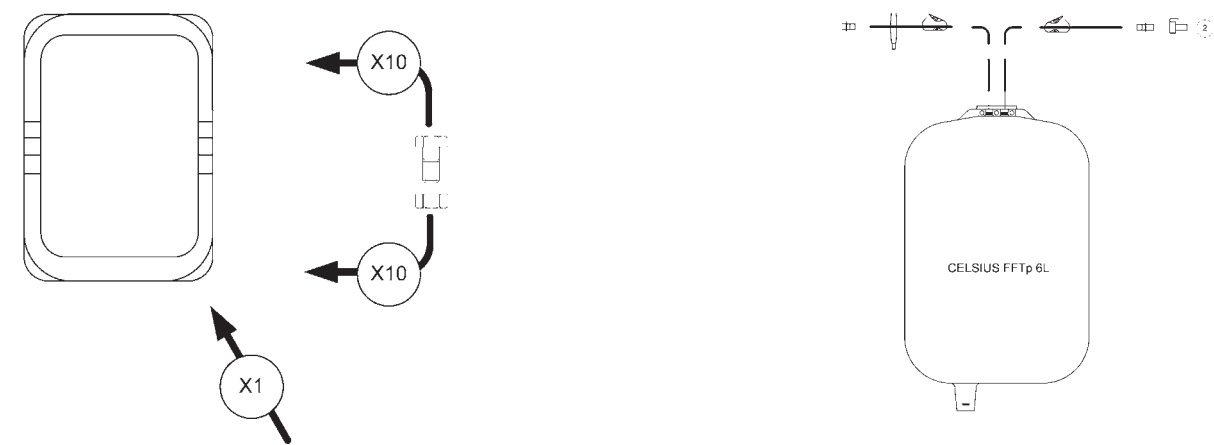
Part Number	Description	Tubing	Port 1	Port 2	Port 3	Qty./Box
FZB212401	Celsius® FFT 4L (3T, TPE), 4L nominal capacity	TPE Clear C-Flex® 374	3/8" x 5/8" x 50 cm (20") and male MPC + sealing cap	1/4" x 3/8" x 10 cm (4") + Clear C-Flex® 374 1/8" x 1/4" x 50 cm (20") and female Luer® Lock with plug	3/8" x 5/8" x 50 cm (20") and male MPC + sealing cap	6
FZB212435	Celsius® FFT 12L (3T, TPE), 12L nominal capacity	TPE Clear C-Flex® 374	3/8" x 5/8" x 50 cm (20") and male MPC + sealing cap	1/4" x 3/8" x 10 cm (4") + Clear C-Flex® 374 1/8" x 1/4" x 50 cm (20") and female Luer® Lock with plug	3/8" x 5/8" x 50 cm (20") and male MPC + sealing cap	3
FZB129268	Celsius® FFT 12L (3T, OPTA, TPE), 12L nominal capacity	TPE Clear C-Flex® 374	3/8" x 5/8" x 75 cm (30") and OPTA male	1/4" x 3/8" x 10 cm (4") + Clear C-Flex® 374 1/8" x 1/4" x 50 cm (20") and female Luer® Lock with plug	3/8" x 5/8" x 75 cm (30") and OPTA male;	3

Celsius® FFT (Bag + Shell)

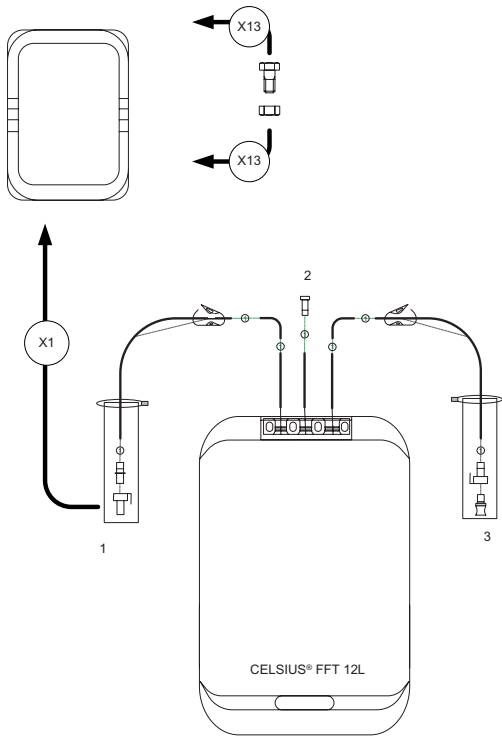


Part Number	Description	Tubing	Port 1	Port 2	Qty./Box
FZB114906	Celsius® FFT 2L (3T, TPE), 2L nominal capacity	TPE Clear C-Flex® 374	$\frac{3}{8}$ " \times $\frac{5}{8}$ " \times 38 cm (15") and male MPC + sealing cap	$\frac{3}{8}$ " \times $\frac{5}{8}$ " \times 38 cm (15") and male MPC + sealing cap + $\frac{3}{8}$ " \times $\frac{5}{8}$ " \times 30 cm (12") + $\frac{1}{8}$ " \times $\frac{1}{4}$ " \times 50 cm (20") and female Luer® Lock with plug	6
FZB129267	Celsius® FFT 2L (3T, OPTA, TPE), 2L nominal capacity	TPE Clear C-Flex® 374	$\frac{3}{8}$ " \times $\frac{5}{8}$ " \times 38 cm (15") and OPTA male	$\frac{3}{8}$ " \times $\frac{5}{8}$ " \times 38 cm (15") and OPTA male + $\frac{3}{8}$ " \times $\frac{5}{8}$ " \times 30 cm (12") + $\frac{1}{8}$ " \times $\frac{1}{4}$ " \times 50 cm (20") and female Luer® Lock with plug	6
FZB212241	Celsius® FFT 6 L (3T, TPE), 6L nominal capacity	TPE Clear C-Flex® 374	$\frac{3}{8}$ " \times $\frac{5}{8}$ " \times 75 cm (30") and male MPC + sealing cap	$\frac{3}{8}$ " \times $\frac{5}{8}$ " \times 75 cm (30") and male MPC + sealing cap + $\frac{3}{8}$ " \times $\frac{5}{8}$ " \times 15 cm (6") + $\frac{1}{8}$ " \times $\frac{1}{4}$ " \times 75 cm (30") and female Luer® Lock with plug	6

Celsius® FFTp (Bag + Shell)

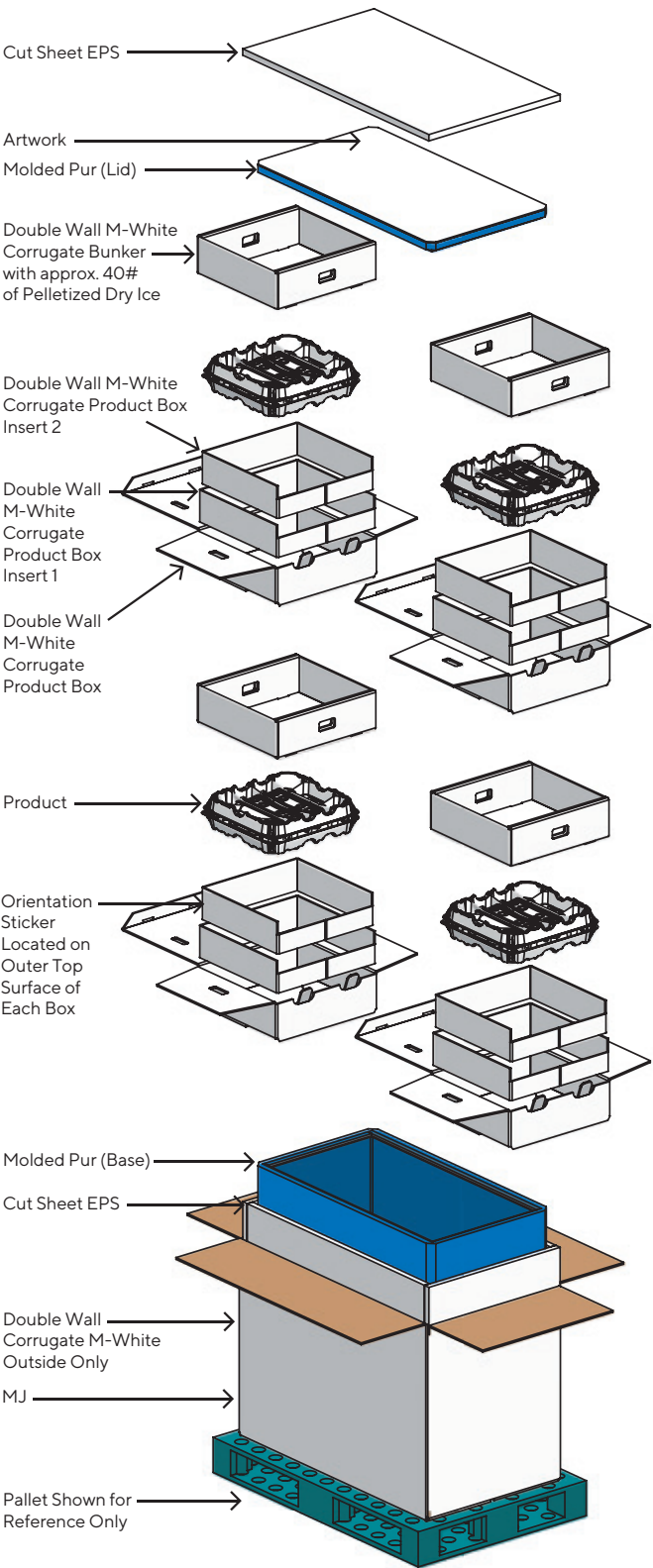
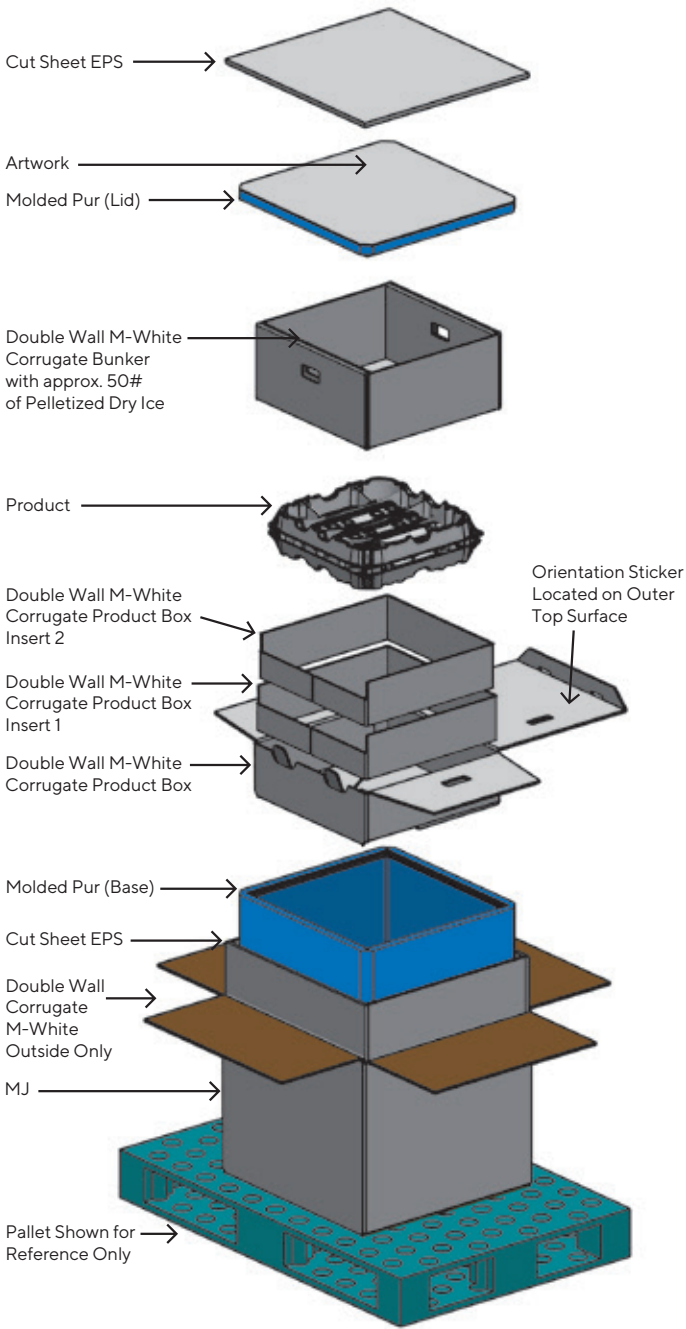


Part Number	Description	Tubing	Port 1	Port 2	Qty./Box
FZB114079	Celsius® FFTp 6L (2T, MPC), for horizontal plate freezer, 6 L nominal capacity	EVA	$\frac{3}{8}$ " \times $\frac{15}{32}$ " \times 40 mm (1.57") + $\frac{3}{8}$ " \times $\frac{15}{32}$ " \times 150 mm (6") + male MPC + sealing cap	$\frac{3}{8}$ " \times $\frac{15}{32}$ " \times 40 mm (1.57") + $\frac{3}{8}$ " \times $\frac{15}{32}$ " \times 150 mm (6") + male MPC + sealing cap	6



Part Number	Description	Tubing	Port 1	Port 2	Port 3	Qty./Box
FZB115784	Celsius® FFTp 12L (2T, MPC), for horizontal plate freezer, 12 L nominal capacity	EVA	$\frac{3}{8}$ " \times $\frac{15}{32}$ " \times 40 mm (1.57") \times $\frac{3}{8}$ " \times $\frac{15}{32}$ " \times 300 mm (12") + male MPC + sealing cap	$\frac{3}{8}$ " \times $\frac{15}{32}$ " \times 40 mm (1.57") + plug	$\frac{3}{8}$ " \times $\frac{15}{32}$ " \times 40 mm (1.57") \times $\frac{3}{8}$ " \times $\frac{15}{32}$ " \times 300 mm (12") + female MPC + sealing plug	2

Celsius® FFT Shippers




Part Number	Description
FTH-SM00103-0006	Shipper; Celsius® FFT 2L 1-unit Shipper
FTH-SM00103-0007	Shipper; Celsius® FFT 2L 4-unit Shipper
FTH-SM00103-0003	Shipper; Celsius® FFT 4L 1-unit Shipper
FTH-SM00103-0004	Shipper; Celsius® FFT 4L 4-unit Shipper
FTH-SM00103-0001	Shipper; Celsius® FFT 6L 1-unit Shipper
FTH-SM00103-0002	Shipper; Celsius® FFT 6L 4-unit Shipper
FTH-SM00103-0005	Shipper; Celsius® FFT 12L 1-unit Shipper

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Specifications subject to change without notice.

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