SARTORIUS

Product Datasheet

Celsius® Pak

Single-Use Containers for Controlled Freeze-Thaw Processes

Benefits

- Single-use
- Scalable
- Proven robustness at low temperature
- Facilitated Validation
- Complete Logistical Solution
- Pre-sterilized, ready-to-use and 100% integrity testing of bag and immediate connection

Product Information

Celsius® Pak combines unique design in disposable container with a protective structural frame. The robustness of the assembly ensures protection, support and ease of handling. Celsius® Pak provides uniform and reproducible freeze and thaw processes for biopharmaceuticals in manufacturing and process development.

Celsius® Pak are specifically designed for controlled freezing, thawing and long term frozen storage of biopharmaceuticals such as:

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

Single-Use System for Controlled Freeze and Thaw Operation

Celsius® Pak are specifically designed to be used with the Celsius® Freeze-Thaw Modules, the only Controlled Freeze-Thaw System in disposable containers. Celsius® Pak are 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.

Celsius® Pak frames provide protection to the contents during all processes, making the assembly robust and reliable and simplifying the handling, storage and shipping of the disposable containers.

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® Pak 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® Pak 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 product over its entire shelf life. A type III drug master file (DMF) has been recorded (applicable for all S71 single-use bags)

Quality Assurance

Sartorius Stedim Biotech Quality Systems for 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.

Technical Data

Specifications

	30 mL Celsius® Pak	100 mL Celsius® Pak	1L Celsius® Pak	2L Celsius® Pak	8.3 L Celsius® Pak	16.6 L Celsius® Pak
Inlet Port	1 on top with female Luer Lock	1 on top with female Luer Lock	MPC Quick Coupling or Plug	MPC Quick Coupling or Plug	1 on top with MPC or OPTA connector and Y splitter with male Luerlock or vent filter	1 on top with MPC or Opta connector and Y splitter with male Luerlock or vent filter
Outlet Port	1 on top with female Luer Lock	1 on top with female Luer Lock	MPC Quick Coupling or Plug	MPC Quick Coupling or Plug	1 on bottom with MPC or Opta connector	1 on bottom with MPC or Opta connector
Vent Filter	–	–	20 cm^2 Hydrophobic Sterilizing Vent Filter	20 cm^2 Hydrophobic Sterilizing Vent Filter	20 cm^2 Hydrophobic Sterilizing Vent Filter	20 cm^2 Hydrophobic Sterilizing Vent Filter
Film	S71	S71	S71	S71	S71	S71
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation

Materials

	30 mL Celsius® Pak	100 mL Celsius® Pak	1L Celsius® Pak	2L Celsius® Pak	8.3 L Celsius® Pak	16.6 L Celsius® Pak
Product Contact Layer	EVAM®[1]	EVAM®	EVAM®	EVAM®	EVAM®	EVAM®
Gas & Moisture Barrier Layout	EVA|EVOH|EVA[2]	EVA|EVOH|EVA	EVA|EVOH|EVA	EVA|EVOH|EVA	EVA|EVOH|EVA	EVA|EVOH|EVA
External Robust, Handling Layer	EVA	EVA	EVA	EVA	EVA	EVA
Fill & Drain Ports	EVA	EVA	EVA	EVA	EVA	EVA
Fill & Drain Transfer Line	EVA tubing or C-Flex®	EVA tubing or C-Flex®	Platinum-Cured Silicone or C-Flex®	Platinum-Cured Silicone or C-Flex®	Platinum-Cured Silicone	Platinum-Cured Silicone
Thermowell	EVA	EVA	–	–	EVA	EVA
Holder	–	–	HDPE[3]	HDPE	–	–

Frames

	8.3 L Celsius® Pak Frame 2G	16.6 L Celsius® Pak Frame 2G
Ends	HDPE	HDPE
Plate & Rods	316 Stainless Steel	316 Stainless Steel
Dimensions (H + W + D)	92.5 cm + 27.5 cm + 19.5 cm (36.4" + 10.8" + 7.7")	92.5 cm + 42.5 cm + 19.5 cm (36.4" + 16.7" + 7.7")

[1] Ethylene Vinyl Acetate Monomaterial
[2] EVA-Ethylene Vinyl Acetate, EVOH-Ethylene Vinyl Alcohol
[3] High Density Polyethylene

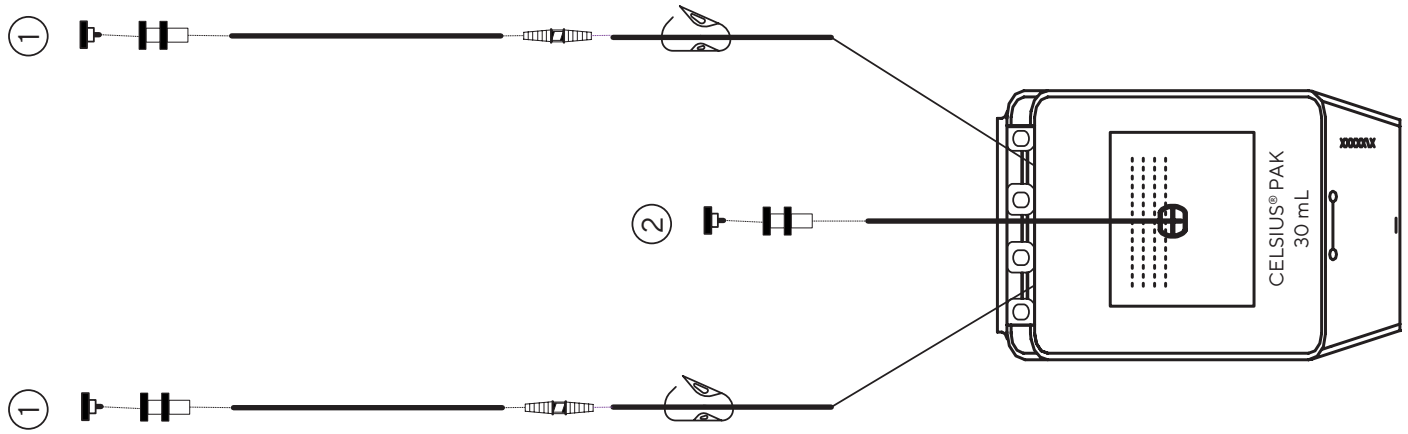
Specifications and material are subject to change.

Ordering Information

Equipment

Part Number	Description	Qty
FTH-CF00016-0009	16.6L Celsius® Pak Frame 2G	1
FTH-CF00008-0015	8.3L Celsius® Pak Frame 2G	1
FTH-CF00000-0029	Celsius® Pak Frame 2G RTD Holder	1
FTH-CF00004-0020	Celsius® Pak 1L & 2L Carrier	1

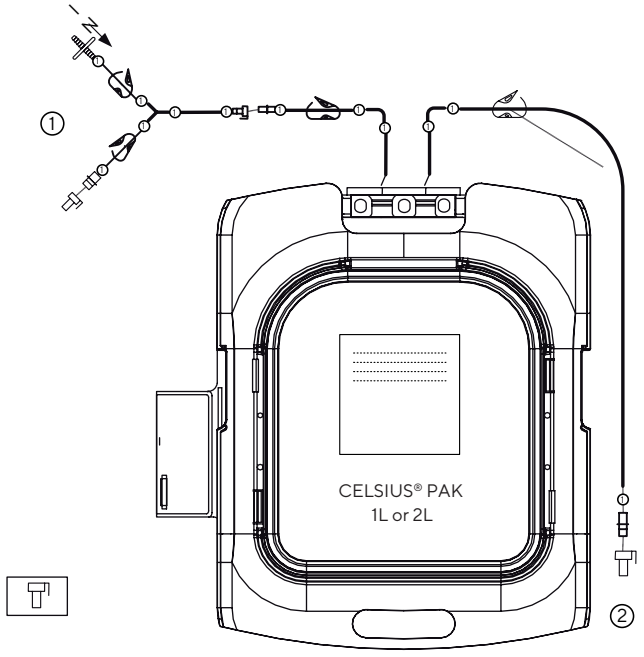
Disposables



Celsius® Pak 30 mL with Thermowell & C-Flex®

Part Number	Description	Tubing	Port 1	Port 2	Qty./Box
FZB114804	Celsius® Pak, 30 mL, Thermowell	EVA	¼" × 5⁄16" × 10 (4") Female LL + plug, pinch clamp	Thermowell sealed end tube 3⁄16" × ¼" × 10 cm (4") Female LL + plug	10
FZB114866	Celsius® Pak, 30 mL, Thermowell, C-Flex®	EVA + Clear C-Flex® 374	⅛" × ¼" × 15 cm (6") + Female LL + plug, pinch clamp	Thermowell sealed end tube 3⁄16" × ¼" × 10 cm (4") Female LL + plug	10
FDP102653	Aluminum Foil Overpouch, Celsius® Pak 30 mL, 250 mL	Alu Foil	N|A	N|A	250
FZB114839	Celsius® Pak, 100 mL, Thermowell	EVA	¼" × 5⁄16" × 10 cm (4") Female LL + plug, pinch clamp	Thermowell sealed end tube 3⁄16" × ¼" × 10 cm (4") Female LL + plug	10
FZB114908	Celsius® Pak, 100 mL, Thermowell, C-Flex®	EVA + Clear C-Flex® 374	⅛" × ¼" × 15 cm (6") + Female LL + plug, pinch clamp	Thermowell sealed end tube 3⁄16" × ¼" × 10 cm (4") Female LL + plug	10
FDP102667	Aluminum Foil Overpouch, Celsius® Pak 100 mL, 500 mL	Alu Foil	N|A	N|A	100

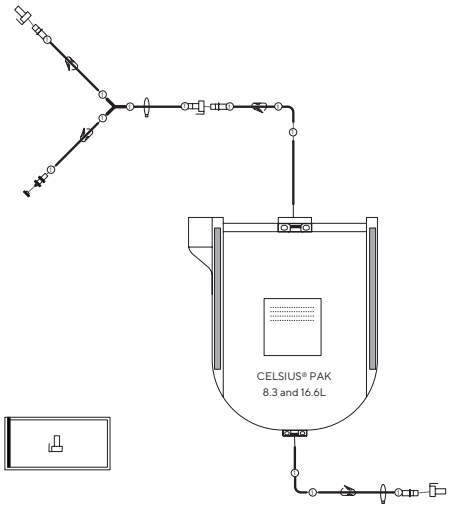
Disposables



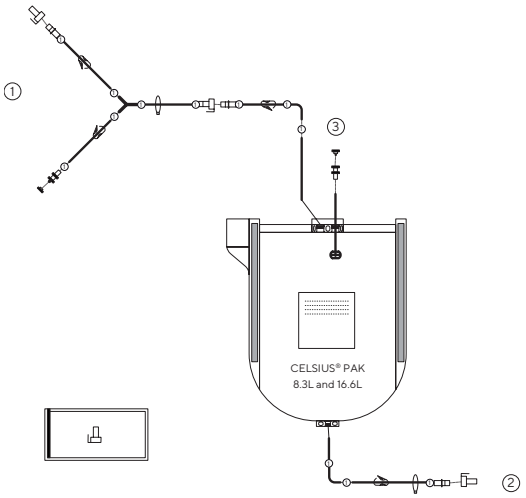
Celsius® Pak 1L or 2L with MPC

Part Number	Description	Tubing	Port 1	Port 2	Qty./Box
FZB115358	Celsius® Pak, 1L, TPE, Midisart BV	EVA + Silicone (pt)	EVA ¼" × 5⁄16" × 6 cm (2.36") + C-Flex® ¼" × ⅜" × 30 cm (12") and Plug + Silicone (pt) ¼" × ⅜" × 15 cm (6") and Midisart® vent filter	EVA ⅜" × 15⁄32" × 4 cm (1.57") + C-Flex® ¼" × ⅜" × 30 cm (12") and Plug	8
FZB115319	Celsius® Pak, 1 L, MPC connectors, Midisart BV	EVA + Silicone (pt)	EVA ⅜" × 15⁄32" × 4 cm (1.57") + Silicone (pt) ¼" × ⅜" × 10 cm (4") + Silicone (pt) ¼" × ⅜" × 10 cm (4") + Silicone (pt) ¼" × ⅜" × 10 cm (4") and Midisart® vent filter + Silicone (pt) ¼" × ⅜" × 10 cm (4") and male MPC + sealing cap	EVA ⅜" × 15⁄32" × 4 cm (1.57") + Silicone (pt) ¼" × ⅜" × 30 cm (12") and male MPC + sealing cap	8
FZB115366	Celsius® Pak, 2L, TPE, Midisart BV	EVA + Silicone (pt)	EVA ¼" × 5⁄16" × 6 cm (2.36") + C-Flex® ¼" × ⅜" × 30 cm (12") and Plug + Silicone (pt) ¼" × ⅜" × 15 cm (6") and Midisart® vent filter	EVA ⅜" × 15⁄32" × 4 cm (1.57") + C-Flex® ¼" × ⅜" × 50 cm (20") and Plug	4
FZB115322	Celsius® Pak, 2 L, MPC connectors, Midisart BV	EVA + Silicone (pt)	EVA ⅜" × 15⁄32" × 4 cm (1.57") + Silicone (pt) ¼" × ⅜" × 0 cm (4") + Silicone (pt) ¼" × ⅜" × 10 cm (4") + Silicone (pt) ¼" × ⅜" × 10 cm (4") and Midisart® vent filter + Silicone (pt) ¼" × ⅜" × 10 cm (4") and male MPC + sealing cap	EVA ⅜" × 15⁄32" × 4 cm (1.57") + C-Flex® ¼" × ⅜" × 45 cm (18") and Plug	4

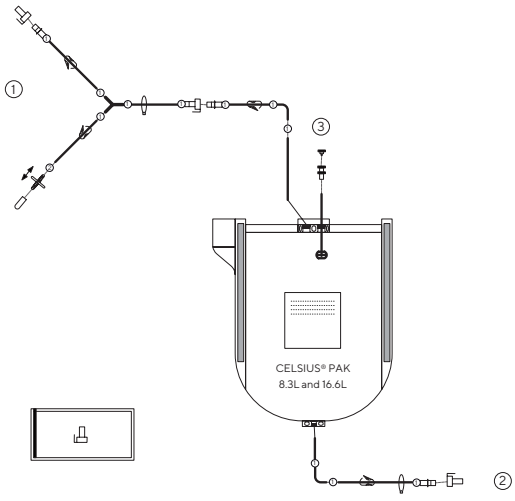
Disposables



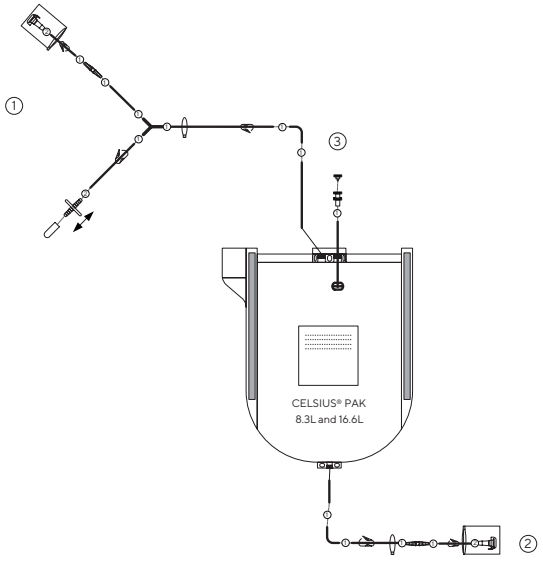
Celsius® Pak 8.3L or 16.6L without thermowell



Celsius® Pak 8.3L or 16.6L with thermowell



Celsius® Pak 8.3L or 16.6L with vent filter



Celsius® Pak 8.3L or 16.6L with thermowell, aseptic connection device and vent filter

Disposables

Part Number	Description	Tubing	Port 1	Port 2	Port 3	Qty./Box
FZB103478	Celsius® Pak, 8.3L, without Thermowell	EVA + Silicone (pt)	EVA ⅜" × 15⁄32" × 10 cm (4") + Silicone (pt) ⅜" × ⅝" × 30 cm (12") + Silicone (pt) ⅜" × ⅝" × 60 cm (23.6") + Silicone (pt) ¼" × ⅜" × 10 cm (4") and male LL + cap + Silicone (pt) ⅜" × ⅝" × 10 cm (4") and male MPC + sealing cap	EVA ⅜" × 15⁄32" × 4 cm (1.57") + Silicone (pt) ⅜" × ⅝" × 175 cm (69") and male MPC + sealing cap	–	12
FZB103152	Celsius® Pak, 8.3L, Thermowell	EVA + Silicone (pt)	EVA ⅜" × 15⁄32" × 10 cm (4") + Silicone (pt) ⅜" × ⅝" × 30 cm (12") + Silicone (pt) ⅜" × ⅝" × 60 cm (23.6") + Silicone (pt) ¼" × ⅜" × 10 cm (4") and male LL + cap + Silicone (pt) ⅜" × ⅝" × 10 cm (4") and male MPC + sealing cap	EVA ⅜" × 15⁄32" × 4 cm (1.57") + Silicone (pt)⅜" × ⅝" × 175 cm (69") and male MPC + sealing cap	3⁄16" × ¼" × 43 cm (17") + Female LL + plug (thermo well sealed end tube)	12
FZB115370	Celsius® Pak, 8.3 L, Thermowell, OPTA, Midisart® BV	EVA + Silicone (pt)	EVA ⅜" × 15⁄32" × 110 cm (4") + Silicone (pt) ⅜" × ⅝" × 75 cm (30") + Silicone (pt) ⅜" × ⅝" × 15 cm (6") and Midisart® vent filter + Silicone (pt) ⅜" × ⅝" x15 cm (6") and OPTA female	EVA ⅜" × 15⁄32" x4 cm (1.57") + Silicone (pt) ⅜" × ⅝" × 182 cm (72") and OPTA male	3⁄16" × ¼" × 43 cm (17") + Female LL + plug (thermowell sealed end tube)	12
FZB115334	Celsius® Pak, 8.3 L, Thermowell, Midisart® BV	EVA + Silicone (pt)	EVA ⅜" × 15⁄32" × 10 cm (4") + Silicone (pt) ⅜" × ⅝" × 0 cm (12") + Silicone (pt) ⅜" × ⅝" × 60 cm (23.6") + Silicone (pt) ⅜" × ⅝" × 15 cm (6") and Midisart® vent filter + Silicone (pt) ⅜" × ⅝" × 15 cm (6") and male MPC + sealing cap	EVA ⅜" × 15⁄32" × 4 cm (1.57") + Silicone (pt) ⅜" × ⅝" × 175 cm (69") and male MPC + sealing cap	3⁄16" × ¼" × 43 cm (17") + Female LL + plug (thermowell sealed end tube)	12
FZB115373	Celsius® Pak, 16.6L, without Thermowell	EVA + Silicone (pt)	EVA ⅜" × 15⁄32" × 10 cm (4") + Silicone (pt) ⅜" × ⅝" × 40 cm (15.8") + Silicone (pt) ⅜" × ⅝" × 50 cm (20") + Silicone (pt) ¼" × ⅜" × 10 cm (4") and female LL + cap + Silicone (pt) ⅜" × ⅝" × 10 cm (4") and male MPC + sealing cap	EVA ⅜" × 15⁄32" × 4 cm (1.57") + Silicone (pt) 3⅜" × ⅝" × 200 cm (79") and male MPC + sealing cap		6
FZB114861	Celsius® Pak, 16.6L, Thermowell	EVA + Silicone (pt)	EVA ⅜" × 15⁄32" × 10 cm (4") + Silicone (pt) ⅜" × ⅝" × 40 cm (15.8") + Silicone (pt) ⅜" × ⅝" × 50 cm (20") + Silicone (pt) ¼" × ⅜" + 10 cm (4") and male LL + cap + Silicone (pt) ⅜" × ⅝" × cm (4") and male MPC + sealing cap	EVA ⅜" × 15⁄32" × 4 cm (1.57") + Silicone (pt) ⅜" × ⅝" × 200 cm (79") and male MPC + sealing cap	3⁄16" + ¼" + 43 cm (17") + Female LL + plug (thermowell sealed end tube)	6
FZB115289	Celsius® Pak, 16.6 L, Thermowell, OPTA, Midisart® BV	EVA + Silicone (pt)	EVA ⅜" × 15⁄32" × 10 cm (4") + Silicone (pt) ⅜" × ⅝" × 75 cm (30") + Silicone (pt) ⅜" × ⅝" × 5 cm (6") and Midisart® vent filter + Silicone (pt) ⅜" × ⅝" × 15 cm (6") and OPTA female	EVA ⅜" × 15⁄32" × 4 cm (1.57") + Silicone (pt) ⅜" × ⅝" × 205 cm (81") and OPTA male	3⁄16" + ¼" + 43 cm (17") + Female LL + plug (thermowell sealed end tube)	6
FZB115377	Celsius® Pak, 16.6 L, Thermowell, Midisart® BV	EVA + Silicone (pt)	EVA ⅜" × 15⁄32" × 10 cm (4") + Silicone (pt) ⅜" × ⅝" × 40 cm (15.7") + Silicone (pt) ⅜" × ⅝" × 50 cm (20") + Silicone (pt) ¼" × ⅜" × 15 cm (6") and Midisart® vent filter + Silicone (pt) ⅜" × ⅝" × 15 cm (6") and male MPC + sealing cap	EVA ⅜" × 15⁄32" × 4 cm (1.57") + Silicone (pt) ⅜" × ⅝" × 200 cm (79") and male MPC + sealing cap	3⁄16" + ¼" + 43 cm (17") + Female LL + plug (thermowell sealed end tube)	6

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