



## Celsius® FFT

### Directions for Use



#### Introduction

Celsius® FFT is a pre-sterilized "ready-to-use" container, composed of a bag and a protective shell, designed for freezing and thawing biopharmaceutical solutions in commercially available equipment such as laboratory freezer, walk-in freezer, cold room, temperature controlled cabinet or water bath.

Celsius® FFT is available in 2L, 4L, 6L, and 12L sizes. Celsius® FFT containers are typically supplied with three lines; the standard configuration has two 3/8" ID tubing lines with MPC connectors and a sampling line having 1/8" ID tubing and a Luer® connector. The configuration may be customized for a specific application.

#### Precautions

The Celsius® FFT container has been designed to provide a high degree of robustness for transportation and storage of material in both liquid and frozen states. However, it is important to exercise caution when handling Celsius® FFT containers. Take care not to drop containers or impact them against other surfaces. Use two hands when carrying, and carry only one container at a time. If you have difficulty handling the container, or need to transport multiple containers, use a cart.



The round holes on the face of the container provide a view of the contents of the bag. Keep sharp objects such as tools at a distance.

Use appropriate personal protective equipment (PPE) such as insulated gloves when handling frozen Celsius® FFT containers. Not only this will protect you but it will also reduce the risk of dropping or mishandling the containers.



Celsius® FFT containers should be oriented horizontally when stored.

#### Unpacking

Celsius® FFT containers are supplied double-bagged in a protective cardboard carton. Use care when opening the carton so as not to damage the packaging.

#### Filling

Because the sterilization process has a tendency to irreversibly seal clamped tubing, Celsius® FFT containers are shipped with the pinch clamps in the open position. Be sure to close all clamps before use.

One of the 3/8" ID lines is for filling and the other is for draining. Since they are identical it does not matter which line is used for filling.

If required by your process, place the container under a laminar flow hood. The container should be in a horizontal orientation. Remove the filling line from the protective perimeter channel. Remove the cap from the fill line. Connect the fill line to your equipment, open the fill line pinch clamp, and fill. It is normal for the shell to expand slightly while filling. The nominal fill volume is indicated on the product label, which may be found on the box or on the overpouch. Do not overfill as this may interfere with stacking and may further jeopardize the integrity of the container during use.

Some Celsius® FFT designs include a sampling line; use as required by your process.

Once filling is complete, close the pinch clamp and place the cap on the fill line connector. If your process requires tube sealing, do it now. Finally, stow the fill line in the protective perimeter channel.

#### Stacking

Celsius® FFT containers have features that enable stacking of one container atop another. Each container in the stack must be of the same type and must have the same orientation. For example, if the first container is oriented with the logo up and the ports facing you, then all containers stacked on top of it should also have the logo up and the ports facing you. Do not stack more than 5 units high.



### Freezing

Celsius® FFT containers may be frozen in commercially available equipment such as laboratory freezers, blast freezers, and walk-in freezers. The product is qualified for use at temperatures as low as -70°C. Contact Sartorius Stedim Biotech to discuss use at lower temperatures.

### Thawing

Celsius® FFT containers may be thawed in a water bath or in free air. Viewing ports are provided for visual inspection of the container contents during thawing. The maximum recommended temperature for Celsius® FFT containers is 40°C.

### Draining

Before draining the container, be sure that it is fully thawed. The draining operation is similar to filling. If required by your process, place the container under a laminar flow hood. Remove the drain line from the protective perimeter channel. Remove the cap from the drain line. Connect the drain line to your dispensing equipment, open the drain line pinch clamp, and then drain by gravity or by pumping out. The container may be oriented vertically at the end of the draining operation in order to maximize product recovery. Close the pinch clamp, disconnect your equipment, and place the cap on the drain line connector.

### Disassembly and Recycling

Before disassembling the shell, be sure that the Celsius® FFT container is fully drained.

To disassemble a Celsius® FFT container, you will need the following:

- Two M10 socket wrenches; a power driver may be substituted for one of the wrenches.

To disassemble the shell, place one wrench on the screw and the other on the nut and turn each wrench counterclockwise.

Remove the bag from the shell and set aside for testing or disposal as required.

The protective shell is made of polyethylene and can be recycled after disassembly.

### Reuse

Sartorius Stedim Biotech provides Celsius® FFT containers ready for use, fully assembled and pre-sterilized. The outer shell of the container may be reused; pre-sterilized biopharm bags may be ordered separately. If you reuse the shell, Sartorius Stedim Biotech cannot take responsibility for issues related to the maintenance of used shells or for improper assembly of a bag in a used shell.

Before each use, inspect for damage including buckling, tearing, and damaged fastener holes. Discard any damaged parts.

Each Celsius® FFT container has two shell parts, an "A" part and a "B" part. The "A" part is readily identified by the printed Sartorius Stedim logo.

To assemble a Celsius® FFT container you will need the following:

- "A" shell
- "B" shell
- Biopharm bag assembly
- Two M10 socket wrenches
- Celsius® FFT 2L: 8 × M6 × 1.0 nut  
8 × M6 × 1.0 × 12mm screws
- Celsius® FFT 4L: 7 × M6 × 1.0 nut  
7 × M6 × 1.0 × 12mm screws
- Celsius® FFT 6L: 8 × M6 × 1.0 nut  
8 × M6 × 1.0 × 12mm screws
- Celsius® FFT 12L: 13 × M6 × 1.0 nut  
13 × M6 × 1.0 × 12mm screws



Place a B shell flat on a table, with the bag cradle facing up. Place a bag in the cradle, and arrange it so that the edges of the bag are inside of the locator posts around the perimeter of the shell. Align the obround handle slot with the fastening detail on the shell.

Place the A shell on top, taking care not to pinch the bag between the two shells. Fasten two or three fasteners by hand in order to fix the two shells together. Finish the assembly by installing the remaining fasteners. Using the socket wrenches, tighten each fastener by turning the wrenches clockwise.

### Ordering Information

Part Number	Description	Qty/box
FZB114906	Celsius® FFT 2L (3T, TPE)	6
FZB212401	Celsius® FFT 4L (3T, TPE)	6
FZB212241	Celsius® FFT 6L (3T, TPE)	6
FZB212435	Celsius® FFT 12L (3T, TPE)	3
FZB115991	Biopharm bag 2L (3T, TPE)	10
FZB212530	Biopharm bag 4L (3T, TPE)	10
FZB212521	Biopharm bag 6L (3T, TPE)	10
FZB212916	Biopharm bag 12L (3T, TPE)	10

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