



# Celsius<sup>®</sup> FFT: Safeguarding Your Drug Substances in Conventional Freeze & Thaw Manufacturing

- Maximum Product Security
- Simple, Easy-to-Use
- Improves Process Efficiency
- Creates Process Flexibility



# Celsius® FFT



Celsius® FFT (Flexible Freeze and Thaw) are sterile, pre-assembled, single-use containers for freezing & thawing biopharmaceutical solutions in commercially available equipment.

Celsius® FFT is a unique bag-in-shell system that replaces traditional freezing and thawing methods.

Celsius® FFT provides exceptional robustness and confidence when handling the frozen container. Purpose-designed Shippers further maximize mechanical and thermal protection during transportation.

## Maximum Product Security

### Safeguards BDS Throughout Lifecycle

Same quality but thicker Flexboy® S71 film plus unique thermo-formed shell protects your bulk drug substances at low temps; proven in real & extreme process conditions

### Confident Handling

Contoured shell protects tubing, connectors and bag ports, and ensures confident handling when frozen

### Pre-Qualified Shippers

Purpose-designed single-use shippers pass rigorous robustness test program and provide excellent thermal performance of > 96 hours at below -40°C

## Improves Process Efficiency

### Stackable

Ribbed shell corners provide stable stacking; stack FFT up to 5-high for efficient use of freezer space

### One-Way Logistics

Purpose-designed shipper is constructed of recyclable materials and uses dry ice to allow efficient disposal after use

### One Supplier

Bag, shell and shipper all provided by Sartorius for single-point accountability and process expertise

## Simple, Easy-to-Use

### Closed System Processing

100% bag chamber leak test, pre-assembled shell and connectors, and gamma-sterilized ensure successful aseptic processing, every time

### Easy-to-Use

Container design and tubing configurations promote easy, confident operations for operator

### Consistent

Shell design provides spacing and vents between stacked FFT for consistent heat transfer to each unit and ensures batch-to-batch consistency

## Creates Process Flexibility

### Easy Implementation

Drop-in replacement to bottles | carboys and uses existing freezers and thawing methods

### Configurable

FFT can be configured to fit to process needs and can be designed into manifolds

### Scalable

Product range up to 12L fill volumes; common film to Celsius®-Paks for efficient process development and samples in 30mL Celsius®-Paks

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