

Compatible with single-use bags of all manufacturers and sizes



# RoSS.pFTU

Scalable Plate-Freezer

Compatible with single-use bags of all manufacturers and sizes.

### Ross.pftU

# Scale Overview Freeze & Thaw

### **MANUFACTURING**

**CLINICAL PHASE** 

COMMERCIAL

LARGE SCALE
COMMERCIAL

BENCHTOP up to 10L



MID up to 100L LARGE up to 400

up to 10



**BENCHTOP** 



LAB SCALE



MID SCALE



LARGE SCALE



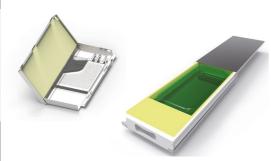
**LARGE SCALE** 

volume per batch {up to 10L}



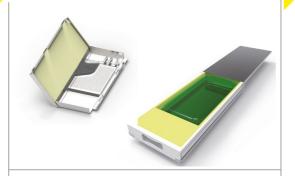
Benchtop plate freezer for clinical studies, clinical trials and cell and gene therapies

Low-volume freezing & thawing of one RoSS® shell or multiple RoSS.KSETs carrying up to 10L volume per batch {up to 10L}



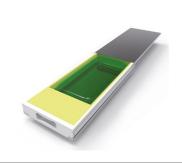
Laboratory plate freezer for clinical studies, clinical trials and cell and gene therapies

Low-volume freezing & thawing of one RoSS® shell or multiple RoSS.KSETs carrying up to 10L volume per batch {up to 100L}



Mid scale plate freezer for small batches and process validation

Freezing & thawing of multiple small-sized RoSS® shells or RoSS.KSETs or max. 5 large-sized RoSS® shells carrying 20L bags volume per batch {up to 400L}



Routine batch freezing

Plate-based freezing system for multiple RoSS.KSETs or up to 16 RoSS® shells carrying 20L bags or up to 24 RoSS® shells carrying 10L bags

volume per batch **{500L}** 



Freezing of extra large volumes and bulk drug substances

Plate-based freezing system for 10 RoSS® shells carrying 50L bags

# RoSS.pFTU

#### FREEZE-THAW YOUR DRUG SUBSTANCE

- In any single-use bag\*
- Easy to implement into existing infrastructure
- At highest possible speed & accuracy
- For best product stability results

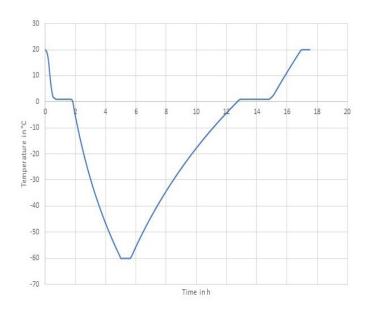
\*protected by RoSS and designed to your preferred bag

#### SCIENCE - FREEZING AND THAWING TEMPERATURE TREND

Freezing and thawing from 8 to 200L (up to 24 RoSS® Shells) and beyond

#### **Conclusion**

The freezing curves and kinetics are very similar and independent of the RoSS® shells loading (min. or full load) as long as the individual RoSS® Shells are identically set up (bag size and filling volume). That's one of the advantages and differentiators of the RoSS® shell that is achieved thanks to the design and combination of polyethylene sidewalls and stainless steel on top and bottom.



### Advantages of plate based freezers over blast freezers

- Energy and heat transport take place directly
- The cooling comes from above and below simultaneously
- Last point of freeze is located at the edges of the symmetry axis. Thus, there is no entrapment of a liquid core that may lead to the bursting of the shell
- No impact on heat transfer because of different stacking or partial filling
- Allows for improved monitoring of the process
- Possibility of partial filling with consistent water column
- Improved scalability due to consistent water column

Reduced cryo concentration effects

- Reduced pH-shift
- Reduced protein aggregation
- Decreased exposure of the protein to extreme conditions (The cryo concentration leads to a pH-shift, high salt and protein concentration. This condition stresses the protein, which subsequently leads to denaturation.)
- Decreased interaction time with the ice front