

NORMABLAST SHIELD

Single-use systems for safe and consistent freezing, storage, transportation and thawing of biopharmaceuticals



One shield suits it all

Improve freeze-thaw quality while simplifying operations

NORMABLAST Shield is the only single-use system for freezing, storage, transport and thawing biopharmaceuticals in bottles. Acts as in an individual airstream for each bottle leading to high freeze-thaw consistency, while minimizing operator handling during the complete cold chain.

The NORMABLAST Shield is designed to attenuate the exposure of biopharmaceuticals to the mechanical stresses of freezing, caused by internal (ice) pressure.

It also allows safe transport and storage, because the shield works as a thermal insulator and also allows significant absorptions of physical impacts in case of mishandling.



Fig. 1 - Assembling the NORMABLAST SHIELD

- **Single-use device** for freezing, storage, transport and thawing
- **High freeze-thaw** reproducibility and consistency
- **Avoids the mechanical stresses of freezing** –
pressure-safe freezing
- **Easy to handle and with light weight**
- **Provides physical protection** to bottles
in case of mishandling

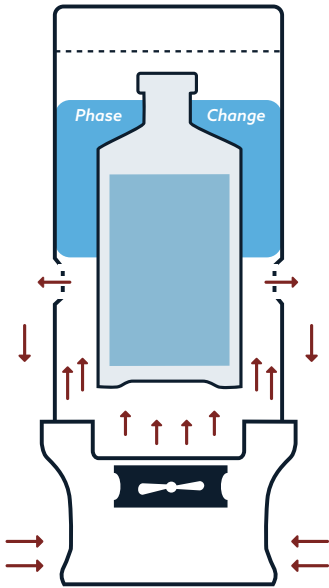
The only single-use system

for freezing, storage, transport and thawing

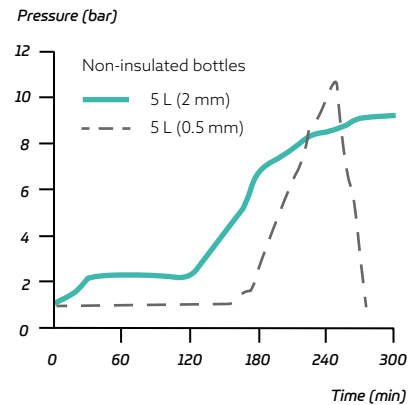
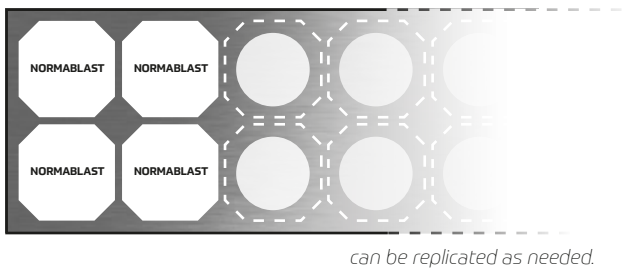
biopharmaceuticals in bottles



Preserving quality and improving cold chain operations



When a batch of multiple bottles is being frozen or thawed, the heat transfer conditions can often vary significantly, depending on if they are closer to walls or ventilation. This leads to deviations in freezing or thawing times (can reach several hours), which compromises product quality and causes operational hurdles. The NORMABLAST Shield acts as an individual airstream allowing all containers to experience the same thermal history.



Bottles are relatively robust compared to bags, however they suffer from the freezing pressure (Fig. 2), which is a cause of mechanical stresses for biopharmaceuticals and containers.

When a solution is freezing, the top of the liquid freezes rapidly, forming an ice-crust that encloses the remaining liquid phase, causing the pressure of the confined liquid to increase. Air bubbles are typically entrapped within the ice-crust forming a foamy-like ice structure which presents a higher interfacial tension.

With the NORMABLAST Shield, the ice-crust is reduced and consequently the internal pressure is reduced, avoiding mechanical and interfacial stresses and preserving the product quality.



Fig. 2 - Above is represented the pressure rise inside 5 L bottles with different wall thickness during freezing. The thinner bottle was able to release the internal pressure by substantial deformation and a convex bottom (at the bottom left). The thicker bottle deforms slightly but the internal pressure was kept high (at the bottom right).

NORMABLAST Freeze-Thaw System

(Large-Scale) for multiple bottles

This NORMABLAST system can be designed to work with different sizes of NORMABLAST Shield, either for bottles or bags, as well. It is **scalable**, can be **tailor-made**, dimensioned and **built according** to the required **capacity** of customers.



Freezes and thaws batches of multiple of bottles or bags ensuring a consistent performance, regardless of the number of containers, or the moment in time.

NORMABLAST Pilot and Lab

for a few bottles and scale-down setups

The **NORMABLAST Pilot** system is compatible with the NORMABLAST Shield and is designed for the early development stage, for small-scale freezing and thawing of a few bottles or bags.

The **NORMABLAST Lab** is an independent and portable system to be adapted to existing controlled temperature chambers or freezers. Can convert a conventional freezer/thawer in a high-performance freeze-thaw system.



Both systems (Pilot and Lab) can also be used for scale-down studies, to mimic the NORMABLAST systems or other freeze-thaw equipment for bags or bottles.

Digital Twin – CFD simulation lab

to anticipate hurdles and validate methods,
saving product



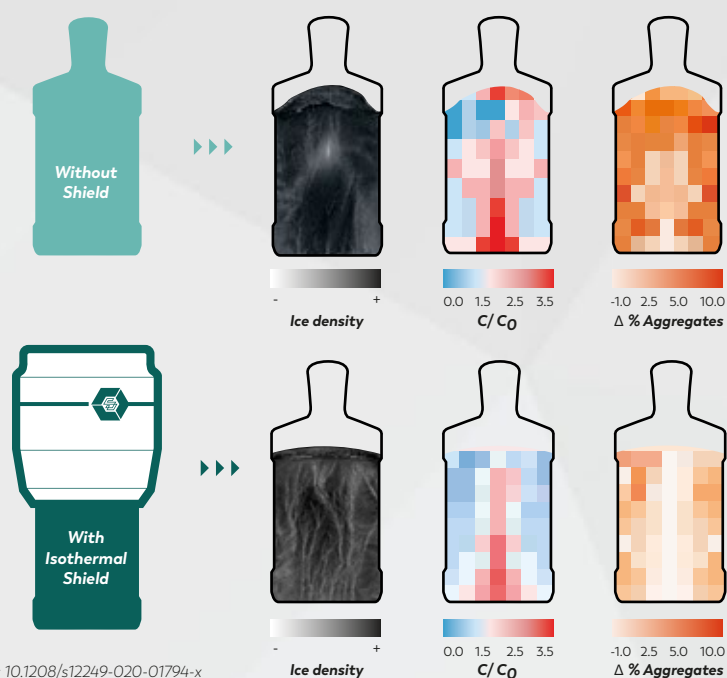
A cloud-based Computational Fluid Dynamics (CFD) platform that simulates and mirrors the freeze-thawing processes implemented on the NORMABLAST systems.

Fig. 3 - Bottle with frozen solution (left) and its corresponding digital model (right).

Case study

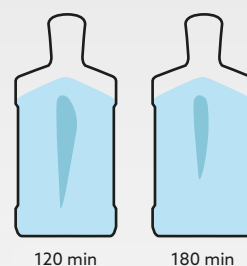
Reducing interfacial and
mechanical stresses in bottles

Without the NORMABLAST Shield the top of the liquid freezes rapidly, forming an ice-crust that encloses the remaining liquid phase, increasing the internal (ice) pressure. With the NORMABLAST Shield, the ice crust is reduced, attenuating the mechanical and interfacial stresses (Fig. 4).



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Without NORMABLAST Shield



With NORMABLAST Shield

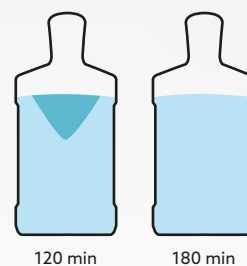


Fig. 4 - Comparison between bottles with and without the NORMABLAST Shield. The images show, from left to right, the MRI of the ice matrix, the local concentration of protein (defined as C/C_0), measured after sampling from the frozen solution, and the local variation of $\Delta\%$ of aggregates (relative to initial solution before freezing).

Customizable to your needs

the NORMABLAST SHIELD can be configured for bottles of different sizes and shapes.



Fig. 5 - NORMABLAST SHIELD with 2 L bottle



Fig. 6 - NORMABLAST SHIELD with 5 L bottle with aseptic closures

PRECISION CRYOSYSTEMS



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