

CryoVault[®]

Freeze & Thaw Platform



CryoVault® Freeze & Thaw Platform

CryoVault® is a scalable, robust, completely single-use freeze and thaw platform for biopharmaceuticals. This end-to-end solution provides the industry leading implementation of this demanding unit processing operation.



SCALABLE

- CryoVault® can be seamlessly scaled from process development through clinical to full scale commercial production. Consistency in freeze-thaw performance throughout the various scales of operation is a key performance attribute of the system.
- The platform is not only scalable from a freeze-thaw performance perspective, but also from an operational standpoint. CryoVault® scales operationally with your volume requirements by providing containers that can hold up to 75 L, along with all the associated material handling infrastructure.



ROBUST

- CryoVault® addresses the need to provide fluid integrity. The system uses robust rigid wall single-use assemblies to protect your product from fill to dispense. We understand the value of your critical biopharmaceuticals and this system provides the secure protection required.
- The platform is based on robust single-use assemblies and an integrated infrastructure that provides process solutions to ensure the security of your product.

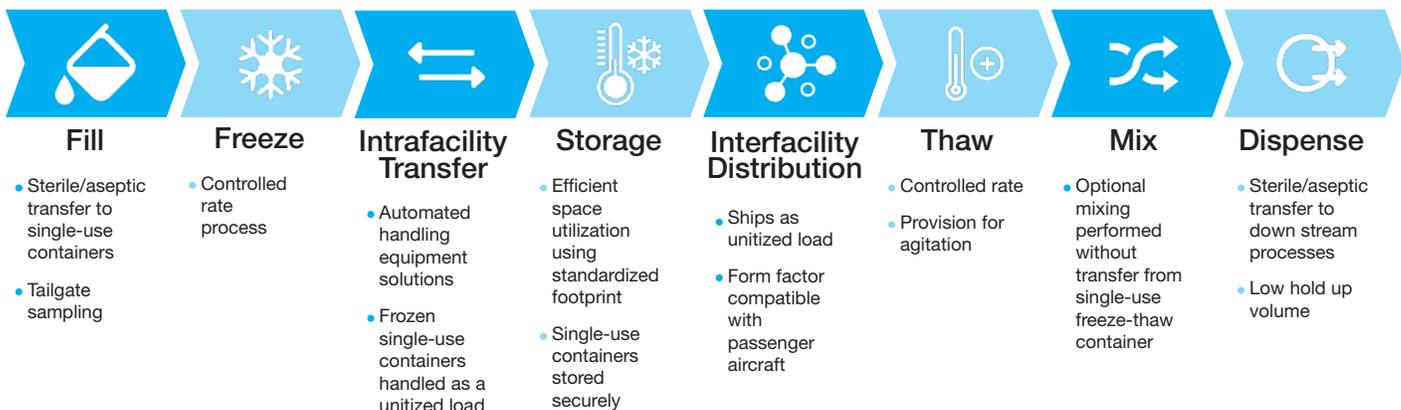


SINGLE-USE

- CryoVault® embraces the operational benefits associated with single-use systems. It is cost effective, simple to operate, clean, and can even be recycled.

End-to-End Process Solution

The CryoVault® platform provides an end-to-end process solution for your entire freeze-thaw process. The system has been proven to provide robust performance from fill to dispense, and every process step in between.



CryoVault® has been designed as a modular system to accommodate a high degree of flexibility for different batch volumes. All system components seamlessly integrate with each other. This allows the end-user to tailor the system implementation to their specific process needs. Meissner's applications engineering team will assist in this process.

Modular Platform

CryoVault® is a modular freeze and thaw platform composed of four components.



① Single-Use Assemblies

The single-use assemblies are rigid HDPE containers with configurable fluid path assemblies referred to as top works. The containers feature a consistent freeze-path length throughout the different sizes to ensure process scalability. Single-use assemblies are currently available in the following volumes:

Process Development and Stability Scale

Clinical and Production Scale



The clinical and commercial production scale single-use containers feature an integrated protective shroud that protects the fluid path assemblies during freeze-thaw, transport, and storage. Each assembly is individually serialized to provide material traceability. The rigid container component is manufactured from a medical grade HDPE resin, which has been rigorously tested, inclusive of the BPOG extractables protocol, and has a DMF. The largest container's ¼" (6.4 mm) thickness provides exceptional robustness and a burst pressure exceeding 50 psi (3.4 bar), while the 20 L container has a burst pressure in excess of 100 psi (6.9 bar). Although burst pressure is only one facet of overall single-use system integrity, providing these values is a good indication of the industry step change in robustness that CryoVault® offers.



② Freeze/Thaw Components

There are two primary clinical and commercial production scale freezer options for the CryoVault® platform. The large scale freezer can accommodate up to four containers of 100 L, totaling a 300 L nominal working volume, or sixteen single-use containers of 20 L, totaling 256 L of nominal working volume, or any combination of 100 L and 20 L containers. The smaller scale freezer is available to accommodate up to a 96 L nominal working volume or six single-use containers of 20 L. Both freezers are programmable to provide fully controlled freeze and thaw cycles. Agitation, provided via gentle oscillation, is available for thawing sensitive proteins and expediting the thaw process.



③ Distribution Components

Shippers, which are designed to provide robust distribution performance, are a key component of the CryoVault® platform. These shippers are robust, and are designed to ship on commercial aircraft, which provides more transportation options than those that can only fit on dedicated freight airplanes. These shippers have been tested per ASTM D4169 and ISTA 3E protocols.

④ Material Handling Components

Material handling infrastructure is one of the most overlooked components of any single-use systems implementation, and it is especially critical for freeze-thaw applications. Meissner offers a wide variety of pre-qualified material handling solutions for CryoVault® at various scales of implementation. These include:

- Automated lifts and pallet handling solutions that facilitate programmable and repeatable material transfer between various process steps
- Integrated pallets that can accommodate up to 300 L of liquid in a euro-pallet footprint
- Carts designed specifically for transport, fill and dispense operations



100 L and 20 L share the same hardware.
(75 L and 16 L nominal working volumes)

Ordering Information

The CryoVault® platform's modular component categories create a menu of options that can be tailored to your specific process needs. Meissner will work with your team to identify and recommend the best components for your process.