

VIA Capsule cryogenic shipment system

CELL THERAPY LOGISTICS

The VIA Capsule™ system provides the conditions and functionality required to ensure cell viability is maintained throughout cell therapy logistics. This smart, liquid nitrogen-free cryogenic shipper (Fig 1) was designed by cryobiologists.

The VIA Capsule system:

- **Delivers efficiencies by eliminating complexity, risks, and costs inherent in liquid nitrogen shipments:** Liquid nitrogen-free technology simplifies shipping preparation and processes for the cell therapy manufacturer, courier, and hospital. It also reduces the total carbon footprint of cryogenic logistics.
- **Provides predictable performance with continually validated and fully traceable shipping:** Integrated smart monitor uploads condition and GPS information to the Chronicle™ software platform. Available in real time.
- **Allows users to manage unexpected events when shipping with World Courier™:** If a delay occurs during transit, cryogenic temperature is maintained using VIA Capsule Charging Stations within the global World Courier quality ecosystem.
- **Enables flexible manufacturing, logistics, and patient scheduling:** Cryogenic hold time is extended when the shipper unit is docked with the electronic cryocooler engine. This converts the shipper unit into a temporary cryogenic storage container.



Fig 1. The VIA Capsule system is comprised of a cryocooler engine and shipper unit with integrated smart monitor.

Compact shipper, compatible with most cryobags and cryovials

Using only electricity, the system's cryocooler cools the shipper unit to cryogenic temperatures prior to transportation. When the cryopreserved cellular product is ready, the cryocooler is removed and the cell containers are securely loaded. Then, the shipper unit is sealed with a low-profile transport cap (Fig 2). Finally, the compact shipper unit is boxed and ready for transit.



Fig 2. The VIA Capsule shipper unit with transport cap and retracted wheels, ready for transit.

Predictable, visible, continually validated shipping

The VIA Capsule shipper can be charged to -192°C . After the cryocooler is disconnected, the temperature rises gradually but stays below cryogenic temperatures ($< -120^{\circ}\text{C}$) for up to 5 days of transit (Fig 3).

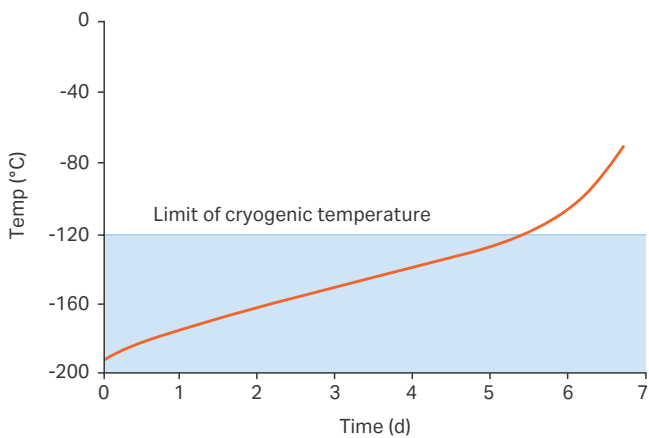


Fig 3. Temperature profile shows gradual warming of shipper unit during transit, from -196°C to -120°C over 5 days.

Throughout the logistics process, the integral smart monitor detects the shipper's internal temperature, environmental conditions, and GPS information. The chamber's temperature and remaining hold time are visible on the shipper unit's LCD display. All data are available remotely, in real time, via the Chronicle logistics dashboards (Fig 4).



Fig 4. Real-time condition monitoring and location information available through the Chronicle software platform.

Chronicle alerts any designated person, by text or email, if predetermined thresholds are exceeded. The software also continually validates the performance of the shipper's insulation. And if the reading is not in line with expectations, the alert provides a warning to allow a risk mitigation strategy to be implemented.

Cytiva certified VIA Capsule Charging Stations

When users choose World Courier as their specialist logistics provider, the cryogenic temperature of the VIA Capsule shipment will be maintained even when an unscheduled delay occurs. World Courier has VIA Capsule Charging Stations strategically positioned throughout their global, Good Distribution Practice (GDP) certified network. At these stations delayed VIA Capsule shipments can be held 'on charge', docked with a cryocooler until the planned logistics transit can continue (Fig 5).



Fig 5. If transit delay occurs, cryogenic temperature is maintained using VIA Capsule Charging Stations within the global World Courier quality ecosystem.

Optional temporary cryogenic storage

When the shipper arrives at the destination, the cellular product can be unloaded or stored temporarily in the shipper unit (validated for up to 6.5 wk). By simply docking the shipper with an electrically powered cryocooler, the cryogenic hold time is extended. This feature is particularly valuable for hospitals without a cryogenic storage facility.

Furthermore, it means the cell therapy can be held within one cryogenic container from loading, post-manufacture, to unloading prior to infusion. This simplified chain of custody reduces risk of damage to the cell containers, temperature excursions, and mix-up of patient samples during multiple transfers.

Logistics autonomy and patient focus

With the ability to sit 'on charge' docked to a cryocooler unit, the logistics timeframe shifts from a highly structured, rigid approach to one with greater flexibility and patient focus. The shipper is available for use as soon as the cryopreserved apheresis product is ready, the manufacturing process completes, or until the patient is ready for their treatment to begin.

Extending the cryogenic hold time while 'on charge' removes the requirement for contingent hold time, which is often built into shipment specifications for liquid nitrogen shipments to accommodate for delays in the patient's or manufacturer's schedules. Thus, the VIA Capsule system provides a more flexible approach to timing of the logistics process.

Efficiencies of a liquid nitrogen-free workflow

Using the VIA Capsule system removes liquid nitrogen from the end-to-end logistics process. This eliminates the infrastructure requirements, labor, and time involved to prepare and charge a liquid nitrogen vapor dry shipper, as well as all the associated safety materials and training. These simplified processes eliminate costs and 'unutilized' journeys (i.e., time spent traveling without a payload) that are often part of owned or managed-service dry shipper logistics. These features lead to improved efficiencies while also reducing the total carbon footprint associated with cryogenic shipping.

To extend some of these efficiencies and cost reductions, remove liquid nitrogen from the cryopreservation steps in the manufacturing workflow and prior to cryogenic cold chain logistics by controlling cooling with Cytiva's VIA Freeze™ range.



Fig 6. Chronicle eSOP tool records processes, chain of custody, and chain of identity. Image shows bar code reading function within eSOP capturing the unique identity of a shipper unit.

Added Chronicle benefits

A complete electronic shipment record can be created within the Chronicle software platform using the Chronicle electronic standard operating procedure (eSOP) tool. By digitizing a manufacturer's end-to-end logistics procedure as an eSOP, an electronic record of the logistics process delivery, chain of custody, and chain of identity is captured by all logistics parties and stored in a single digital space. In Chronicle this information is then automatically linked to the VIA Capsule shipment's condition data. Users choosing World Courier as their logistics provider are also able to electronically book (eBook) the shipment, print the shipment documentation, and maintain a record of the courier handling events within this single digital space.

The electronic shipment record is automatically united with the manufacturing electronic batch (eBatch) record held within Chronicle to provide a complete record of manufacturing and logistics processes. These additional Chronicle features are available using the Chronicle credit system.

VIA Capsule system key features

Cryogenic temperatures	Cryocooler cools shipper unit from ambient temperatures to -192°C. When docked with cryocooler for extended periods, shipper unit maintains a -182°C temperature.
Hold time	A fully charge shipper unit, cooled to -192°C, has up to 5 days standby time when entirely passive. After 5 days without charge, the temperature reaches -120°C.
Flexible payload	Compatible with most cell container types (i.e., cryobags up to 750 mL and most commonly used cryovial formats). These are secured in a protective sample loader, held within the shipper's thermal core.
Monitored conditions	The shipper unit is digitally enabled with an integrated smart monitor. Continual measurements are synchronized to the Chronicle software platform in real time. These include the internal thermal core's temperature and environmental conditions such as external temperature, humidity, and tilt. The data is accessed using the standard Chronicle credit method.
Retractable wheels	Wheels extend for stable, easy maneuvering within a facility. These lock in a closed, compact position for transport.
Reusable outer transport shell	Lightweight cardboard and foam outer shell provides protection from impact and dirt.

VIA Capsule system specifications

Power requirements

Cryocooler power requirements Rated Power 400VA, 100-240 VC, 50/60 Hz

Dimensions and weight

Charge configuration: Height: 1090 mm
shipper unit with Footprint diameter - wheels closed: 372 mm
cryocooler Footprint diameter - wheels open*: 730 mm
Weight: 39.9 kg approx.

Transport configuration: Height: 840 mm
shipper unit with Footprint diameter - wheels closed: 372 mm
transport lid Footprint diameter - wheels open*: 730 mm
Weight: 32.7 kg approx.

Transport ready shipper, Height: 990 mm
within transport shell Width: 426 mm
Depth: 466 mm
Weight: 38.2 kg approx.

Transport ready Height: 600 mm
cryocooler, within Width: 400 mm
transport shell Depth: 400 mm
Weight: 10.5 kg approx.

Shipper outer transport Height: 990 mm
shell, without payload Width: 426 mm
Depth: 466 mm
Weight: 5.5 kg approx.

Cryocooler outer Height: 600 mm
transport shell, Width: 400 mm
without payload Depth: 400 mm
Weight: 2.3 kg approx.

*Outer diameter with wheels pivoted out to their fullest extent.

Ordering information

Product	Description	Product code
Main instrument	VIA Capsule Cryocooler	29435429
Main instrument	VIA Capsule Shipper	29435428
Accessory	Sendum Tracking System	29435205
Accessory	Thermal Core Bag	29483894
Accessory	Thermal Core SBS	29484272
Accessory	Thermal Core Removal Tool	29484296
Accessory	Thermal Core Screw Driver Assembly	29492489
Accessory	VIA Capsule Shipper Cap	29463250
Consumable	Sample Loader SBS	29435432
Consumable	Sample Loader Cryobag	29435430
Consumable	Transport Box Shipper	29441698
Consumable	Transport Box Cryocooler	29462958

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