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## Bulk Reusable Passive Temperature Controlled Packaging For Deep Frozen Shipments

Source: Peil BioThermal  
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When COVID-19 turned the world upside down, it also sparked an immense amount of innovation. What individuals and businesses thought was impossible previously turned possible, and what wasn't a priority before soon became urgent.

The pace at which COVID-19 vaccines moved from clinical trials to commercialization is unprecedented. It put strain on a supply chain that was not equipped to handle vaccines that required deep frozen temperatures and at a volume greater than most shipments for commercial pharmaceutical products. Technology and infrastructure needed to adapt quickly.

Cold chain manufacturers modified existing temperature-controlled packaging or created new solutions to meet the temperature requirements for deep frozen vaccine storage. Product development that can take years was accomplished in less than a year--on the same timeline as the COVID-19 vaccine rollout.



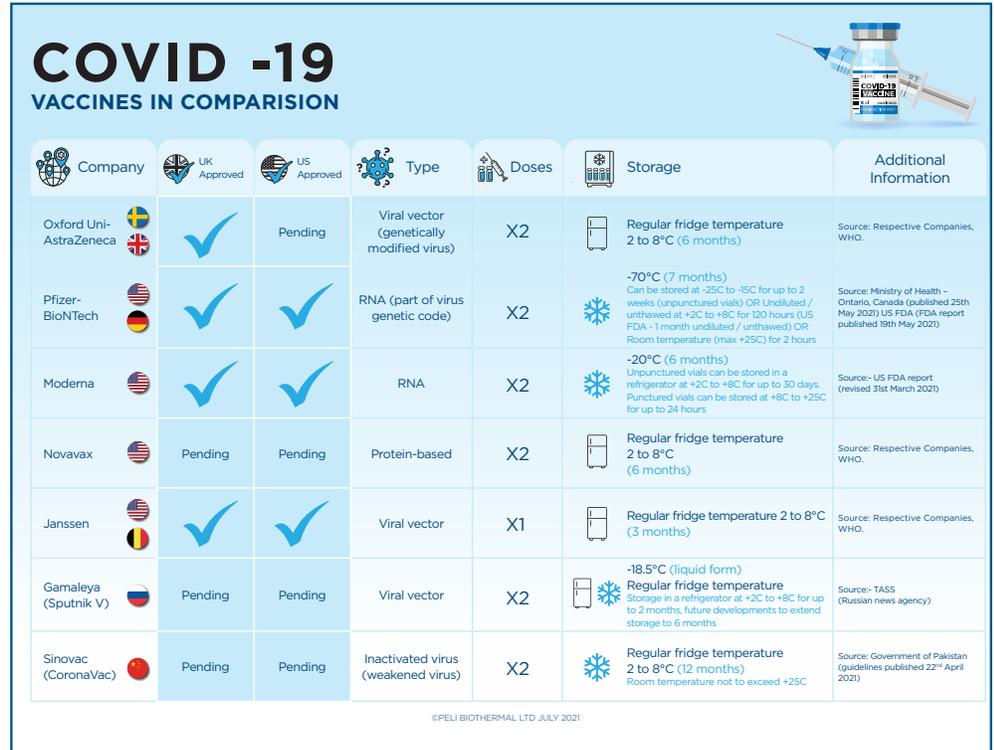
Peli BioThermal's solution uses the Crēdo™ Cargo passive bulk shipper, known for its lightweight, sturdy design with tough external wall construction to absorb and deflect impacts, to create a new passive system that achieves deep frozen temperatures for a minimum of 84 hours with dry ice.



## COVID-19 Vaccine Technology

The first four COVID-19 vaccines approved either in Europe or the United States were viral vector or mRNA vaccines. Viral vector vaccines remained stable at refrigerated temperatures for three to six months while mRNA vaccines initially required deep frozen temperature ranges of -20 degrees Celsius to -70 degrees Celsius, depending on the manufacturer (see figure 1).

mRNA, or messenger RNA, was first discovered in the 1960s. For decades mRNA was studied and refined. Scientists focused on its stability and safety, as well as mechanisms to deliver it into the cells of living organisms. Throughout the years, bringing mRNA into the mainstream was abandoned by many companies because of its instability and the cost to manufacture. However, this work became stepping stones to the first mRNA vaccines for COVID-19.



Company	UK Approved	US Approved	Type	Doses	Storage	Additional Information
Oxford Uni-AstraZeneca	✓	Pending	Viral vector (genetically modified virus)	X2	Regular fridge temperature 2 to 8°C (6 months)	Source: Respective Companies, WHO.
Pfizer-BioNTech	✓	✓	RNA (part of virus genetic code)	X2	-70°C (7 months) Can be stored at -25C to +5C for up to 2 weeks (unpunctured vials) OR Undiluted / unthawed at +2C to +8C for 120 hours (US FDA - 1 month undiluted / unthawed) OR Room temperature (max +25C) for 2 hours	Source: Ministry of Health – Ontario, Canada (published 25th May 2021) US FDA (FDA report published 19th May 2021)
Moderna	✓	✓	RNA	X2	-20°C (6 months) Unpunctured vials can be stored in a refrigerator at +2C to +8C for up to 30 days. Punctured vials can be stored at +8C to +25C for up to 24 hours	Source: US FDA report (revised 31st March 2021)
Novavax	Pending	Pending	Protein-based	X2	Regular fridge temperature 2 to 8°C (6 months)	Source: Respective Companies, WHO.
Janssen	✓	✓	Viral vector	X1	Regular fridge temperature 2 to 8°C (3 months)	Source: Respective Companies, WHO.
Gamaleya (Sputnik V)	Pending	Pending	Viral vector	X2	-18.5°C (liquid form) Regular fridge temperature Storage in a refrigerator at +2C to +8C for up to 2 months, future developments to extend storage to 6 months	Source: TASS (Russian news agency)
Sinovac (CoronaVac)	Pending	Pending	Inactivated virus (weakened virus)	X2	Regular fridge temperature 2 to 8°C (12 months) Room temperature not to exceed +25C	Source: Government of Pakistan (guidelines published 22nd April 2021)

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Figure 1

Without data on the viability of the mRNA vaccines at warmer temperatures, manufacturers and the Food and Drug Administration relied on science that showed mRNA is easily destroyed by enzymes breaking apart the mRNA vaccine molecule. This process would happen more slowly at lower temperatures, so until enough data was available, mRNA vaccines required deep frozen storage.

### Types of Temperature Controlled Packaging

Temperature-controlled packaging on the market could achieve deep frozen temperature ranges. However, most options were single use, small volume parcels or active systems. Each type of shipper has its own unique advantages and disadvantages, and not every type of shipper was right for deep frozen vaccine shipments at scale.

#### Active Systems

Active containers are most similar to refrigerators. They use mechanical or electric systems powered by an energy source, combined with thermostatic control to maintain product temperatures. Systems often require “plug in time” to charge prior to use and at key touch points.

Active systems require a closed-loop distribution system to ensure appropriate maintenance and recovery of reusable equipment. While these systems maintain good temperature control, they are expensive to purchase, run and

maintain. They are also more costly to ship because they are heavier, they could require maintenance during transit and they are available in fewer sizes than other types of shippers.

#### Hybrid Systems

Hybrid systems are similar to active systems, but they incorporate a phase change material (PCM) bunker. The active element of the system charges a “PCM battery” that is used when the system is not being charged by a power source.

Hybrid systems share many of the same advantages and disadvantages as active systems. However, hybrid shippers have fewer components that may require maintenance.

#### Passive Systems

Passive systems use PCM, water coolants or dry ice and insulation to keep a payload at the right temperature. These systems offer more flexibility than active and hybrid systems, including single-use options that accommodate different types of distribution systems. Once components are conditioned, passive systems require no touch points to recharge.

Overall, passive systems have fewer shipping restrictions and their lower weight contributes to reduced freight costs. There are also more size options and no maintenance required during transit. However, passive systems do have shorter shipping durations than active and hybrid systems.



## Crēdo™ Cargo Dry Ice Shipper with Deep Freeze Container

A passive shipping system was the ideal solution for COVID-19 vaccines. With fewer restrictions and no maintenance required during transit, it could withstand the challenges posed by a fractured supply chain, including short-term delivery delays and last mile deliveries where power sources were inaccessible.

When the COVID-19 pandemic hit, there was an urgent need for a passive shipper that could ship deep frozen pharmaceutical payloads in bulk. Creating something new would take too long, so Peli BioThermal innovated to reengineer one of its existing packages to meet this need.

The standard Crēdo Cargo passive shipper is 1,686 liters and validated for three temperature ranges: 2 - 8 degrees Celsius, 15 - 25 degrees Celsius and sub -18 degrees Celsius. To achieve deep frozen temperatures, a new deep freeze container is housed within a Crēdo Cargo shipper. It takes the place of PCM coolants and maintains payload temperatures between -90 degrees Celsius and -60 degrees Celsius for a minimum of 84 hours.

The bulk system is almost fully reusable, except the dry ice which sublimates with time, and is available through the Crēdo™ on Demand Rental Program.

### Preparing Crēdo Cargo Dry Ice Shipper

The Crēdo Cargo dry ice shipper maintains the durability characteristic of Peli BioThermal's temperature-controlled packaging products. The deep freeze container includes a dry ice bunker atop a separate payload space with small openings in the floor of the dry ice bunker for allowing direct convective cooling of the payload space by dry ice loaded into the dry ice bunker. With the deep freeze container removed from inside the shipper, open the deep freeze container door and load the pharmaceutical payload into the payload space. Using the included cargo straps inside the deep freeze container, secure the payload to the deep freeze container's built-in airline tracks. Close and lock the access deep freeze container door. A tamper-proof ID can be added, if required.

### Future Uses

COVID-19 showed the world that the distance between clinical trials and commercial product launch can be suppressed, and this may become the expectation when new, life-altering vaccines and therapies reach clinical trials. Initially, many products require deep frozen temperatures to ensure viability while data for storage is collected and assessed.

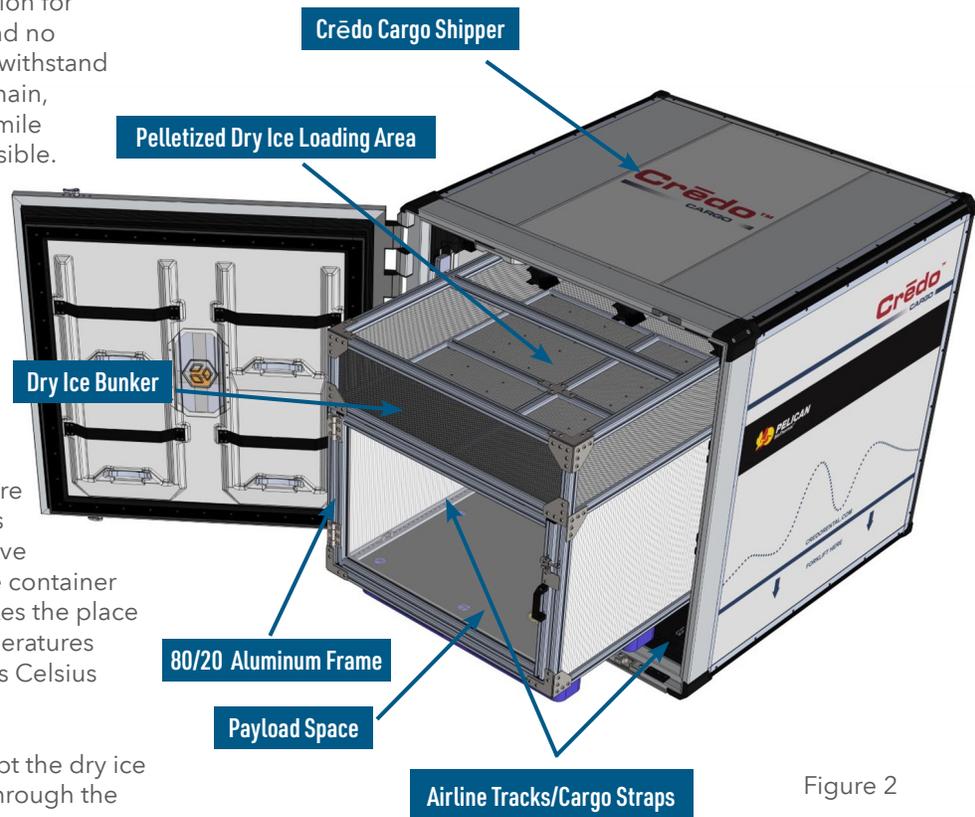


Figure 2

Spread a thin layer of dry ice pellets over the base of the deep freeze container before adding additional layers until the desired mass or airline limit is achieved. Before inserting the deep freeze container back into the Crēdo Cargo shipper, attach one end of the provided cargo straps to the rear load/look ring on the shipper's airline track. Pull the cargo straps forward so they extend out of the Crēdo Cargo shipper and leave the excess strapping on the shipper's roof while installing the deep freeze container.

Using a lift aid such as a forklift, install the deep freeze container's inside the shipper. Secure the deep freeze container to the Crēdo Cargo shipper by looping each cargo strap up and over the deep freeze container and attaching it to the load/look ring on the opposite side's airline track to form an X shape on top of the deep freeze container. Close the Crēdo Cargo shipper door and lock (see figure 2).

The need for deep frozen shippers for pharmaceutical payloads has long been important for cell and gene therapies, as well as other pharmaceutical products in early-stage clinical trials. However, as speed to market increases, the need for bulk shippers that offer deep frozen temperature ranges will continue to increase.

## About Peli BioThermal

Peli BioThermal offers the widest range of temperature-controlled packaging and service solutions to the global life sciences industry, including a complete portfolio of services and software to support end-to-end temperature-controlled packaging. From discovery to distribution, our products ensure that delicate life science materials arrive intact and effective. Customers trust us with their most valuable health-giving and life-saving products because of our expertise in ensuring temperature stability is maintained throughout the distribution chain and for our ability to meet them wherever they operate globally. The economic value we bring our customers is total cost of ownership for all our owned or rented packaging, services and technology offerings.

[Learn more](#) about our Crêdo on Demand rental program.

To learn more and discuss your bulk packaging needs, please visit [pelibiothermal.com](http://pelibiothermal.com)

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