

## CASE STUDY

# How Orthocell Ltd Adopted the CryoSure<sup>®</sup> Solution for Shipping Advanced Cell Therapies

Shipping temperature sensitive pharmaceutical products and biologic medical devices globally presents a unique set of challenges, driven by the necessity for maintaining product integrity, compliance with regulatory requirements, and ensuring patient safety. Finding the right packaging solution for your shipment can overcome these challenges - without compromising on your environmental impact.

Shipping temperature sensitive healthcare products can be a complex process - regulatory requirements are understandably strict, and even a minor deviation from storage and transportation requirements can compromise the efficacy and safety of a product. Manufacturers must navigate these requirements to guarantee that their products reach their destinations safely and in perfect condition.

This case study explores how Orthocell Ltd worked with Envirotainer to understand the solutions available for shipping their treatments, and how they were able to ensure the quality of their specialized biologic medical products as they reached their destination on the other side of the world.

Orthocell Ltd, based in Perth, Western Australia, is a pioneering company focused on the treatment of musculoskeletal disorders. The organization is focused on its mission to introduce cutting-edge medical solutions for optimized patient outcomes. In pursuit of this commitment, Orthocell requires reliable and environmentally friendly shipping solutions and efficient cold chain logistics to ensure the safe and effective transportation of their products.



## THE PROBLEM

Orthocell's Autologous Chondrocyte Implantation (OrthoACI<sup>™</sup>) offers treatment for symptomatic defects of the articulating cartilage of the joints, using the patient's own healthy cartilage cells to assist the regeneration of damaged cartilage. OrthoACI<sup>™</sup> is a highly customized treatment – each procedure is tailored to the individual patients' requirements. Because of the personalized nature of this therapy, product safety and quality are paramount to ensure the successful treatment of the patient.

Orthocell faced several challenges with their existing packaging solution. They relied on a traditional dry ice shipping solution, specifically polystyrene boxes, to transport their products. However, this method raised concerns regarding the quantity of dry ice required and how long it was able to maintain the required temperature of below -70°C.

Additionally, Orthocell was looking to adopt a more sustainable packaging solution, aligning with their commitment to environmental responsibility. Given the sensitive nature of the product, temperature monitoring was also desired to ensure product integrity throughout the shipment.

## THE SOLUTION

To address Orthocell's shipping challenges and to ensure their strict product requirements were met, the CryoSure® X2 solution was proposed. The primary requirement was for a packaging solution that could maintain a stable temperature of below -70°C consistently throughout the shipment. The CryoSure® X2 (1.6 l size) is validated to have a duration of >21 days – offering Orthocell above the required duration, whilst also allowing for additional contingency time should there be any delays, without risking product integrity.

The CryoSure® solution would also support Orthocell's desire to have a reusable solution which decreases their carbon footprint. As a fully reusable cold chain shipping solution, CryoSure® is designed to be volume efficient, have a low weight, and require less dry ice than other traditional dry ice solutions - reducing both carbon emissions and transportation costs.

The real time Live Monitoring service offered with CryoSure® would also allow Orthocell to track the temperature and location of the shipment 24/7, providing visibility into its status, and prove the integrity of the valuable cargo inside when it reached its destination.

*"As we began to work through the requirements, it soon became clear that we had the right solution to meet their needs"* said Jonathon Haydn-Evans, Regional Senior Sales Manager, Envirotainer. He continued, *"We presented the CryoSure® solution and its performance data to the Orthocell team and they were impressed that it would be able to meet their requirements while still contributing to their sustainability goals."*

As the discussion progressed, Jonathon was able to provide in-depth validation documentation to ensure compliance with quality standards and regulatory requirements. This documentation provided Orthocell with the assurance that the proposed solution met all the necessary criteria for safe product transportation.

## RESULTS

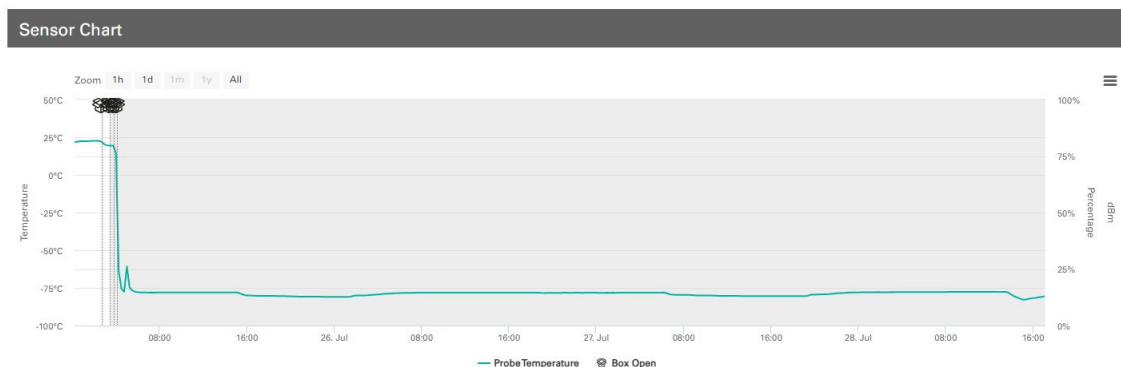
Having shipped the OrthoACI™ product using the CryoSure® X2 in July 2023, Envirotainer and Orthocell observed the following outcomes:

The temperature stability and dry ice duration of the shipment was a success, maintaining the required temperature of below -70°C throughout the entire journey. This achievement was crucial in preserving the efficacy of the product and ensuring product integrity.

The Live Monitoring service provided Orthocell with real-time visibility of the shipment all the way from its origin to its destination. This capability minimized the risk of product loss and would have allowed for prompt intervention if any issues had arisen during transit. The post-shipment Insight Report service has also given Orthocell further insights into their shipping processes for future process improvement.

By transitioning to the CryoSure® solution, Orthocell has also been able to align their shipping practices with their sustainability values without compromising on quality.

In the words of Eda Daryal Senior Supply Chain Manager from Orthocell Ltd: *"The CryoSure® solution mitigates most if not all risks currently faced when shipping biologic medical device products globally below -70°C as well as reducing our carbon footprint. Thank you Envirotainer, for ensuring our life changing products can be delivered safely anywhere in the world."*



Temperature sensor data throughout the live shipment as shown in the Envirotainer Portal

## CONCLUSION

The CryoSure® solution offered Orthocell the means to safely transport their product from Western Australia to the USA efficiently, while still maintaining a stable product temperature of below -70°C throughout the entire journey.

By working together to fully understand the product requirements and the wider goals of Orthocell's business, Envirotainer was able to find the best solution for the shipment - protecting the quality and integrity of the product while also supporting Orthocell's commitment to patient care and environmental responsibility.

**About Orthocell:** Orthocell is a regenerative medicine and medical device company dedicated to the development of breakthrough products for the treatment of musculoskeletal disorders.



**About CryoSure®:** The CryoSure® dry ice -70°C shipping solution delivers your most treasured product in perfect condition. It eradicates deviations through a consistently reliable and secure shipment cycle. By combining groundbreaking innovation, technology and service backed by Envirotainer's 35-year industry experience and expertise CryoSure® sets an entirely new standard in -70°C shipping. It has unmatched performance, superior duration and is the most sustainable solution on the market.



Find out more about CryoSure® at: [www.envirotainer.com/products/cryosure/](http://www.envirotainer.com/products/cryosure/)