

ICS + World Courier: United in our purpose—impacting the health and future of patients with failing hearts

How a unique partnership forged an innovative, end-to-end clinical trial logistics plan for the world's first auto-regulating, bioprosthetic artificial heart

The Aeson® total artificial heart, developed by Carmat, is designed to prolong the lives of people suffering from irreversible end-stage heart failure, giving them the precious time necessary to coordinate a human heart transplant. Located in Vélizy-Villacoublay, France, Carmat needed a solution to facilitate storage and distribution for their life-saving prosthesis currently in U.S. clinical trials. ICS and World Courier were equal to—and very appreciative of—the challenge.

"This unique opportunity came to us from World Courier, who had a prior relationship with Carmat for product shipment services," explains Ann Pham, Director of Business Development at ICS. "It was a great way for our organizations to collaborate on a very meaningful international program that ultimately helps save lives."

Working together, teams from ICS and World Courier tailored a first-of-its-kind, integrated solution for Carmat in which World Courier manages shipments from France to ICS and ICS provides 3PL storage and distribution in its US-based facilities.

"This was a wonderful example of World Courier and ICS working together to provide an end-to-end solution to a manufacturer," says Michele Taylor, Manager, Strategic Accounts, at ICS. Taylor notes the initial challenge in solutioning for Carmat was how to take the manufacturer's well-defined, highly complex program and distribute the Aeson® heart and power supply within ICS compliance requirements and on a timeline that adjusts based on patient need.

"On the ICS side, associates from the Implementation Team, Account Management, Operations, Compliance, Distribution, and Transportation teams were involved in numerous strategic touch points to support the Carmat effort. I haven't seen anything on this level before," continues Pham. "It's a completely custom program, in which experts across the various functional ICS teams united to design robust storage and distribution processes specific to Carmat."

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Alexandre Eleonore, Industrial Director, Carmat



A custom process

Because the Aeson® heart had only undergone clinical trials in Europe, ICS had to devise and implement US-focused work instructions for every prosthesis storage, handling, and distribution action completed for Carmat, cooperating closely with client counterparts to make sure the process was created properly for their revolutionary device.

"We held video calls with the client to show them the process in real time," says Amanda Duncan, Operations Manager at the ICS Distribution Center in Louisville, Kentucky. "The first call took five hours, with ICS offering strategic counsel and, together with Carmat, making necessary work instruction changes to align with their requirements and set up the program for success."

Because the prosthesis is a replacement for the human heart, the work instructions are extremely detailed for both inbound and outbound activities. Batteries must be checked for a full charge; every one of the 10+ containers associated with the device must be examined, resealed, retagged, placed on pallets, and wrapped for shipment. In short, during each step of the process, everything is examined, verified, and validated by a special Carmat-specific ICS distribution facility team.

Adding to the challenge is the fact that this life-saving medical device includes items that require precise temperature control. (The Aeson® system consists of an implantable bioprosthesis and an external, portable power supply.) "We had to install temperature monitors inside several containers," says Duncan. "And because the prosthesis has both ambient and temperature-controlled items, we had to ship them out on two trucks after verifying the temperature of the refrigerated truck once it arrived."

A unique integrated 3PL solution

Reflecting the uniqueness of the prosthesis, the integrated 3PL solution developed for Carmat is like no other, requiring numerous non-standard processes for shipping, receiving, and storage that extends across many cross-functional areas. Close collaboration and clear communication, both internally and with Carmat, were critical. Plus, language, cultural, business etiquette, and time zone differences all had to be overcome.

"We worked through all those things together, showcasing our ability to act as a true partner and guide Carmat in the right direction with our recommendations and best practice strategies," says Pham. Carmat's Industrial Director, Alexandre Eleonore, concurs. "We are very proud to have been able to start clinical studies in the U.S. We needed a trusted partner to provide high quality service to the patients and hospitals we work with. The ICS teams provide us with great support in this mission."

"The process is very time consuming and labor intensive," adds Pham. "But it is worth every bit of effort and more when you think about the ultimate outcome—extending someone's life. It's amazing to see Carmat in the news, knowing that everything we're doing is making a material difference. It's very fulfilling." Duncan agrees. "The product leaves our facility and is immediately used to save someone's life," she says. "That's what makes this unique, and it's a prime example of what ICS does each and every day for all our manufacturer partners."

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