CASE STUDY

3i Event Launches Design, Development, & Manufacture of Complex Delivery System For Breakthrough Interventional Device

CUSTOMER SITUATION

The goal of this interventional cardiology startup was to develop and commercialize a novel technology for the minimally invasive treatment of a common, chronic cardiovascular condition. The core innovation was an electromechanical implant, a revolutionary alternative to an invasive surgical procedure. The customer team was focused on developing the implant and needed a partner that could take full ownership of the design and development of the catheter-based delivery system, on an aggressive timeline.

The customer faced many challenges of a typical startup, including a small team with limited capital and design and development experience, and the need to meet a key milestone to raise more funding for product commercialization.

This startup was referred to Vention by another customer, based on its reputation as a strong partner for design, development, and manufacturing of interventional medical devices.

VENTION SOLUTION

The Vention team started with a 3i Project Booster Session, a stand-alone, affordable, brainstorming event. The event included a detailed analysis of the procedural steps for delivering the implant and user workflow, as well as concept generation for the delivery system's key functions.

The output of this 3i event became the roadmap for translating the customer's needs into a full product development project (PDP) plan and for the architecture of the delivery system design.

The customer then engaged Vention to continue with concept refinement. This complex delivery system comprised more than 100 components with 4 distinct subassemblies, including an introducer sheath, a dilator, and a 2-part delivery handle with both mechanical and electrical systems. The procedural mapping done in the 3i event was critical to ensuring that the delivery system allowed the user to intuitively walk through each step, and correctly place and ensure functionality before safely and reliably deploying the implant.

The Vention team brought decades of experience in the design and development of catheter-based devices. The team worked collaboratively on usability engineering as well as designing the key functional and safety features to ensure safe and intuitive device use. In the development phase, the team incorporated design for manufacturability and assembly (DFMA) and material selection expertise to achieve a manufacturable solution.

CONTINUED, NEXT PAGE >

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Having worked with many startups, Vention brought critical program management experience coaching startups through the PDP process. The Vention team also contributed expertise in catheter manufacturing and assembly. Rapid prototyping was done in-house, and the team's DFMA work helped smooth the transition into small-volume builds.

Vention had the flexibility to align its Quality Management System with the customer's document control requirements. In addition, the customer was able to leverage Vention's supply chain to procure tooling and components faster and more economically than if it were working on its own.

Vention developed and manufactured the delivery system, manufactured the finished device assembly with the implant, and managed sterilization for the customer's Early Feasibility Study—the critical milestone for the company's continued funding.

OUTCOME

The customer completed an Early Feasibility Study of this novel implant using the interventional delivery system developed and manufactured by Vention. The study confirmed the efficacy of the technology and paved the way for a broader clinical study that is currently ongoing.

Outsourcing the development of the delivery system significantly accelerated the time to clinical trials, as the customer team did not have the engineering or manufacturing capacity to develop both the implant and delivery system simultaneously.

Time from receiving clinical development funds to starting the Early Feasibility Study was about 12 months.

The customer achieved its key clinical endpoint without hiring a full-time product development team or investing in a certified cleanroom or manufacturing facility, and with a low capital expense investment in tooling and equipment. Reaching this milestone significantly increased the core value of the technology and positioned the company for broader commercialization efforts.

Vention is currently in discussions with the customer for development of a next iteration of the device.

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