CASE STUDY

Fast Iterations and Rapid Ramp-Up Dramatically Speed Time to Market

CUSTOMER SITUATION

A large medical device company provided a mechanical thrombectomy device for neurovascular intervention that was deployed via a competitor's catheter delivery device. The company wanted to develop its own catheter delivery device so it could provide its customers a complete system. Its internal team had been working on the project for nearly 2 years without significant progress.

The customer initially called on Vention to develop prototypes for the designs it had developed internally. But the customer was so pleased with Vention's innovation, speed, and effective collaboration that it expanded the opportunity for Vention to take the product up to design validation. The customer gave Vention an aggressive 6-month deadline, with a requirement that the device had to function as well as or better than a competitor's device.

A few months into the project, the customer expanded the project scope and asked Vention to develop in parallel a smaller version of the device with a similar design and construction. The goal was to provide the customer with both devices and documentation for design validation in support of its FDA submissions, within 6 months.

VENTION SOLUTION

The customer's team had developed some designs internally, but asked the Vention team to come up with its own ideas after studying the competitor's product. The result was a collaborative design that included the best features of both teams' designs.

Because of the challenges of reaching the anatomy, the design required varying characteristics along the length of the device. As a femoral access catheter, it required stiffness in the proximal end for pushability, and flexibility in the distal end to access the cerebral artery. The resulting design was extremely complex: The outer jacket consisted of 2 materials with 9 durometer or dimensional transitions along a tapered shaft. The device was reinforced with an alternating-pitch nitinol coil with 19 discrete pitch changes. This required the development of a new shape setting process and customized machinery that could produce a pitch change every few millimeters along the length of the device.

The Vention team first built proof-of-concept prototypes for the more challenging distal end of the device, then built complete device prototypes and collaborated with the customer to evaluate the designs in benchtop anatomical models and cadaver studies. The team was able to iterate very quickly. Within the first few months, team members made more than 15 iterations with various durometer and pitch transitions to find the optimal balance of stiffness and flexibility. Vention applied a Design for Manufacturability (DFM) mindset and process, making key design changes up front that would enable lower-cost manufacturing.

Vention also effectively managed the supply chain from design and development through manufacturing transfer. The team generated component specifications, chose vendors from the customer's preferred supplier list, ordered all materials, received and inspected materials, and managed all suppliers.

After design verification, Vention quickly ramped up to manufacture 2500 of each device for design validation. No machinery capable of manufacturing the alternating-pitch nitinol coil was commercially available within the timeline. So within 6 weeks, the Vention team designed and built a custom coil-winding machine that increased throughput and provided increased process control.

CONTINUED, NEXT PAGE >

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As capacity continued to ramp up, Vention built 2 additional coil winders within a few weeks to meet the customer's needs. The Vention team smoothly transferred manufacturing to the customer, who was so happy with the coil winders that it purchased 2 additional machines to support its manufacturing line.

In addition, the Vention team generated and managed all manufacturing documentation to support the customer's FDA submission, including process flow diagrams, material traceability, process failure mode effects analysis (PFMEA), and lot history records to support validation testing performed by the customer.

OUTCOME

Vention met the customer's aggressive 6-month time frame for both devices. Fast design iterations and rapid manufacturing ramp-up allowed Vention to provide devices and documentation the customer needed to complete validation testing in support of its FDA submission.

The Vention team exceeded the customer's performance requirement, with a device that peformed not just as well as—but better than—the competitor's. Vention also leveraged its manufacturing transfer expertise to smoothly transition manufacturing to the customer's facility, building custom coil-winding machinery to meet the customer's needs in just 6 weeks.

Partnering with Vention enabled the customer to complete design validation and submit its FDA applications much more quickly than it could have done if it had developed the device internally, resulting in faster time to market. Both devices are now commercially available.

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