

Outsourcing to Vention Accelerates Portfolio Expansion



CUSTOMER SITUATION

The new CEO of a mid-size medical device company wanted to increase market share by developing 2 new products to complete its portfolio of minimally invasive, catheter-based cardiac devices. The internal team was at full capacity developing one product extension and sought an outside partner to handle the full product development program for the other, a lower-cost device. Requirements included:

- Launching within 15 months after initial product concept discussions
- Meeting unit cost targets for this lower-cost device
- Achieving performance equal to or better than a competitive benchmark product already on the market

The customer chose to work with Vention because of Vention's catheter product development expertise and ability to make a seamless transition from product development to manufacturing. The customer also had confidence in Vention's cross-functional team and Quality Management System.



VENTION SOLUTION

Vention developed several prototypes with a range of complexity to help the customer's marketing team define its requirements. The customer set a cost target, and the Vention team developed a prototype to meet the customer's goals.

The design phase leveraged Vention's expertise in catheter design, material development, and design for manufacturability (DFM). Vention handled key secondary operations including cutting, tipping, cleaning, final inspection, and packaging for 8 SKUs. One of the project challenges was developing and validating the RF tipping

process used to form the catheter tip. The operation was complex because of the tip's asymmetric geometry, and because there were 4 different tubing materials that each responded differently to the process.

Vention effectively managed the supply chain from design and development through manufacturing and assembly. The team selected, qualified, and managed all suppliers, and had the flexibility to work with the customer's preferred suppliers.

The team also performed a supply chain Failure Mode and Effects Analysis (FMEA), a process Vention developed as part of its Quality Management System. This involves applying the tools of failure mode and effects analysis to identify and mitigate supply chain risks, which are often overlooked in the product development process.



OUTCOME

Vention was able to meet the customer's requirements within an aggressive time frame:

- Met deadlines for 510(k) and CE mark submission and clearance
- Met deadlines for initial European launch and US commercial launch
- Met unit cost targets
- Product performed equal to—and in some cases, better than—benchmark competitive product in all test parameters

Working with Vention as an extension of its team, the customer successfully accelerated the expansion of its product portfolio. The customer is currently working with Vention on another catheter development project.

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