

Pushing Technology Limits Helps Startup Launch Novel Balloon Catheter



CUSTOMER SITUATION

A small startup company had a big idea for a medical balloon catheter to treat atrial fibrillation with cryoablation, a novel application at the time.

The customer envisioned a system comprising a console to deliver a pressurized refrigerant via a single-use cryoablation catheter. The unique design featured an inner and an outer balloon. The refrigerant would be delivered through the inner balloon, and the outer balloon was designed to serve as an added safety measure to contain the gas in the unlikely event that the inner balloon should leak or burst.

This application required a low-profile device with ultrathin walls that could be delivered and removed through tortuous anatomy, while inflating to a very large diameter. The medical balloon had to maintain high pressure with high burst strength. In addition, the balloon had to withstand and remain flexible at very low temperatures.



VENTION SOLUTION

First, the customer convened a brainstorming session at its offices. It also invited Vention to attend a cardiology conference to discuss the product with end users. The resulting

requirements for the medical balloon design and manufacturing were extremely challenging:

- Very large diameter (20 mm–40 mm)
- Very short length (shorter than balloon diameter)
- Small-diameter balloon necks

No company had ever made a medical balloon with these ratios—Vention was breaking new ground. The team had to push the limits of technology and develop new internal processes to produce balloons that met these requirements.

The Vention team began working on prototypes for the customer's design of 2 noncompliant balloons. However, testing revealed that the profile of 2 noncompliant balloons would be too large and too stiff.

The Vention team came up with the idea of using a compliant medical balloon of a different, more elastic material for the outer balloon. This reduced the profile and stiffness, without compromising strength and burst pressure needed for safety. The team worked closely with the customer on many iterations, often sending samples to test overnight and tweaking the design the next day.

As Vention's pioneering Advanced Polymers team was the first to manufacture balloons for the medical device industry, Vention brought a deep understanding of material properties, the medical balloon-forming process, and precision extrusion technology to develop the best components for the application.

Throughout the design process, the team used Design for Manufacturability to ensure efficient manufacturing of a high-quality medical balloon. It was an extraordinary challenge to manufacture balloons with such difficult dimensional requirements along with tight specifications at production volumes.



OUTCOME

Vention innovated on the customer's original design to develop a medical balloon that met the customer's complex requirements for this unique, balloon-inside-balloon catheter design.

In addition, Vention was able to manufacture them within very tight tolerances at production volumes.

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ventionmedical.com/case-studies
info@ventionmedical.com

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It took several years for the customer to get the device through the FDA approval process, given its complexity and its risk profile. The device was a commercial success and became the customer's flagship product, leading to acquisition by a major medical technology company. Adoption of the technology has been growing steadily.

Vention continues to manufacture these medical balloons and is currently working with the customer on next-generation medical balloon designs.