

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 advanced temperature therapy, a novel application at the time.

The customer envisioned a system comprising a console to deliver their advance therapy via a single-use catheter. The unique design featured an inner and an outer balloon in order to effectively deliver the therapy and provide an additional safety barrier for the surrounding anatomy.

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.



NORDSON SOLUTION

First, the customer convened a brainstorming session at its offices. It also invited Nordson MEDICAL 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:

- Large balloon diameter (20 mm–40 mm)
- Short balloon overall length (shorter than balloon diameter)
- Small catheter size

No company had ever made a medical balloon with these ratios—Nordson MEDICAL 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 Nordson MEDICAL 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 Nordson MEDICAL 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 Nordson MEDICAL's pioneering Advanced Polymers team was the first to manufacture balloons for the medical device industry, Nordson MEDICAL 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

Nordson MEDICAL 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, Nordson MEDICAL was able to manufacture them within very tight tolerances at production volumes.

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.

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

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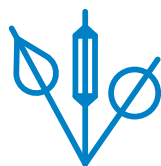
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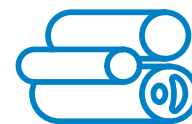
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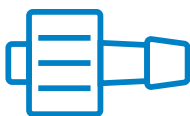
Catheters & Cannulae



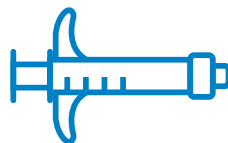
Medical Balloons



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