CASE STUDY

OPTIMIZED PRODUCT DESIGN:
Improving Costs, Manufacturability and Accessibility to Achieve Market Success

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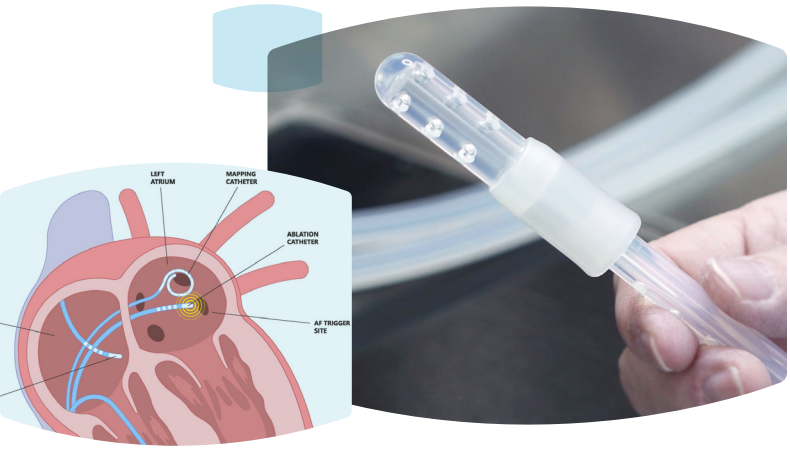
There are millions of people around the world affected by atrial fibrillation (AFib). Innovations in cannulas and other medical device technology have enabled electrophysiologists and cardiothoracic surgeons to perform minimally invasive ablation procedures as an alternative to conventional approaches. Ensuring a successful heart ablation treatment requires a device with the optimal blend of flexibility and rigidity. Lubrizol supported a medical device OEM when they implemented enhancements to a cannula that helped clinicians perform ablation procedures with shorter recovery times and improved patient comfort, compared to traditional methods.



CUSTOMER TYPE

A global provider of innovative technologies for the treatment of atrial fibrillation and related conditions.

CUSTOMER CHALLENGE

Traditionally, ablations for AFib procedures take place inside the heart (endocardial). Endocardial treatment is invasive, open-heart surgery requiring long hospital stays and recovery times for the patient. Recent studies have shown that the endocardial method combined with ablations on the outside of the heart (epicardial), known as a convergent procedure, have proven to be more effective in treating AFib patients.

This medical device OEM sought to manufacture a therapy device for this procedure that uses a cannula to make a small, one-inch incision to reach the patient's heart. The OEM faced the unique challenge of creating a cannula large enough to hold the fixture, rigid for support, soft for implantation, and gentle on the patient's body.

SOLUTION

To develop a cannula with the necessary performance characteristics, the OEM leveraged Lubrizol's comprehensive trusted contract manufacturing capabilities, including extrusion, molding, assembly, encapsulation, packaging and more. As a registered manufacturer of the product, Lubrizol worked with the customer through each stage of the process, from prototyping to development to commercialization.

In the medical device industry, speed to market is a major competitive advantage. Regulatory challenges can be a roadblock to getting a device in the hands of physicians quickly. Lubrizol's decades of regulatory guidance and expertise proved beneficial to the OEM's premarket approval application required by the Food and Drug Administration (FDA) – the most stringent device marketing application required by the agency.

OUTCOME

Lubrizol also made critical improvements to the device that helped the OEM control costs making the device more accessible in the market. Lubrizol offered scalability allowing for agility to support end user demand and the OEM's need for higher production volumes. By overcoming the necessary regulatory hurdles, Lubrizol helped the OEM quickly achieve market success in both the U.S. and Europe.

To discuss a specific inquiry or project need, please contact us to be connected with our dedicated team of material experts. And to learn more about how Lubrizol delivers value beyond the device, visit our resource page.

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