CASE STUDY

SPECTRUM PLASTICS GROUP
A DuPont Business

Leading cardiovascular company leverages vertically integrated capabilities for intricate implantable component

Challenge

A world-leading cardiovascular and endovascular medical technology company needed a specially designed micro seal for an implantable cardioverter defibrillator. The micro component would be used inside the device to isolate electrical contacts and prevent fluid ingress into the electrical path.

The micro part needed to precisely meet tight dimensional tolerance specifications, and required a two-step molding process. The inside core of the part needed to be injection molded using PEEK, then over-molded with silicone. Because silicone is a rubbery, not solid material, it added complexity to the development and design for manufacturability of the component. For the initial project, the company preferred to use a single-cavity approach, as this provided less variability than multi-cavity.

The global company sought the advantage of working with a contract manufacturing partner from end to end. They chose to rely on our in-house vertically integrated capabilities with robust quality systems and long history of consistently transforming high-temp, medical-grade plastics, metals and other exotic materials into implantable devices and components.

Action

In the first phase of the engagement, our team designed and built intricate prototype molding tools needed to micromold the PEEK and silicone components. From there, our team worked closely with the global company's product development team, taking several concepts through iterative rounds of prototyping and testing of various seal geometries. With diligence and precision, the exact specifications and requirements were met. Then, we leveraged the knowledge gained through prototyping, and transitioned to a single-cavity production tooling approach, moving the program through process validation and into production for the product launch.

Within a few years, the demand for the cardiovascular company's defibrillator device increased year over year, until finally demand was outpacing production. The company needed help maximizing production of the micro seal to keep pace with demand. We successfully designed, developed and qualified additional tooling and manufacturing processes, using a multi-cavity, tight tolerance, micromolded PEEK inner core first shot, and a multi-cavity micromolded liquid silicone rubber outer seal for the second shot. The solution increased production and helped reduce overall manufacturing costs.

Result

We provided an end-to-end solution, leveraging vertically integrated capabilities that seamlessly enabled the development, testing and validation processes for the component.

The cardiovascular company continues to rely on us to consistently and reliably manufacture the micro seal for this device, and has awarded similar product programs to the contract manufacturer's roster.

Capabilities used

- Rapid tooling and prototyping
- Design for manufacturability
- Precision toolmaking
- Micromolding
- Liquid silicone over-molding
- Process validation
- High precision automated metrology
- Medical cleaning and packaging

Deliver your medical device promise

We make products that sustain – and save – lives.

We manufacture medical devices and components. That's all we do. And we do it with the utmost precision, consistency and rigor, because for you – and your customers – quality is essential. Reliability is a must. And delivering on what's promised is vital.

Learn more about how we can help bring your medical devices to market – with confidence.

- Contact **+1.651.633.4200**
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