DUPONT Spectrum™

In a race against time, startup takes advantage of our pure medical expertise and vertical integration for novel Class III device

Challenge

To gain U.S. Food and Drug Administration (FDA) approval and be first to market in the United States, a startup with a novel Class III mitral valve repair therapy needed to first fine-tune some of the product's delivery system components. Behind schedule with deadlines and competitors looming, the startup turned to our deep engineering expertise and vertically integrated capabilities.

The program involved a product transfer from another supplier that failed to consistently meet the intricate specifications. The startup asked us to review and validate the existing tooling, and in parallel to redesign and build a portion of the fixtures and molds for manufacturability.

Adding to the challenge, the product already had launched on market in the European Union, and the company aimed to minimize or avoid the need for revalidation processes. Plus:

- **The program had a complex supply chain** requiring outsourced vendors for specialized parts and subassembly, which we would have to manage while designing components, and ensuring overall quality, final assembly and ontime delivery.
- **The device included some expensive components** to be assembled, so the manufacturing yield had to maintain high levels in order to meet cost targets.
- **The final product and packaging** also had to meet stringent cleanliness requirements, as a Class III device.

In total, the project entailed molding, validating and assembling 14 plastic parts with 25 purchased parts and blister tray medical packaging, along with sterilization management of the completed device. And, it all had to be done within months.

Based on a long history of successfully developing and manufacturing complex medical devices, our team – all under one roof – quickly guided the startup toward an absolute-quality solution.

Action

Testing the existing components revealed a portion did not meet the product specification criteria to be transferred, so we got to work building several new injection molds for production. In the process, the startup's team required some scope changes for the program, resulting in several part geometry and material changes that required multiple iterations of product re-validation to occur in parallel with keeping the supply chain moving.

At each stage, our vertically integrated capabilities enabled the team to rise to the challenges – in record time. End to end, our team worked closely with the startup through design for manufacturability, tooling, injection molding, device assembly, testing, sterile tray packaging and sterilization management, all while managing and incorporating the outsourced components and subassembly.

As an FDA-registered contract manufacturer adhering to Good Manufacturing Practices (GMP), our quality systems and documentation management and control were key to success.

Result

We met the Class III product requirements and the startup's aggressive timeline. The improved device remained on market in the European Union, and gained investigational approval from the FDA.

After the project was completed, the startup's senior director of quality and operations noted that we met their program's needs throughout the whole process, and was instrumental in helping mitigate and eliminate possible production issues. In her follow-up feedback she explained:

> "Our team's persistence, knowledge, experience and strong quality system were key to our success. Our technical abilities are far above the competition."
>
> *– Senior Director of Quality and Operations*

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

- DFM
- Injection molding
- Tooling
- Process validation
- Mechanical Assembly and Packaging
- Sterilization management

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.

Visit spectrumpdupont.com to learn more about how we can help bring your medical devices to market – with confidence.

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