CASE STUDY

SPECTRUM PLASTICS GROUP
A DuPont Business

Global OEM enlists us to take tool from ‘napkin sketch’ to life-saving medical device components

Challenge

A world-leading cardiovascular OEM planned to create simpler and safer tools for precisely inserting and guiding leads into a patient’s heart. The novel “introducer sheaths” needed to be designed to meet stringent part specifications for two implantable cardiac rhythm management therapies. But the user requirements and product performance specifications for the tools were not fully known or clearly defined.

The OEM enlisted us, a longtime, trusted contract manufacturing partner, to help bring the new market technology’s “napkin sketch” reliably to market.

Action

The OEM assigned our engineering team to design specific elements of the product, including how the handle halves would interface and be held together during the assembly process. The team also evaluated and made material option recommendations.

After the initial design concept and 3D model creation, our engineering team worked closely with the OEM team through an iterative series of design modifications, sharing CAD data and 3D printed models to refine the design. We created a set of prototype molds and components used to finalize the proof of concept, perform initial functional testing, gather user feedback and prove out manufacturing uncertainties.

Following a series of modifications to the prototype designs, the team solidified product specifications and began production tooling. We:

- Designed all the molds and fixturing necessary to manufacture the introducer sheath. This involved a variety of manufacturing processes, including injection molding, pad printing, press fitting and ultrasonic welding. We also completed the device packaging and labeling.
- Provided all the manufacturing documentation needed – including inspection plans, work instructions and measurement methods – for evidence the product meets specification and quality attributes.
- Developed all the manufacturing processes utilizing statistical methodologies, including design of experiments (DOE) and capability studies to refine processes and perform process validations along the way. Through the iterations, our team resolved dimensional tolerance issues and product visual/cosmetic problems. They also worked with the OEM team to develop the sterile packaging system, labeling requirements and sterilization processes.

Result

We met the world-leading OEM’s critical timelines for clinical trials and the product launch dates.

Capabilities used

- Product development
- Prototyping
- Moldmaking
- Design for manufacturability (DFM)
- Injection molding process simulation
- Design of experiments (DOE)
- Process validation
- Sterile barrier packaging and labeling

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**
- Visit **spectrumplastics.com**

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