DUPONT Spectrum™

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

Challenge

Overmolding is an injection molding technique that applies a thin layer of plastic over an injection-molded plastic part known as the substrate or insert (which can also be made from other materials, including metal).

This common manufacturing process is used across a variety of industries, from popular consumer products to healthcare, electronics, and aerospace.

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

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For questions or more information, visit **spectrum.dupont.com**

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