

Accelerated time-to-market keeps critical launch on track

Challenge

The market need was strong, the timing tight and the challenge steep: A large OEM set out to address the demand for real-time glucose management for critical care patients. Timing for the product launch was critical – and tight. But the supply chain was complex, consisting of numerous thermoplastic and silicone injection molded components, two sub-assemblies and two purchased components.

Action

Donatelle's technical team quickly rose to the challenge with a gamut of resources, including project management, design for manufacturing, material selection, production tool design and build, liquid silicone molding, medical washing, device sub-assembly and full process validation. We reviewed and analyzed the product concept and goals, then provided strategic insight to improve the design and make it more manufacturable. This upfront rigor ultimately expedited the design freeze. Our rapid tool lead times were critical in getting products into the customer's hands for testing. We also authored validation protocols and completed the molding and medical parts wash validations. Within four weeks of the design freeze, we completed the complex multi-cavity injection mold tooling and first-shot samples.

Result

Donatelle's vertically integrated capabilities with all resources located in one facility, enabled our customer to maximize project management efficiencies and streamline the development process. Partnering with our customer's design and manufacturing functions to provide components and sub-assemblies for final device assembly, we were able to complete tooling in very short lead-times, with first-off samples used for immediate customer testing. The program was successfully ramped up for production and launched in the market.

Capabilities used

- Product development
- DFM
- Production tool build
- Thermoplastic injection molding
- Liquid silicone molding
- Secondary operations
- Process validation



Deliver your medical device promise

At Donatelle, 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.

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“ The product was developed and delivered on time. Donatelle was able to resolve issues with few revisions and little involvement or time required by our staff. ”

– Senior R&D Engineer for OEM