

Struggling to find a solution for cardiac device component, global OEM entrusts Donatelle's innovative engineers

Situation

To replace a tedious and expensive legacy process, a globally recognized leader in cardiac pacing solutions developed a unique solution to stabilization involving the use of a thin wall thermoplastic component integrated with over-molded silicone. If a high-quality, producible design could be achieved, the component would increase reliability and lower manufacturing costs for three different medical devices in three different product groups. Conceptually, the complex, novel component worked well, yet so far, no supplier could translate the idea into a sustainably repeatable manufacturing process.

Already engaged in other projects with the original equipment manufacturer (OEM), Donatelle's engineering team learned of the ongoing product development and quality struggles with the incumbent suppliers. They became determined to solve the part's manufacturability challenges. To instill confidence in the global OEM, the engineering team invested time and resources into building a prototype with similar geometry and features, which offered the opportunity to vet tooling and manufacturing elements critical to the success of producing this challenging product. Impressed, the global OEM's product teams enlisted Donatelle to deliver the as-yet out-of-reach novel solution.

Challenge

Along with extremely stringent tolerances and specifications, the component required a thermoplastic substrate to be over-molded in a

separate tool with silicone. If not done correctly, the high temperatures of the silicone over-molding tool could warp the thermoplastic first shot, causing the product to go out of specification and be unusable.

The product design also required filling ultra-thin wall sections on the first shot and localized areas on the silicone in the second shot without tearing or otherwise damaging the material. In addition, the product required an advanced technology inspection cell to be designed, built and qualified that could consistently and reliably detect the clear silicone material and verify the compliance of features critical to product performance. Another challenge came midstream when the OEM needed to change one of the three devices, which triggered a redesign and rebuild of the tooling in an already compressed time schedule. Through it all, continuity needed to be maintained across the OEM's product groups.

Solution

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Results

Through diligence, patience and innovation, the Donatelle team became the first contract manufacturer to deliver a consistent, repeatable component solution for the cardiac medical device that met the needs of all three product groups. Ecstatic, the globally recognized leader's team awarded Donatelle with two more projects within the same program, and another for a new platform.

Capabilities used

- Rapid tooling and prototyping
- Design for manufacturability
- Precision in-house toolmaking
- Injection Molding
- Liquid silicone over-molding
- Process validation
- High precision automated metrology



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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