

Pushing the limits of micro manufacturing, Donatelle helps OEM create implantable grade component to improve cardiovascular device

Challenge

A global OEM came to Donatelle with a concept to replace an existing component used in the tip of a catheter, designed for ablation of cells on the heart to treat atrial fibrillation. The OEM sought help with a micro-spring component application used to hold thermocouples in the tip assembly of the catheter. They wanted to develop a spring using micro injection molding with PEEK material to replace the existing, high-cost technology.

The Class II device needed a specially designed micro component with a wall thickness of approximately 40 microns and weighing about one-tenth of a milligram. The extremely thin micro component also had to fit into the existing device, while meeting the stringent requirements of implantable medical devices and the repeatability of high-volume manufacturing.

To meet the challenge, Donatelle's engineering team needed to figure out how to reliably design, manufacture and inspect an extremely tiny component, while holding the customer's proposed tolerances.

Action

With other macro and micro parts, the team put product designs through rigorous simulation software testing to help predict potential manufacturing issues. However, in this case, due to the nature of the exceptionally small component, simulation software offered limited benefits in accurately representing the molding process. So, in collaboration with the OEM team, the Donatelle engineering team pushed the boundaries of micro manufacturing, going through several iterations of designs, prototypes and tests to determine the exact right formulation to produce the microscopic component with integrity. Warpage of the part during the molding process and cooling once outside the mold also had to be managed.

In addition to developing the component for consistent, repeatable production, the team needed to remove the microscopic gate from the part and devise inspection methods for quality assurance of the component.

As even the most subtle change in airflow could disrupt the inspection process, managing the inspection and handling environment was critical. For inspection, the team used vision systems to measure and evaluate if the component met customer print specifications. Advanced automation took care of the delicate handling, inspection and packaging.

Result

Marking major engineering and manufacturing milestones for both the OEM and Donatelle, the engineers successfully collaborated to create an improved, more cost-effective microscopic component. The global OEM's product manager praised the Donatelle team's dedication and precision. The upgraded device launched on market to overwhelmingly positive feedback from physicians.

Today, Donatelle annually produces hundreds of thousands of the micro components for the cardiovascular device. Donatelle also produces micro and macro components for the global OEM on several other critical medical devices.

Capabilities used

- Product development
- DFM
- Prototyping
- Production tool building
- Micromolding
- Packaging



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.

Learn more about how we can help bring your medical devices to market – with confidence.

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