CASE STUDY

Donatelle
Manufacturing that changes lives®

Delivering on LSR market demands for critical cardiac component

Challenge

In a heated race against competitors, a global medical device company came to Donatelle for help perfecting a silicone seal component to meet a new ISO standard.

The standard, ISO 27186:2010, specifies a four-pole connector system for implantable cardiac rhythm management devices which have pacing, electrogram sensing and/or defibrillation functions. The ISO standard includes requirements for the connector portion of an implantable lead, as well as for the mating connector cavity attached to an implantable pulse generator. The silicone seal's purpose was to serve as a lockout to prevent fluid ingress and maintain electrical isolation. Essential dimensions and performance requirements are specified together with appropriate test methods.

In this particular case, a seal with micro-features is needed to reliably isolate the four-pole electrical contacts between the pacemaker and defibrillator and fit inside the 6.3-millimeter medical device.

Action

From a design perspective, the microscopic silicone seal had to be precisely injection molded to meet the rigorous new ISO standard, and be robust enough to reliably maintain the locations of the contacts. If the locations migrated, the device could not deliver the therapy needed.

Unfortunately, the industry's widely-used concept for silicone seals does not meet the standards to maintain the location of the seal consistently in this type of device. So, Donatelle partnered with the customer's team of engineers to offer a solution to mold the silicone, and cost-effectively manufacture the component reliably.

With this evolved concept in mind, the team performed a number of scientific studies with different seal geometries and tolerance studies to determine the ideal "design for manufacturability" formula, and created a series of prototypes to prove feasibility. Through this process, they changed the part geometry to derive the optimal sealing design for function and reliability, as well as to dial in the tight tolerances and precise specifications required to meet the stringent ISO requirements.

Result

At the time, at least four major original equipment manufacturing companies were trying to create a market-winning silicone seal component. With a proven product design ready for production, the global OEM tapped Donatelle's vertically integrated capabilities. With state-of-the-art automation, controlled environments and rigorous inspection protocols, the silicone seals were successfully manufactured – and brought to market within the planned timeframe.

Furthermore, as adoption of the product grew, Donatelle delivered again by retooling the cavitation approach to produce more products from each mold. This meant the global OEM continued to meet its growing market demand.

To date, Donatelle has manufactured more than one million silicone seals for the company using our vertically integrated manufacturing and engineering capabilities.

Capabilities used

- Product development
- DFM
- Prototyping
- Production tool build
- Injection molding
- Silicone injection molding
- 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.

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

- Contact **+1.651.633.4200**
- Visit **donatellemedical.com**

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