

Full product line, tight timeline

Challenge

Developing a new medical device, especially a long-term implant, is never easy. But bringing an entire metal implant line of over a hundred parts to market raises the difficulty factor to a whole new level. That was the challenge a growing medical device company brought to Donatelle, along with the requirement that we complete everything – design, manufacturing, packaging and sterilization processes – within nine months.

Action

The breadth and depth of our engineering resources enabled us to dedicate a program manager exclusively to the project and to assemble a multi-disciplinary engineering team that acted as an extension of the customer's company. Because our team was involved early in the design phase, we were able to leverage our manufacturing engineering expertise to provide Design for Manufacturability analysis. This input was incorporated into the final designs, ultimately resulting in a product that was optimized for manufacturing, as well as meeting strict tolerance requirements.

Parallel to finalizing designs and qualifying manufacturing and assembly processes, we brought our packaging, validation and sterilization experts in on the project. Flawless execution in these areas was critical to our customer, since the scope and timeframe of the project left no room for error. Thanks to Donatelle's experience, the customer had complete confidence that process validation was effectively applied to ensure consistency throughout the product lifecycle.

Result

The entire product line was completed and ready to roll out – on time, as promised. Taking full advantage of Donatelle's vertically integrated manufacturing and engineering capabilities, our customer was able to focus on specifications, launch, marketing and building success for the product line in the marketplace.

Capabilities used

- Product development
- DFM
- Production tool build
- Injection molding
- Precision machining
- Secondary operations
- Assembly & packaging
- 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**

“ The dedication of your prototyping team and program manager was critical to our successful product launch. The first doctor to use the device said he ‘absolutely loved it’. Great job by all!”

– Sr. Engineering Program Manager for OEM