

Vertical integration adds value – and viability

Challenge

A medical device OEM came to Donatelle with a problem. One of their products, a device used for rapid sternal access in the administration of medications, was occasionally failing during training – a serious issue in the emergency situations for which the device was designed. The company needed to address this reliability problem to gain confidence and share in the marketplace.

Action

By carefully analyzing the product's design and problems in the field, we were able to identify some inherent design challenges. The firm that had originally developed the product excelled in ergonomic design, but lacked the manufacturing experience to head off potential problems in areas like molded part design and tolerance stack-up.

With a clear understanding of the customer's product roadmap and the barriers they faced, Donatelle took the lead in managing the redesign process. We addressed the tolerance stack-up issues and design for manufacturing concerns, then moved to the next step – building prototype tools to support the customer through initial testing and validation. The customer successfully utilized these prototype devices in initial reliability testing and in its cadaver lab.

Armed with a proven design and parts matched to work together, the customer prepared for production. This involved 18 total tools transferred to Donatelle. We were able to rebuild six of these with relatively minor changes, two required major refurbishment and one needed a complete rebuild in order to meet the ISO Luer standard. We also helped update and correct packaging issues and took over management of the sterilization process.

Result

Donatelle's thoughtful analysis and manufacturing knowledge helped the customer transform a great product idea with a flawed design into a more viable and successful device. Having experienced the difference our guidance and vertically integrated capabilities make, this company now works with Donatelle throughout its entire product development process.

Capabilities used

- Product development
- DFM
- Prototyping
- Production tool build
- Injection molding
- Precision machining
- Secondary operations
- Assembly & packaging
- Process validation
- Sterilization management



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**

“Our relationship with Donatelle has evolved to the point that we view them as an extension of our operation. We compete in the marketplace with relatively complicated medical devices that would require a very large engineering team without Donatelle's help. Donatelle has skills that are hard to hire. Via this partnership, I am able to bring world-class engineering to a product, both in development and manufacturing, within a budget I can afford.”

– President and CEO for OEM