

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
- Precision Machining
- Assembly and Packaging
- Prototyping
- Secondary Operations
- Process Validation
- Injection Molding



“Our relationship with Donatelle has evolved to the point that we view them as an extension of our operation. We compete 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.”

**– President and
CEO for OEM**