

Tall order, high stakes

Challenge

A fast-growing medical device company aiming to be a global leader in minimally invasive spinal therapies asked Donatelle for design assistance in improving an existing device. The product, a bone cement mix and transfer system, had a high profile and projected high-volume sales. And the project would require developing new tooling, component molding, assembly, packaging and finished product sterilization.

Action

Combining the customer's experience and user feedback with our technical team's expertise, we made recommendations for design improvement, along with Design for Manufacturability (DFM) direction. Once the redesign was finalized, we manufactured production tools, then moved to full process validations. Donatelle's engineers authored the validation protocols, completing molding, packaging and sterilization validations while meeting project deadlines.

Result

With the product design complete, we managed inventories of the new device to allow a smooth ramp-down of the previous design and a quick ramp-up of the new and improved design, without stockpiles of inventory. Bottom line: On-time delivery of the system improved to 100 percent and quality issues were eliminated.

Capabilities used

- Product development
- DFM
- Production tool build
- Injection molding
- 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**

“ We really appreciate how the team at Donatelle kept our project on time and then ensured a seamless transition to the new design. Fantastic job every step of the way!”

– Director, Global Supply Chain for OEM