Medical Manufacturer Uses RAPID INJECTION MOLDING *to Improve Product Design*

Innovative technology is rapidly changing the way one medical-device manufacturer upgrades its products to better meet customer needs and maintain a competitive edge in the market. Tensys Medical Inc., a San Diego-based medical-device manufacturer, often relies on prototyping to identify potential improvements in the design of its medical devices. But tight turnaround times and limited budgets have historically restricted Tensys' ability to build functional prototypes. Fortunately, through a process called rapid injection molding, Tensys was able to build the prototypes it needed to support a new product development program. As a result, Tensys engineers beat their internal deadline, allowing them additional time for preliminary testing and further design improvements.

SENSING IN REAL TIME

Tensys manufactures the T-Line® Tensymeter, a noninvasive device designed to measure, in real time on a beat-to-beat basis, arterial blood pressure. Unlike the standard method used to monitor a patient's blood pressure during surgery — a cuff-based system that provides intermittent measurements every three to five minutes — the T-Line extracts beat-to-beat radial arterial pressure using a transdermal pressure sensor.

The T-Line provides continuous blood pressure status, allowing medical staff to constantly monitor a patient's response to anesthetic agents and surgical intervention. This helps anesthesiologists quickly recognize and treat rapid changes in blood pressure to prevent unfavorable patient outcomes such as stroke, postoperative heart attack or even death.

Introduced in 2002, the T-Line has proved popular with clinicians and anesthesiologists nationwide. As the new product gained acceptance, Tensys worked to gather feedback from its core users, focusing particularly on ways to improve and enhance the device. Users said they wanted the T-Line to be easier to operate, so Tensys simplified the product by redesigning its key components.

"Although the application process for using the T-Line is relatively simple, some of our users rotate between different hospitals and may use the device only once every few weeks, so they may have to re-acclimate themselves to the process," said Russ Hempstead, senior engineer, Tensys. "To help reduce the learning curve, we removed a few steps from the application and redesigned certain components."

Specifically, Tensys engineers redesigned the T-Line's plastic sensor frame to allow medical staff to place the sensor over a patient's radial artery. With the previous sensor frame, the sensor itself was attached to the frame via polyethylene tape, which was manually applied during manufacturing. The new design integrates a serpentine "arm" that is fabricated as part of the original sensor frame and eliminates the manual labor and costs associated with the prior method of sensor attachment. It also recenters the sensor after any shifts due to patient movement, helping users more easily maintain proper placement of the device.

ADDRESSING PROTOTYPING AND PRODUCTION CHALLENGES

Although the redesigned sensor frame improved the product's functionality, the new design's unique geometry posed a challenge for Tensys' current prototyping and production techniques. Company engineers first used stereolithography (SLA), a rapid prototyping method, to create a master part. This master was then used in rapid tooling efforts to create urethane castings of the T-Line components. Although the castings provided a conceptual design check, the limited material selection and short tool life posed testing and design verification constraints for Tensys Medical engineers. The challenging geometry also jeopardized Tensys' production plans.

"With huge wall thickness variations and sharp transitions, the sensor frame design is an extremely challenging one for a molder to accommodate," Hempstead said. "When I presented the design to a number of different molders, they seriously thought I was joking because, at first glance, it looks like it will never fill properly."

With a rough prototype in hand in the form of a cast urethane part, Tensys Medical engineers contacted their existing production molder in hopes of keeping production on track for the approaching deadline. But the design's challenging geometry also presented problems for their production plans. Because of the design's unconventional geometries, Tensys' production tool vendor wasn't able to construct the tool properly. As a result, the new tool created a tremendous amount of flash — excess material caused when plastic leaks from a mold cavity and sticks out from the edge of the part.

"When flash occurs, you need to manually trim each part," Hempstead said. "This usually isn't a big deal for us if we're dealing with prototypes; but in a production situation, it's not acceptable because of the quality and expense."

Tensys engineers and the production tooling vendor were struggling to get production tooling underway. In the interim, a Tensys design engineer came across information about a prototyping and low-volume production process that seemed well suited for the redesigned T-Line — rapid injection molding. With a deadline approaching, engineers decided to take an unconventional step back in the process and check out rapid injection molding's abilities for prototyping and pilot production.

EXPLORING NEW METHODS TO MEET DESIGN NEEDS

Tensys was particularly attracted to rapid injection molding because of its fast turnaround time and low costs. Developed by The Protomold Company, based in Maple Plain, MN., rapid injection molding utilizes proprietary software technology and high-speed computer numerical control (CNC) machining to produce injection-molded parts from 3-D computer-aided design (CAD) models in as little as three days.

Tensys design engineers accessed Protomold's Web site at www.protomold.com and submitted their 3-D CAD file for the redesigned T-Line. Within 24 hours, Protomold sent Tensys an interactive ProtoQuote® — a Web-based price quotation that illustrates the effect of using different materials, compares lead-time options and lists final price points based on quantity. It also includes Protomold's suggestions for potential design improvements.

"The fact that I can simply upload a CAD file directly to the site, add a few detailed notes and just walk away, easily saves me 50 percent of the time I typically would spend on the logistics of a quote," Hempstead said. "If I had gone to a different molder, I would have been forced to deal with incompatibility issues and trying to meet another vendor's CAD file format or 2-D drawing requirements. Not having to translate my CAD files or correlate software versions allows me time to conduct other work."

Protomold's ProtoQuote also gave Tensys engineers valuable design guidance on how to work within the rapid injection molding process specifications, highlighting areas where wall thickness was significantly greater or less than nominal and areas where draft was less than three degrees, prohibiting texture additions. Based on the ProtoQuote suggestions, Tensys design engineers revised their CAD file and submitted an order for 25 sensor frame prototypes. Within just six days, Protomold delivered the company's completed parts.

"We subjected Protomold to a difficult trial by submitting our toughest part as a test, and the company rose to the challenge," Hempstead said. "Even better, the company amazed us by delivering a final product while our production vendor was still struggling to produce a workable tool. Overall, rapid injection molding delivers in a time frame 90 percent faster than other molders we've worked with, which poses huge benefits for us."

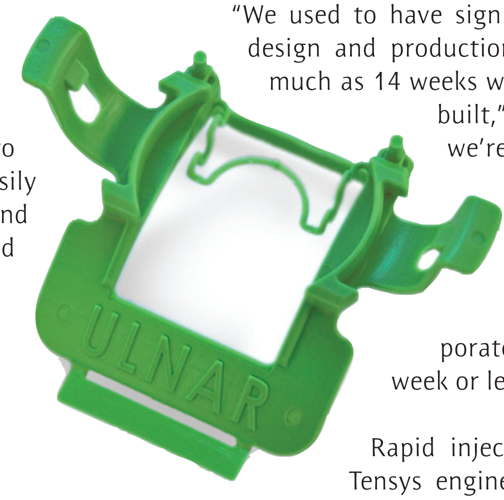
Pleased with the rapid injection molding prototype results, Tensys Medical engineers immediately stopped production tooling to shift efforts toward further improving the T-Line component designs, while keeping on target with the original timing specifications.

SQUEEZING MORE OUT OF BUDGET AND SCHEDULE

Originally, Tensys sought to place a single order for a prototype to meet its internal deadline. But Protomold's quick turnaround allowed Tensys design engineers to use the additional time savings to conduct preliminary validation tests and further improve the product design through successive iterations.

"Before we discovered rapid injection molding, we were struggling to make a schedule that would let us create production parts we needed," Hempstead said. "But once it became apparent we could meet this need using rapid injection molding, we began asking ourselves, 'What else can we improve before we get to production?'"

Protomold's rapid injection molding process allowed Tensys design engineers to significantly shorten the product design and development program time cycle.



"We used to have significant lag time between design and production, sometimes waiting as much as 14 weeks while our tools were being built," Hempstead said. "Now we're able to do more design work and testing because everyone here knows we can use Protomold's rapid injection molding process to incorporate our design changes in a week or less."

Rapid injection molding also helps Tensys engineers reduce the costs of production tooling and final parts. "The tooling costs from Protomold are 50 to 60 percent lower than prototype tooling quotes from other molders," Hempstead said.

Tensys now relies on Protomold to supply its prototypes and, in cases where the needed quantities are prohibitively high for standard rapid prototyping methods, for pilot production parts. In fact, Tensys is currently developing 30 tools in conjunction with Protomold. And Tensys is working with Protomold on the fifth design iteration of the T-Line redesign.

FIND OUT MORE

To learn more about Tensys and its medical device offerings, visit the company's Web site at www.tensysmedical.com. For an in-depth look at the benefits and potential applications of rapid injection molding, visit Protomold's Web site at www.protomold.com.