

Molder/moldmaker sits on the cutting edge of a life-saving device

Mastercraft Precision Injection Molding & Tooling, Phoenix, AZ

By Clare Goldsberry

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The medical industry is a good one for molders and moldmakers who relish seeing how their work can make a difference—sometimes a huge difference—in a person's life. This processor even got to work with one of the first patients for a device it helps manufacture.

The artificial heart has long been recognized as one of the truly great medical device innovations, but the goal of a true artificial heart replacement that offers patients mobility and a near-normal lifestyle was always just beyond reach. That was the case until [Thoratec Corp.](#), which has been working on heart pumps for 20 years, developed the Heart Mate II, an artificial heart that works with the heart, rather than being its total replacement.

Boston-based Thoratec Corp.'s left ventricle assist device (LVAD) has been in development and testing for several years, but it wasn't until researchers at the company found that plastic and metal didn't work like a real heart muscle, and changed the direction their design was taking, that the real breakthrough came. The resulting Heart Mate II, a device that works more like an electric motor than a pump, is fully implantable and was given U.S. Food & Drug Administration (FDA) approval in 2008.

Thoratec's Pleasanton, CA manufacturing operations needed a new supplier for the Heart Mate II, as the company had outgrown its first supplier of the supporting products to its LVAD heart device.

Development of the Heart Mate II required a number of plastic components, including a base unit that contains

all the electronics; a battery charging station for the battery packs; two battery packs that the patient wears to hold the batteries that keep the motor running; and a belt clip—a total of 22 plastic parts in all.

[Mastercraft Cos.](#), consisting of moldmaker Mastercraft Mold and custom injection molder Polycraft Industries, was contacted by Thoratec's senior buyer, Judy Benenato, who knew Mastercraft as a premier supplier to her former employer, Hospira, and she introduced Thoratec to Mastercraft. "We're 60% medical in the customers we service," says Dale Behm, COO of Mastercraft. "We've established long-term customers and partnerships, and provide concurrent engineering on large programs such as the Heart Mate II that require heavy engineering and design."

After working with Thoratec's engineering and marketing staff for several months, Mastercraft was awarded its first program, the belt clip, in October 2008. Currently, Mastercraft is in the completion stage on molds for all 22 components, all naturally with tight-tolerance molding specifications. The molds



Tom Tirone (left), one of the first recipients of Thoratec's LVAD, enjoyed offering feedback to the OEM and its molder/moldmaker Mastercraft Cos.

represent a second generation of tooling for the device, and are being redesigned to solve some of the challenges that were discovered from the first generation of molds.

Working to his company's advantage, recalls Behm, was that Thoratec required a supplier that had both moldmaking and molding capabilities in-house. Mastercraft's operations are housed in a two-building campus in Phoenix, AZ, and include a 20,000-ft² mold manufacturing facility that includes a design engineering department using 2D and 3D solid modeling with SolidWorks and Pro/Engineer, and FeatureCam for surfacing.

The molding facility, Polycraft Industries, is a 40,000-ft² facility with 32 injection molding presses ranging from 40-440 tons, with six of those presses in Clean Environment Manufacturing Cells (see article on p. 50 for more on these), three more in a cleanroom, and two used for mold sampling. Secondary services include sonic welding, silk screening, painting, pad printing, hot stamping, and subassembly.

"Thoratec looks to us as the manufacturing experts for their plastics requirements, both in mold design engineering and processing," says Behm. "We have extensive expertise in molding medical equipment and bring a lot of value add to the table. Additionally, Mastercraft has 40 years in business and is a debt-free company, something that OEMs look hard at in these economic times."

Mold designs altered for lighter, better components

Many changes were made to the new molds to improve form, function, and manufacturability, says Bob Corey, engineering manager/new business development for Mastercraft. "We offered Thoratec various options on their tooling, including interchangeable inserts in a family mold and multi-unit die (MUD) designs on some of the very small parts," he recalls. "It all goes back to the mold design to get a successful part."

The original base unit, to which the patient is tethered at all times, weighed nearly 50 lb, so that while it was designed to be mobile, it wasn't really something that the patient or caregiver could carry easily from one room to another. Mastercraft redesigned the new base unit, reducing the size and weight of the unit by 30%-40%.

Mastercraft Mold also redesigned both molds for the battery charger housing to eliminate assembly steps and reduce costs. Thoratec had started out using an ABS structural foam material, and then went to a glass-filled resin to try to get the parts it needed. The parts were cracking and had bad sinks. The new battery charger housing molds are built for PC/ABS. No longer necessary is a blowing agent that was used to mold the glass-filled material with the original tooling, saving both labor and assembly costs. Processability of the parts was improved by providing adequate draft on the textured mold surfaces.

Some previous suppliers it approached had told Thoratec that some of the parts were not moldable. Mastercraft, however, chose to re-engineer those parts and, by laying parts down in the tool and using cylinder core pulls, was able to mold them easily, it says. A hot runner system was chosen over a cold sprue to produce a better-looking part.

The batteries are worn in holster-like carriers on a belt around the waist. One of the first patients to have the Heart Mate II implanted, Tom Tirone of Glendale, AZ, helped Thoratec redesign the new way to carry

the batteries so it was more convenient than the original version's backpack style. The holsters help distribute the weight of the batteries on each side of the waist, and make it easier for the patient to move around.

"We offered Thoratec a turnkey operation here at Mastercraft, showing them options in both design and processing that they were unaware of previously, and working with Thoratec's engineers in both Boston and Pleasanton all through the tool build to get them exactly what they wanted," says Corey. "That's the input they were looking for in the redesign of the parts and molds for the new tooling." Ultimately the new version not only offers improved functionality for patients; it also is less expensive to manufacture. Mastercraft's team says it is proud of the work it does for Thoratec, especially after meeting Tirone. "This isn't just about molding parts," said Behm. "We're impacting people's lives."

Patient gets involved in device design—and marketing, too

Tom Tirone, 73, is a retired police officer from Buffalo, NY, who now lives in Glendale, AZ. He had been suffering from heart disease for a few years, and as he described his condition, "I was like the walking dead." A doctor who was treating Tom's wife noticed one day that he looked bad, so he was sent to Thunderbird Hospital, where he coded for 40 minutes.

"I was in the right place at the right time," Tom says of this experience. Doctors, including his son-in-law, a paramedic, worked on him for the entire 40 minutes and ultimately saved his life. However, the doctors told him there was nothing more they could do. He then went to the Mayo Clinic for care. Although initially his name was to be added to a heart transplant list, that plan was shattered when, during testing, doctors found a cancerous polyp. Suddenly, he no longer was a candidate for a heart transplant.

While a doctor at Mayo knew of the Thoratec device, it was not yet FDA approved. But in 2007, Tom got a call from a doctor at Mayo who told him the FDA had given approval for the device to be used as a "bridge" device for people awaiting a heart transplant. "The doctors at Mayo set me up for getting this device," Tom said. "You know, when I got this device, it was new to the doctors there, too. I was only the second patient at Mayo to receive this."

Tom received the device on July 3, 2007. Today, he says, "I'm feeling great! I work out at rehab three times a week. I was one of the lucky ones that got this device, and not a heart transplant." The device allows him to enjoy life with his wife, three grown children, and many grandchildren, all of which have been a big help. "The support you get from your family and your caregiver, which is my wife, is wonderful. They become the experts," he notes.

Tom's out of the two-year study, and visits the cardiologist every three months for a checkup. "I can keep this device as long as something else doesn't go wrong," he says. And if he were to be offered a heart transplant again? "I'm staying with what I've got and not doing any transplant," he states.

If there is one thing that Tom wants out of this experience, it is to educate as many people as possible about Thoratec and the LVAD device. "Cardiologists don't even know about this device as an alternative to a transplant," he says. He added that he has enjoyed meeting the Thoratec people and the staff at Mastercraft, where the new tooling for the next generation of the LVAD is being completed. "Overall, this has been a real positive experience." —Clare Goldsberry

