



## ***Breakthrough Medical Devices: Manufacturing Efficiencies Ensure Recovery Speed***

***Mako Surgical Relies on ThermoFab for Speed and Cost-Effectiveness in Delivering Surgical Robots that Provide an Alternative to Knee Replacement Surgery.***

### **Challenge – Barriers to Medical Prototype Production**

Breakthrough medical products. We hear about them all the time in the news — from miracle drugs that give hope to the hopeless to “smart” equipment that turns invasive medical procedures into non-invasive outpatient routines. But before these innovative products are mass produced, they go through trials — be it federally monitored clinical trials (as the case for new drugs) or trial runs in hospitals where doctors and medical staff test innovative equipment. Of course, this trial equipment still needs to be manufactured. Mass production of parts (think high volume) usually involves injection molding along with significant time to market. But the time and development involved with injection molding proves prohibitive when only low-volume orders are placed, which is the case for medical pre-production and production. What’s a medical products company to do — especially when it has a product it knows could potentially revolutionize an area of medicine?



### **Surgical Creates Innovative Design Concept. But Who Can Manufacture It Quickly and Effectively?**

These are questions Florida-headquartered Mako Surgical faced when developing its second-generation Tactile Guidance System™ (TGS™), an advanced robotic-arm solution for minimally invasive orthopedic knee procedures, known as MAKOpasty®. Up until now, the general approach for arthritic knees and other knee issues has been to use cortisone shots and eventually replace the entire knee joint, which is comprised of three compartments. Because surgeons aren’t able to isolate a specific compartment manually, they would remove and replace the entire knee after a course of cortisone and therapy. This is an invasive procedure with a lot of recovery time and pain to manage, not to mention the 12-inch scar it leaves on the patient.

Mako has created a small implant, delivered by a surgical robot. The robot can get into the specific compartment of the knee that needs replacement. It enters through a small incision. Ultimately, this procedure postpones and potentially eliminates the need for a full knee replacement. In addition, the Mako surgery allows for a new knee, and the patient can walk out of the hospital on the same day. It’s minimally invasive, meaning less pain for the patient. Plus, it saves the patient and hospital time and money in treatments and care.

Because of the different parts the Mako robot requires and because of the small quantities needed during this pre-production stage (100 over the course of a year), injection molding was not an option due to the cost of tooling.



### **Solution – ThermoFab’s In-House Engineering, Tooling, & Painting Cut Down on Time to Market**

ThermoFab helped Mako with the manufacturing of the second-generation robot by enhancing the design to make it a sleeker and more service-friendly model. ThermoFab reviewed Mako’s original designs, and their expert engineers provided suggestions. Mako’s Manager of Robotic Design, Brian Schmitz says, “ThermoFab was very responsive and very open to view our designs without a commitment to the shop.” ThermoFab manufactured all the coverings based on Mako’s design and ensured that the fits and materials would work well in production. ThermoFab’s manufacturing process—which creates a product that can hold tighter tolerances, yet without the long lead times associated with the injection molding process — worked well with Mako’s vision for its product. Timing was a critical factor. Mako needed 16 different parts that ThermoFab was able to turn around in about 12 weeks — other shops would have required 12 weeks per part. ThermoFab has in-house tooling. Most other companies need to subcontract the tooling. Finally, ThermoFab has an on-site paint shop, allowing it to finish the product to specific color and silk-screening requirements. This saved the client significant time.

### **Results**

A Production Partnership Worth Duplicating!

A breakthrough medical product — delivered on time and on budget — that can help doctors help patients walk pain-free. What more could you ask for?