





#### Machining

# Precision Manufacturing: One Shop's Journey in Making Medical Equipment Parts

Holly Martin | Feb 12, 2019

What does it take to make parts for precision manufacturing? What is it like to be a small manufacturer for medical parts? We explore the opportunities with a fresh perspective from a Michigan-based company doing it today: Rocket Machining & Design.

Precision manufacturing is big business—especially in medical manufacturing. In the U.S., the market is expected to reach \$173 billion in 2019, *according* to medical device consulting firm Emergo. Small- to medium-sized job shops looking for new markets might find a good fit in the lucrative medical supplies and devices market. But with the opportunity there are challenges in the types of equipment and skills required to compete for jobs manufacturing these small, complex parts.

One example of a successful entry into precision medical parts manufacturing is *Rocket Machining & Design*, which opened its doors on Dec. 17, 2017, and completed its first part on Jan. 31, 2018.



Medical parts by Rocket Machining & Design

Located in Springfield, Michigan, Rocket Machining & Design is not far from Kalamazoo, headquarters of medical device giant *Stryker* (see sidebar). Though Rocket started out in other types of machining work including automotive, energy and fluids, the company was soon introduced to Stryker through its MSC representative.

"It's been a great relationship, and recently we've grown and taken over a lot more of Stryker's work," says Duane Spurling Jr., managing partner for Rocket Machining.

Many of the parts Rocket Machining & Design is making are components and prototypes for surgical instruments.

## The Types of Machines Needed for Medical Parts Manufacturing

For its medical work, Rocket uses Haas CNC machines, including a TL-1 and an ST-30, as well as Haas mills and a surface grinder.

"Currently we're turning the medical parts and then putting them in the mill, or vice versa, which has been kind of rough," says Spurling.

"Now that we're seeing more of these parts come through, we know it's important for us to get a machine that's done-in-one production, so we are actually in the process of purchasing a live tooling lathe, maybe a Haas ST that can handle barstock up to 20 mm wide," he says.

Need to know the preferred techniques for working with medical-grade titanium, cobalt chrome and nickel-based stainless-steel alloy? Read "8 Must-Know Tactics for Precision Medical Machining."

# Regional Concentrations of Medical Manufacturing 'Hotbeds'

"Medical device manufacturing is one of those industries that isn't subject to economic ups and downs because people get sick regardless of the economy," says Lauralyn McDaniel, an industry manager of medical device manufacturing at *SME*.

According to McDaniel, one of the factors driving high levels of device production is the aging baby-boom generation.

"With an increase in population experiencing chronic diseases has come an increased need for devices to address them," she says. Such devices include pacemakers, implants, insulin pumps and other hybrid devices that administer drugs. Hybrid devices have been a growth area for about 15 years.

"The three major concentrations of medical manufacturing in North America are Southern California—the largest by far, Minneapolis and New England/Philadelphia," says McDaniel.

Manufacturers in Minneapolis tend to specialize in low-volume, high-complex devices, such as neuromodulators, insulin pumps and new devices to treat kidney diseases, she says. That area also includes a belt that runs down through Milwaukee to Chicago and then over to Warsaw, Indiana.

"Warsaw has a concentration of orthopedic device manufacturing facilities, including Smith & Nephew, Depuy and Johnson & Johnson," says McDaniel. "And 100 miles north of Warsaw sits Kalamazoo, Michigan, which boasts a small but growing concentration of medical device companies, including Stryker and Upjohn (Pharmacia)."

Companies in the Boston-Philadelphia-New Jersey corridor focus on manufacturing orthopedic devices. According to McDaniel, this submarket is somewhat flat. However, that doesn't mean the overall medical device market is shrinking—it has shifted to other types of products and crossed over into the growing market for biotechnology and new sensor technologies such as microfluidics.

McDaniel says the orthopedic market has become less concentrated in the Northeast, with the exception of a large presence for additive manufacturing (3D printing) of orthopedic implants in New Jersey.

## Typical Tooling and Materials Needed for Medical Parts Manufacturing

Rocket Machining & Design uses mostly *Walter* cutting and turning tools—and it's been a learning process.

"We've had to work on identifying the right carbide inserts, clearing up problems with the flushing and trying to find the right nose radius," says Spurling. "When you're machining such small pieces, it's

important to be able to get the things that we want out of the tool."

For most of its medical prototypes, Rocket uses A2 and 17-4 stainless, though they've also used 303, 304, 4140 steel bar and 440 stainless a handful of times.

"Some of our stainless [materials] we have pre-hardened from the beginning, so we'll have to hard-turn things," says Spurling. "It's very crucial to be able to turn those materials and have the correct carbide, because it'll eat tooling up very quickly."

#### The Importance of Micro Cutting Tools for Medical Equipment Parts

Medical device parts require the right tooling for small, detailed work. To that end, the company uses a variety of Horn micro-machining tooling.

"For these devices, we've gone down to diameters of .0005 or .0006, tiny groove widths that are basically .0001 or .00015, and extremely fine thread pitches tapping 440 and 17-4 Ph stainless," he says.

"Tapping those pieces, especially on a lathe, has been very tough, so when someone wants that type of fine pitch, having the right tooling is critical," he says.

#### **Prototyping Medical Instrumentation**

In spite of its young existence, Rocket has already worked on quite a few prototypes for new medical instrumentation designs.

"These prototypes can be anywhere from internals for electric motors that are going to go into the Stryker guns, to backing, to medical assembly components," says Spurling.

"We got to be a part of the development of one of the new Stryker motors, and I believe there hasn't been a new one for the past 15 years," says Spurling. "So we're kind of on the front end of seeing what's to come."

## Making the Right Adjustments for Quality Control

Rocket Machining is working toward its ISO 9001:2015 quality management certification, as well as an inspection certification for its lab, which is already fitted with dust, temperature and humidity controls.

"One of our quality control processes is in-process, first part inspection, so the first part to come off will be completely gone over and signed off on by either our production manager or first shift leader," says Spurling.



An isolated medical part by Rocket Machining & Design

To ensure quality control, the company will turn multiple pieces at different sizes to accommodate changes in specs due to post-processing, and then ship them out for any type of heat treatment or plating.

"We take into account the possible expansion of the material that's going to be heat-treated, especially for A2, because sometimes the tolerance might not be met initially, but we'll assume for growth," he says. "Also, if a coating thickness is specified at four microns, we'll make the part four microns undersize, and the plating company is responsible for meeting that requirement."

## A Future in Medical Parts Manufacturing

At this point, Rocket makes just a few pieces of each part. But even though the company is young, Spurling sees a large opportunity for profitability with medical parts manufacturing.

"We know we've got to take more steps, and we're in the process of getting more certifications to be able to eventually do production work for Stryker," he says. "We take great pride in our machining area, and the way we conduct our business is very clean and precise and orderly—and that was one of the things that got us in with Stryker and the medical industry."

Spurling has advice for shops looking to break into the medical device market.

"When you're quoting and trying to produce these pieces, one of the things that you have to account for is the level of difficulty that comes with them, but with that also comes an opportunity to make a lot more money," he says.

How do you do quality control for medical parts without having your ISO certification? Jump in on the conversation over at the metalworking forum. [registration required]

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