



Pioneer Surgical's 36,000 sq.ft. manufacturing space includes the latest technology in machining and manufacturing equipment

Medical device manufacturer, Pioneer Surgical, has built a reputation for innovation and responsiveness with help from highly skilled people and powerful CAMWorks® software

Discontent can be a powerful thing. It was for Dr. Matthew Songer. Twenty years ago it spurred him to create Pioneer Surgical (www.pioneersurgical.com), a medical device manufacturing company based in Marquette, MI. Songer, an orthopedic surgeon, wasn't satisfied with some of the orthopedic devices available to him at the time. As he saw it, one of their key drawbacks was the use of monofilament wire to attach devices to bone. Exposed to real life stresses, the wire would occasionally slide, or loosen, or even break, all of which was bad news for the patient. For Songer, 'occasionally' was just too often.

Songer came from an engineering family, so he was used to the way engineers think. Putting on his engineering hat, he reasoned that since the tensile properties of coil are superior to those of wire,

provided that the metal used is the same in both cases, then why not try coil? The young firm, founded in Songer's garage, began putting that insight to the test.

The eventual result was products like the Pioneer Sternal Cable System. Employing multi-strand stainless steel cable, which is tensioned and then secured with a tensioner/ crimper, also of Pioneer's design, the system provides a more stable and precise attachment to the bone. This promotes faster and a more complete healing of fractures than is the case with traditional monofilament wire. It is also substantially less susceptible to failure when compared with monofilament wire. This, and its subsequent products and innovations, rapidly propelled the young company; so rapidly, in fact, that five years after its founding, Pioneer could boast of both an extensive line of orthopedic products, and of alliances with industry leaders such as Zimmer Inc., Synthes USA, and DePuy Spine.

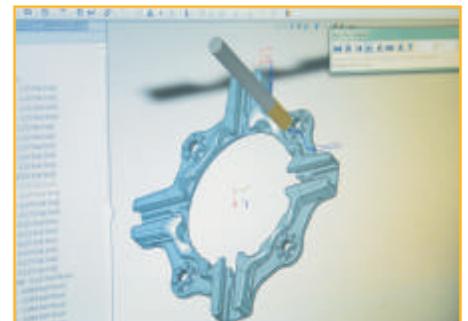
Building on the success of its orthopedic business, Pioneer launched a line of spinal fusion devices including vertebral spacers, cervical plating systems and comprehensive spinal fixation systems, which have also pleased surgeons, patients and the market.

As the young company grew, so did its attention to manufacturing. Along with the pressures of an ever increasing volume of parts, the company understood that no device, no matter how innovative, can deliver full benefit unless it is made well. As a result, high quality and high precision machine tools began to line the floor of Pioneer's expanded, 36,000 sq. ft. facility.

Uncommon Challenges

"We face challenges that a typical machine shop doesn't," notes Pioneer production manager Martin Hillock. "For one thing, prototyping is a major aspect of our operations, much more so than in most other types of manufacturing". Prototyping is central to the medical design process, with its near constant stream of new products and the need for speed in getting these useful products to market. It is even more essential at Pioneer, which has always deemed itself as a 'surgeon-driven' device manufacturer, working closely with hospitals and doctors to give them the tools they need on a timely basis.

"We send our engineers into the field to meet with the doctors, to sit down with them and have them explain to us the types of problems they are having with the devices they are working with, and what they are trying to achieve," says Hillock. "Sometimes we even send an engineer right into the operating room to get an understanding of where the doctor is struggling. Our design process begins right there, in the operating room. We'll rapidly

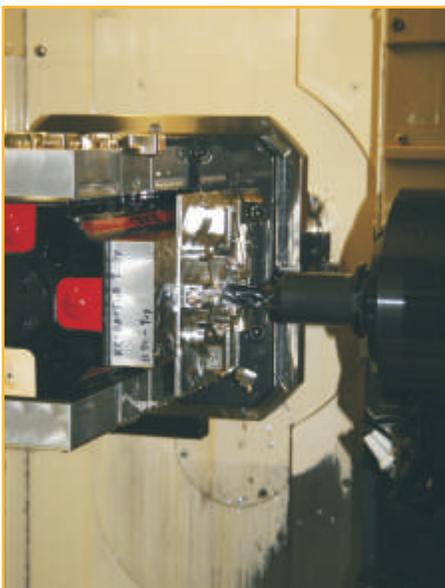


CAMWorks provides a CAM model of a retractor body. The retractor body is the end component of the retractor instrument that is used in a lateral (from the side of a patient) approach to a spinal surgery. It more or less creates and holds open soft tissue in order for a surgeon to insert an implant, which is used in fusion of the spine.

put the new device into the hands of the doctor to see how he likes it, and continue on from that point until he has what he needs.”

Getting the doctor what he needs typically entails several iterations. “You have to be able to adapt quickly because we’re constantly changing at that point,” Hillock continues. “The design may change 10 times, so it’s very important to have CAM software that can quickly accommodate those changes, update the toolpaths and change other affected machining parameters, and rapidly get the process going again. That’s where CAMWorks has been a major benefit for us.”

CAMWorks (www.camworks.com) is a 3D feature-based CAM software from Geometric (Scottsdale, AZ) that provides an array of tools to simplify and automate even complex programming tasks, speeding design and programming changes. Like a great many other firms, Pioneer employs the popular SolidWorks® design software, and the fact that CAMWorks is integrated seamlessly within SolidWorks yields a number of benefits.



Retractor body being machined on the Tsugami FMA 3

It allows, for instance, the use of a single file for a company’s CAD and CAM systems. This eliminates time-consuming file transfers. Plus, using the SolidWorks design geometry to generate toolpaths ensures that the part machined is the same as the part that is modeled; this aids in accuracy and precision that is valuable in any manufacturing application, but particularly in the world of medical device manufacturing, where the parts are destined for use within the human body.

Hillock notes that CAMWorks’ tight integration within the SolidWorks environment facilitates associative machining. As a result, any revision to one of our part designs, and there are typically many, updates the SolidWorks solid model as well as the CAMWorks file, allowing CAMWorks to automatically generate the required new toolpaths, the tool list and, if it is necessary, the fixture modifications as well. This has resulted in major time savings for us on revisions.

Enhancing Flexibility with Software

“Flexibility is extremely important for us,” he stresses, “not only in the prototype work we do, but in terms of customization, or ‘specials’ as well”. Hillock outlines a situation, where after a prototype is finally completed and released commercially, a doctor might come to Pioneer with an ‘if only’ request.

“A doctor – let’s call him Doctor A – might come to us and say, ‘I’ve seen that product you’ve just developed and it’s a good one, but if only it was modified slightly it would be so much better for my particular patients and my particular needs.’ We’ll make it for him. That’s what we do in our specials department. Not everyone will do that, but it’s something the medical community really appreciates. Granted, it

sometimes causes quite a bit of havoc around here, but it’s an important part of our niche as a responsive, innovative and surgeon-driven device manufacturer. Again, it’s something that CAMWorks, with its rapid response and time saving capabilities, has been instrumental in helping us accomplish.”

A key part of those capabilities is a CAMWorks’ feature called Automatic Feature Recognition (AFR). Using AFR, CAMWorks identifies the areas to be machined, and then uses its proprietary Technology Database (TechDB™) to automatically generate the toolpaths. And not only toolpaths for the part currently being produced, but also automatic programming of families of parts, along with similar features on new parts, as well as the ability to incorporate manufacturing information directly into the solid model. This not only eliminates most of the time consuming CAM system rework due to design updates, but also speeds the transition from design to finished part on new projects.

Speeding the transition from design to finished part is important not just for prototype and special work, of course, but also for the new products, which Pioneer continues to bring out. Along with continued replenishment of its orthopedic line, the company has launched several spinal-related product lines in Europe, including the NuBac®, NuNec® and BacJac® lines aimed at alleviating the effects of Degenerative Disc Disease (DDD), which is believed to be the main cause of lower back pain for millions of people worldwide.

In the past, patients who suffer from DDD have had limited alternatives to total disc replacement/arthroplasty or spinal fusion

surgery. Although these procedures relieve pain, side-effects such as surgery-related complications, invasiveness, and revision risk spurred Pioneer to search for alternatives. The result has been a full line of cutting-edge motion preservation devices that include the NuBac nucleus replacement device, the NuNec artificial cervical disc, and the BacJac interspinous decompression system, currently being sold outside the United States.

When dealing with the often complex part models of these new devices, a CAM system's ability to recognize more features in less time can result in major time savings. Here again, just as with the prototype work, CAMWorks' features like the Technology Database that is used to store and apply knowledge-based machining information, plus the associativity that allows the software to automatically update manufacturing models with design changes, helps accelerate new product development. One might expect that advanced software of this order would be a major challenge to learn. Not so, says Hillock.

"At the time we acquired our first seat of CAMWorks we weren't very advanced CAM users, but we had heard good

things about it and it seemed pretty user-friendly, so we decided to give it a try. In retrospect, it's clear that was a good move."

"It really didn't take us as long as I thought it would take to become proficient," he continues. Along with the intuitive nature of the software, the training and support received from the CAMWorks distributor played a key role in Pioneer's relatively rapid ramping up. "I've got to give them very high marks," says Hillock. "Whenever we've had a problem they've always been extremely quick to respond to it. They've been excellent."

Pioneer's involvement with CAMWorks has grown from the initial single seat to a total of six today, the most recent one purchased to aid the company in its foray into five-axis machining. "We recently bought a Haas five-axis machine for our production floor and we also have a Haas five-axis in our prototype department," Hillock reports. The new five-axis capability holds the promise of allowing Pioneer to machine complex parts in a single setup, speeding production, and eliminating the possibilities of the types of errors that can creep in with multiple setups.

"It's all part of Pioneer's tradition of ongoing innovation", says Hillock. Over his many years with the firm Hillock has been a contributor to that innovation, and he has also been a beneficiary. "I had back surgery two years ago. I had to get two vertebrae fused and they put some of our product in me, and," he adds with a smile, "it works just fine".



Amongst Pioneer's several machining centers, is a Tsugami FMA 3

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