

BY
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The Problem

Entering the tough medical device market

The Solution

Investment in ISO, equipment, and OEM partnerships

Adapting To *Change*

Quebec orthopedic manufacturer's strategies for growth

Medical device manufacturing in Canada is entering a new era, with cutting edge designs greatly expanding the opportunity for organizations providing technologies that were only dreamed of a few years ago. One good example is PPD Meditech in Waterville, QC, which is building market share by combining metalworking skills with its traditional expertise in plastic moulding.

"PPD Meditech is part of the PPD Group," says Jean-Pierre Simard, vice president, sales & business development at PPD Group. "Company president Daniel Morrisette and his brother Sylvain started PPD Group in 1960 with two other brothers. Then Greg Pye started up PPD Meditech more than ten years ago, and he remains the company's business development manager."

In the late 20th century PPD Group gained traction in numerous markets, including agriculture, transportation, industrial equipment, and consumer goods. Having an established industrial foundation for support then made it

possible to invest in the longer-term vision required by PPD Meditech, which specializes in orthopedics.

"We saw the opportunity to shift into medical, and could draw on our other expertise," says Simard. "Specifically, we could move in that

manufacture of medical devices. With that on hand it was easier to get FDA approval and to partner with original equipment manufacturers (OEMs) like Warsaw, IN-headquartered, Zimmer, which specializes in joint replacement technologies.

"Zimmer asked us to machine to medical grade, and we developed the technology," says Simard. "We knew this was a highly regulated industry, but we also knew it was a growth market. There is value based on innovation, and our company likes engineering."

This also means that PPD Meditech sometimes partners with other metalworking shops that are machining different parts, specifically for joint reconstruction. The result is an intersection of high-grade cobalt-chrome with medical grade plastics such as UHMWpe and PEEK.

"There is a cobalt-chrome articulating feature on the femur,



Acetabular cup implant for hip replacement. PPD Meditech combines metalworking machining with biomedical plastics to create orthopedic implants.

direction because we knew we could be strong in machining both bio materials and metal."

To get into the market PPD Meditech made a strategic decision to focus on the United States, running its facility in accordance with ISO 13485 certification for the design and

some of which we outsource,” says Greg Pye from PPD Meditech. “This is a highly polished material that articulates against the base plate.”

The mix of cobalt-chrome with medical grade plastics reflects the new reality in medical device manufacturing, wherein advances in materials are defining a highly segmented industry. It is certainly an aspect of PPD Meditech’s success: the company has grown partly as a result of an intense and exclusive focus on niches within the medical market.

“We are active in biologics, joint reconstruction, trauma, spine, and a bit of cardio,” says Simard. “However, our primary focus is joint reconstruction within orthopedics, which makes sense because the overall medical market is very large, and our sector is growing given the aging population.”



PPD Meditech is growing in part, because of its ability to combine metalworking with plastic moulding technologies to create parts.

As well, PPD Meditech benefits from the fact that the larger PPD Group, though more than willing to provide resources, nonetheless allows the medical division to focus exclusively on its specific competencies.

“If you have a company that has different areas of expertise, it makes sense to organize each division around its core business, and that’s what we’ve

done with PPD Meditech,” says Simard. “For us medical is not an add-on: the business has all it needs from start to finish to help our customers, from the development process to production.”

Another lesson from PPD Meditech – which operates out of a 20,000 sq ft facility – is that any company active in the sector has to be prepared to adapt to innovation, whether from the competition or within a partner network. This happened to the company when an OEM it supplies in the

THE EQUIPMENT | Man and Machine



PPD MEDITECH does its own large tooling design and manufacturing, including nickel shell tooling. When machining parts for its customers the company combines metalworking machining with biomedical plastics to deliver state-of-the-art parts for orthopedic implants.

“On the metalworking front, we use a Matsuura MC-550VX CNC milling machine for roughing hard metal parts,” says

Greg Pye, PPD Meditech’s business development manager. “We rely on it to fabricate metallic moulds that are then used for polymers.”

The Matsuura machine is a vertical centre running at 8,000 rpm, with a machining capacity of 21” x 16” x 18”. Though not a new machine, the MC-550VX is nonetheless popular among medical manufacturers requiring exact tolerances and decent surface finishes.

PPD Meditech also has a Fanuc Robocut Alpha-1iD EDM for metal fabrication, specifically high speed wire cutting. The Fanuc’s precision is aided by the manufacturer’s patented pulse control, which can track the discharge pulses per unit time to determine what is contributing to the cutting, and what isn’t. The Fanuc EDM also has a nanometer for axis movement control.

“And we have a Zeiss Duramax, as well as five Mitutoyo coordinate measuring machines,” says Pye. “We use these to measure machined metal parts to insure they are to specification.”

The Mitutoyo calipers can come with onsite sensor technology. This uses an electromagnetic inductive sensor to repel substances that might result in false readings. Given the need for clean rooms and precision in medical device manufacturing, as well as the shift to on-demand manufacturing, the ability to repel dust and oil for the most accurate measurements is critical.

United States changed its sourcing model.

“The customer went forward and changed the paradigm for the industry,” says Simard. “Normally for a knee replacement you would pick from 22 versions, and then adapt to fit the person with little variation. But this customer is now doing patient-specific knees, with an integral design for each individual.”

The result is that PPD Meditech still works off a basic design, but now must respond to hospital scans with turnarounds of only a few days. This involves machining in an on-demand environment – and to the highest specifications.

“We can get the shiniest surfaces, with no abrasion problems,” says Simard. “The surface quality is as a result of our own machining processes, which involve advanced techniques and tools. To accomplish this we work in collaboration with specialists in the cutting industry for high precision production tolerances.”

For PPD Meditech, a big part of the value-add is their ability to execute precision dry machining, which results in less contamination for complex shapes. Having a clean production environment is crucial, from prototyping to production runs. This and other industry-wide requirements are where PPD Meditech’s example is worth noting: in medical, manufacturing is often done in partnership, and requires the highest standards throughout the supply chain. To get a deal supplying to an OEM, a shop has to deliver to these standards, and be able to adapt to innovation – whether from within or in the external market. SMT

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1. PPD Meditech's facility in Waterville, QC.

2. Another example of a biomedical plastic implant manufactured using metalworking machining and compression moulding technologies.



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3. Metal parts are inspected on one of five CMMs in the facility as part of the quality control process.



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