

how many great ideas can we fit inside one medical device?

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impossible is just an excuse

how many do you need?

impossible is just and excuse

how can we help you accelerate your business?

push ahead

Medical device companies the world over face common pressures:

Save more lives, faster.

Make more people healthier, safely.

Innovate new devices, profitably.

All while dealing with the rigors of the regulatory environment, volatility in the costs of essential materials and components, and the never-ending race to be the first to market without burning through your entire budget. In the tough, competitive medical device industry, it's good to have a partner.

Pulse Technologies: advanced innovation + contract manufacturing

Specializing in CNC micro-machining and assembly, scratch-free surface finishes, electrode coatings, custom alloy development

Think of it as ideas + execution: the marriage of groundbreaking materials, technologies and processes with full capabilities for outsourced component manufacturing and assembly, from prototype to production. That's the complete package we offer to our medical device OEM partners, who comprise a substantial number of the world's leading and largest innovators.

Plus a "never say never" spirit of collaboration and drive

The Pulse people. Think of them as pure energy. From our always-accessible R&D and manufacturing engineers to our ever-vigilant quality specialists to our always-thinking machine technicians, every Pulse person understands what it means to help create an implantable medical device.

They know the impact that tiny mechanism of metal or plastic can have on someone's life and recognize the imperative that its components be in perfect working order—every time. It's what makes them pull together to get the job done. It's also what makes them knowledgeable, helpful, friendly—and easy to work with.

Insight, creativity and ownership

We are always working to anticipate and explore what you might need next—whether it's a lighter material



WHAT GROUNDBREAKING DEVICE WILL YOU BE DESIGNING AND MARKETING IN FIVE YEARS?

AND WHAT CAN I DO TODAY TO HELP MAKE THAT DEVICE EVEN BETTER?

or a smoother surface or a process that can be made automated and repeatable. We are always asking, "why not?" and "what if?" which leads quickly to "let's try...." All of which contributes to a sense of pride and ownership in our part of your medical device and also your success as a company, which drives our ideas to prototype and collaboration and production.

Investing on your behalf: intelligence and infrastructure

Since its founding some 20 years ago, Pulse Technologies has made significant investments in next-generation capabilities for the medical device industry.

- Beginning as a precision contract manufacturer, the company then moved into specialized coatings, subsequently adding customized alloys, and then process innovations as well.
- In 2005, we built a world-class custom manufacturing facility to meet the changing demands of our OEM partners.
- Today, our professional staff includes R&D as well as manufacturing engineers.

Connections to the right people at Pulse

Having the right person to talk to whether it's an engineer or production manager—at the right time is crucial to accelerating your device to market. We give you direct access to the person you need for the fastest answer, all the while coordinating internally so our entire team stays abreast of your project.

An exclusive focus on the medical market Pulse Technologies directs all of its efforts to the implantable medical device market, focusing on these sectors:

- Cardiac
- Vascular
- Orthopedic, Spinal
 and Extremity
- Neurostimulation
- Specialty device markets, including cochlear and ophthalmic implants

what happens when we think freely?



Through a combination of micromachining and secondary finishing (electro-dynamic surface finishing) we created a scratch-free surface finish for a hemolysis pump that extended the useful lifetime of the device.

Result? The surgeon has more time for the operation, the operation is less intrusive and traumatic for the patient, the incidence of hemolysis decreases substantially. Even better, the process is automated and repeatable. Eighteen minutes of hand polishing is replaced with electro-dynamic surface finishing so precise that the medical device maker doesn't inspect every surface for compliance. We also worked closely with the device engineer on design for manufacturability, improving the cost and quality for production volumes.

How we did it: by asking the right questions, and investing in the technology and processes that could make it happen, ahead of the client's need.



Pulse developed a replacement alloy for platinum when it became clear that platinum's high price, and the volatility of that price, was becoming a liability for medical device makers. Our solution provides radiopacity as well as electrical and mechanical biocompatibility that's similar to platinum, with machining characteristics that are similar to or better than platinum. Containing no precious metal, our alloy is a stable-price solution for medical device makers across a broad range of components.

How we did it: by thinking ahead. Platinum had been the material of choice since the 1970s, when it was inexpensive and easily available, but now, it failed to offer the competitive advantages that every medical device manufacturer wants.

Platinum is not the only material for which we can custom tailor a replacement. We're always looking for ways to create a more suitable alloy for a specific product.

We developed a specialized coating for stimulation and sensing electrodes that increases the efficiency of the electrical signals and reduces polarization by 50 percent. This technology enables electrodes to be manufactured at half the size of those with competing coatings. Smaller electrodes means smaller, less invasive leads, while increasing device impedance and battery life. Our integrated machining and coating operations make this a cost-effective, high performance solution that exceeds industry standards.

How we did it: by continuously experimenting with and searching for new technologies that improve performance and quality of life for patients. We're all in the business of solving tomorrow's problems. Our imaginations are fueled by your ideas, frustrations, and speculations, too. So we invite you to share with us what you're hoping to achieve next. We'll start thinking about it right away.

How we do it: through collaboration with you.

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what do you need to bring it to market?

quality, delivery, price + integrity

Just as Pulse Technologies has invested in advanced technology, we've also grown our contract component manufacturing and assembly operations to support our clients. We specialize in machining precious metals, titanium, exotic materials and stainless steel alloys, and also manufacture plastic components using PEEK, HDPE, and a wide range of other materials.

from prototype to full-scale production & assembly

A wide range of contract manufacturing capabilities

Materials

Precious metals including platinum, iridium, tantalum, gold, silver, palladium

Metals including titanium, stainless steel, MP35N, CoCr, plus exotics

Plastics including PEEK, HDPE, Udel, Radel, UHMWPE, Delrin, polycarbonate

Swiss Screw Machining

Up to 11 axis micromachining

Multi-spindle machine for high volume production

Thread whirling capability

Contour milling

Outside diameters as small as .012" (0.305mm)

Small hole diameters to .006" (0.152mm)

Thin wall machining to .0015" (0.038mm)

Milling

Small intricate part and feature machining on 3 – 5 axis machines

High capacity multi-pallet mill and mill/turn machines up to 7 axis

Tolerance and positions to .0002" (0.005mm)

Laser Machining

4 axis machining

Ability to cut tube as well as sheet stock with reduced slag and re-case

Beam sizes as small as 0.001" (0.025mm)

Accuracy of +/- . 00004" (0.001mm)

Laser Welding Weld spot as small as .004" (0.100mm) Weld seams as small as .002" (0.050mm) Micro-welding of fine wire down to

.002" (0.050mm) diameter

Similar and dissimilar welding applications

Can weld most metals—precious metals, SS, titanium Ability to control weld overlap

- Laser Texturing
- Controlled surface roughness for improved bonding strength
- Electrical Discharge Machining Wire and Ram capabilities
 .002-.012" (0.0500-.305mm) wire diameters
 Holes to .004" (0.102mm)
- Precision Finishing and Marking Laser marking

Micro-blasting Deburring

Tumbling

Electro-polishing

Passivation

PVD Coating

Titanium Anodizing State-of-the-art in-line automated color titanium anodizer for precise color control

Part masking capabilities

Metallurgy and Metrology Laboratory Contact and optical coordinate measuring machine

Scanning electron microscope Laser micrometers

Irradiation

- Grinding
- Heat Treating

Design for manufacturability

Rely on our robust engineering department for assistance with design for manufacturability. We deal with it every day, and have a long history of finding efficiencies and performance enhancements. Our engineers understand that time is of the essence and that personal responsiveness is key to building the relationships that allow us to help you with design.

A state-of-the-art manufacturing facility and high-capacity equipment

Our purpose-built facility in Quakertown, Pennsylvania features an expandable 40,000 square feet (3,725 square meters). We make a standing offer to our medical device partners that we will add the space and equipment you require to get the product you need. Our facility also includes a Class 10,000 clean room.

Quality: built into everything we do

"Quality in everything we do" is a motto at Pulse that doesn't just live on plaques in the company lunchroom. It's on the lips of most Pulse employees on a daily basis. We treat it with the utmost seriousness designing engineering processes to support it, expecting our employees to uphold it (and to call it out whenever they see a slip) and having it measured and tested and certified.

Because of our significant experience in the medical device industry, we have an intimate understanding of the safety and regulatory requirements for implantable devices. Our people, processes and technologies all support those mandates. We are ISO 9001:2008 and ISO 13485:2003 certified and compliant with 21 CFR Part 820. Component shipments include Certificates of Compliance and Material. We can also provide First Article Reports, SPC Production Reports, and any specialized testing results required. You will also find that we deliver:

- Real-time statistical process control at the machines to save time and cut waste
- Dock to stock, Kanban and consignment arrangements with major device makers who have put their trust in our quality assurance
- Rapid response to quality issues
- Consistency from prototype to production

- A full suite of metrology gauges, tools, fixtures and equipment
- Continuous review of processes to find efficiencies, validated against best practices and shared with our partners

Speed—from quoting to prototype to assembly

Speed is in our DNA. When it's time to produce for you, we talk fast, walk fast and drink a lot of coffee. Rapid response is an integral component of competitive advantage and is built into all of our processes—from pricing (choose from expedited quoting, matrix pricing or time and materials) to prototype design to component manufacture and assembly.

what can the people of Pulse tackle for you today?

pure energy to push you ahead

The people of Pulse are how we do what we do for our medical device companies, and the patients who carry our work with them wherever they go. We look for people who share our sense of challenge, integrity, and pride, and then we invite them to help us build a culture based on collaboration, honesty, and fairness. The result is a camaraderie that drives us to pull together to get the work done, and done right. World-class employee satisfaction creates world-class results for our clients.

► The people of Pulse are ready to take up your challenge. Call 267.733.0200



At Pulse Technologies, we create innovative materials, technologies and processes for medical device components that advance performance, improve competitive advantage and boost profitability. Our focus is on implantable device components within the cardiac, vascular, spinal/extremity and neurostimulation sectors. We also offer a robust outsourced component design and manufacturing solution to leading medical device makers, with a special emphasis on design engineering to enhance manufacturability. With an unfailing commitment to quality, delivery, cost-efficiency and collaboration, Pulse Technologies has risen from a precision machining company to a full-service partner in medical device innovation.

2000 AM Drive Quakertown, PA 18951 T: 267-733-0200 I F: 267-733-0201 Sales@PulseTechInc.com

PulseTechnologies.com

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