Medtronic

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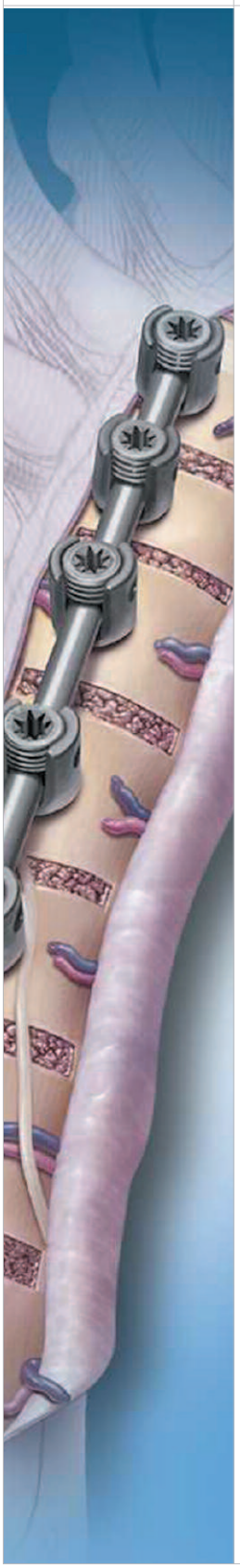

Validating the Shot Peening Process

Over-peening, under-peening, and poor record keeping are just a few of the liabilities that keep many companies from shot peening in-house. However, due to equipment and testing advancements and the availability of professional training, validating the shot peening process in today's manufacturing environment has become a reality. Validate is defined as "to declare or make legally valid, to make with an indication of official sanction, and to establish the soundness of; corroborate." Validation is a tremendous responsibility in the context of shot peening but one that a world-class medical implant manufacturing is capable of assuming.

Medtronic's Spinal and Biologics business, based in Memphis, Tennessee, is the global leader in the spinal treatment market and is committed to advancing the treatment of spinal conditions. The Spinal business collaborates with world-renowned surgeons, researchers and innovative partners to offer state-of-the-art therapies for spinal, neurological, orthopaedic and oral maxillofacial conditions. Medtronic facilities in Warsaw, Indiana; Memphis, Tennessee; and Humacao, Puerto Rico share the responsibility for manufacturing titanium bone screws that anchor spinal fixation systems. These fixation systems are designed to assist with stability of the cervical, thoracic, and lumbar spine when performing modern spinal fusion surgery and help patients suffering from degenerative disc disease, trauma, tumors, severe curvatures and other degenerative diseases of the spine.

Not many companies have the resources of Medtronic but their strategy can be scaled to fit limited budgets and smaller facilities. If your company already has an in-house shot peening program, you can pick up some ideas on how to validate and thereby improve your processes. The following is an account of the Electronics Inc. staff's involvement with the project.

Homework

Medtronic had several reasons to bring the shot peening of the bone screws in-house: the need for validated process control, an ever-increasing number of bone screws to be shot peened and the likelihood of shot peening a larger portion of the part. Plus, given the scope of the company, Medtronic was more than capable of implementing a successful manufacturing process.

The Electronics Inc. staff first met Medtronic engineers at the 2006 EI Shot Peening Workshop in Indianapolis. The engineers read about the workshop in *The Shot Peener* magazine and attended the workshop to learn more about shot peening. The workshop proved to be a good learning opportunity. "The workshop gave us a thorough understanding of shot peening," said Scott Hatfield, Manufacturing Engineer at the Warsaw facility, "but it also met our higher expectations because our questions on our specific goals were addressed, too. The information was provided in an enjoyable format and the instructors were very engaged in the learning process. Because we were new to shot peening, it was very helpful to see all of these vendors in one place at the trade show and we were able to learn more about products like shot peening machines, separators and speed masking."

Collaboration

As the shot peening training company for Medtronic, Jack Champaigne and Tom Brickley of Electronics Inc. were invited to Medtronic's Shot Peening Titanium Symposium in June 2007. The Symposium was organized by Mark Pelo, Medtronic's Director of Advanced Manufacture Engineering. The Symposium was a gathering of outside vendors and Medtronic staff. The Outside Support Team included representatives from Cam-Met, Inc., Electronics

Inc., Industrial Metal Finishing, Lambda Research, Metallurgical Services, Inc., Progressive Technologies, and Technology for Energy Corp. Medtronic team members included manufacturing management, engineering, product development, prototype development and program/project analysts from Medtronic's three facilities. The symposium, held in Medtronic's auditorium in Warsaw, Indiana, was an open forum to review a standardized peening validation requirement for all of Medtronic's manufacturing facilities and outside suppliers.

The goal of the Symposium was to discuss a validation strategy that every vendor and each designer, engineer and operator, in all Medtronic manufacturing facilities, must follow. The final validation strategy will ensure that every bone screw is shot peened correctly according to company specification, no matter which facility shot peens it.

"Medtronic understood that they had limitations in their understanding of shot peening so they brought together everyone in their company that would be affiliated with shot peening and their outside resources," said Tom Brickley. "It was an incredibly professional event and I think it was a valuable experience for everyone." "They were very professional about attendance, asked many questions, and reviewed their present practices and research methods," said Jack Champaigne. "Medtronic understands the necessity of quality since they have to operate under FDA regulations," he added.

Equipment Selection

At the Electronics Inc. workshop trade show, the engineers reviewed products, met with several vendors and began a discussion that would result in the purchase of a Progressive Technologies robotic shot peening machine. The Progressive Technologies machine was chosen after a careful evaluation of machines from four manufacturers. "Progressive Technologies was our choice because they stepped up to our design challenge," said Mark Pelo. Medtronic's machine had to be flexible and specialized: flexible enough to accommodate several different products now and new products in the future (Medtronic brings products to the market continually); and specialized to provide crucial information. Because Medtronic will get validation information from their machine, they will meet the FDA's demands that the shot peening process be controllable and repeatable and they will save money in the long run due to fewer destructive tests of the implants. "Progressive didn't offer us a cookie-cutter solution. They are very creative. For example, when we asked for a particle sampler in real time, they gave it to us," said Pelo. Marty Hilbrands, the Progressive Technologies Sales Engineer for the Medtronic project commented, "The team at Medtronic should be commended for taking ownership of their shot peening processes. Their desire to understand and invest in the technology will no doubt pay off in the years ahead."

Training

EI's next involvement was during on-site training of Medtronic's shot peening operators and inspectors from Indiana and Puerto Rico in January 2008. Jack Champaigne and Dr. John Cammett of Cam-Met, Inc. trained 15 employees to the requirements of MIL-S-13165, AMS 2430 and the FAA approved course #AGL/1207/0006/8. "My impression of the group was that they were all very interested in learning the basics of shot peening, they were aware of the importance of the process, they wanted to do the process properly, they were relating to their current practices and realizing that some of these practices were not correct," said Champaigne. Every Medtronic employee passed the Level I Certification Exam. Level II and Level III shot peening training by Electronics Inc. will take place later this year. Their shot peening operators are also being trained by Progressive Technologies on the machine.

Testing, Verification and Implementation

A Medtronic team took the information gathered at the Symposium and wrote a validation strategy. Based on that strategy, they are developing operational qualifications that will be used consistently in every facility. The standardized validation elements are Almen Strips, Velocity, Recipe Control, Media Sampling, Fatigue Life and X-Ray Diffraction. To meet FDA requirements, Medtronic is fatigue life testing the screws and connectors in human movement simulations beyond the life expectancy of a typical implant. One of the exciting aspects of this project is that Medtronic engineers are also investigating the benefits of shot peening a larger portion of the implant, for even greater benefits to the patient. The studies are expected to be completed by July 2008 and the in-house shot peening program will start soon after. Approximately 250,000 screws will be shot peened yearly at the Indiana and Puerto Rico plants.

Reflection

In less than two years, a group of six Medtronic engineers in Warsaw, Indiana have created an in-house shot peening methodology for bone screws that will become the standard for additional product lines in this global company. The system will be applied to existing and future implant systems that can benefit from shot peening. "Shot peening allows us to design implants that are smaller, stronger, lighter and less invasive for patients," said Mark Pelo. "We are really pleased with what we've accomplished with shot peening," added Hatfield. The group is preparing an abstract of their shot peening protocol for the Science and Technology Conference this fall. The Medtronic conference explores many issues facing its scientists and engineers and the team is looking forward to sharing their shot peening knowledge base with others. ●