Oxford Performance Materials
www.oxfordpm.com

Facts

Challenge

Production and FDA approval of patient specific polymeric cranial implants based on CT or MRI scans.

Solution

Speedy manufacturing of individual cranial implants made of PEKK on an EOSINT P 800 by EOS.

Results

- Customized: fewer side effects due to patient specific manufacturing
- Osteoconductive: bone cells grow into PEKK implant and increase its long term stability
- Economic: better treatment outcome at reduced costs
- Integrated: self-contained production and supply chain

Patient specific medical care: this model of a skull demonstrates how an implant is customized to fit the cranial opening (courtesy of Fred Smith Associates).

US Regulator FDA Awards First Approval for Customized 3D-Printed Polymeric Cranial Implants

e-Manufacturing Solutions

OPM's Additive Manufactured Cranial Implants Offer Improved Patient Outcomes at Reduced Surgical Costs

Short profile
Since 2000, Oxford Performance Materials (OPM) has built its business solely on PEKK material. Headquartered in South Windsor, Connecticut (USA) the company has produced a number of bony void replacements as well as developing a variety of biomedical and industrial materials.

Address
Oxford Performance Materials
30 South Satellite Road
South Windsor, CT 06074
USA

Oxford Performance Materials (OPM) made medical history when they received the first Food and Drug Administration (FDA) 510(k) clearance for their polymer additive manufactured OsteoFab™ Patient Specific Cranial Device (OPSCD). The customizable implant made of the plastic material PEKK is designed to restore voids in the skull caused by trauma or disease. Manufactured in a matter of hours with Additive Manufacturing (AM) technology by EOS, the implant saw its first use just a few days later when the device was successfully implanted in a patient missing a significant portion of cranial bone.

Challenge
However, PEKK has a high melting point relative to other polymers. And the EOSINT P 800 is the only industrial 3D-printing system in the world which can process the high-temperature polymer by means of additive layer manufacturing. But it wasn't just a matter of buying the system one day and making a product the next. Scott DeFelice, President and CEO of OPM, explains the arduous path to commercialization of patient specific implants: "For starters, you need an ISO 13485 compliant facility that has design controls and an appropriate clean manufacturing environment. Furthermore you need to be compliant with CFR 21 cGMP (*current Good Manufacturing Practice*s). Add to that a completely validated process and ISO 10993 biocompatibility data on your finished parts. In short, you need a lot of stuff in your bucket."

Solution
The high-temperature plastic has a number of mechanical and thermal qualities that make it highly suitable for cranial reconstruction. It has a density and stiffness similar to bone, it is lighter than traditional implant materials such as titanium and stainless steel, it hardly reacts with other substances and it is radiolucent so as not to interfere with diagnostic imaging equipment.

Perhaps its most exciting attribute is bone's affinity to the material. "Based on research studies, it is osteoconductive," says DeFelice. In some implants, the surrounding bone pulls away from the site over time and you have to rely on screws to hold everything in place forever. "Since PEKK has shown osteoconductive properties, long-term implant stability may be easier to achieve than with other materials. And given the correct implant design, results are getting even better. You can obtain a multiplying

Self-contained production and supply chain: the patient specific cranial implants made of high-temperature polymer PEKK can be delivered in less than two weeks (courtesy of Fred Smith Associates).

effect by increasing surface area and achieving intimate contact between the implant and native tissues," explains DeFelice.

Patient specific medical care is becoming increasingly important. So OPM also faces the challenge of producing low-volume parts with complex shapes that are adapted to a person's anatomy. That's why Additive Manufacturing technology by EOS was a logical choice. "From a practical perspective, traditional production processes often have substantial limitations in terms of tolerance and geometry, such as draft angles in moulding and corner design for CNC tooling," explains DeFelice. In addition, AM doesn't require the upfront costs of tooling and moulding and doesn't generate the level of waste that subtractive cutting and milling do.

After intense navigation of regulatory hurdles, it was possible to start creating of a patient specific cranial implant. DeFelice sets the scene: "Based on a CT or MRI scan of the injured area, a slice file is generated which divides the data into cross-sectional layers. After review by a physician, it is sent to OPM. Using 3D design software, a team of design engineers create an implant based on the file to precisely fit that patient's anatomy. Once you have that, you get approval of the implant design from the surgeon, and then print the part."

The manufacturing is entirely automatic. The EOSINT P 800 lays down a thin layer of powder on its build platform. Guided by the lowest slice of the implant design file, a high-temperature laser melts a cross section of the implant design. When that layer is done, the build platform lowers, the system distributes a new powder layer on top of the old one, and the laser melts the next cross section. The process is repeated until the entire implant is built.

Once the implant has been removed from the powder cake, it's ready for quality inspection. "In addition to mechanical and analytical testing, we use a structured light scanner to run 100 percent line-of-sight metrology inspection to certify the dimensional accuracy of the final product," DeFelice says. The implant is then shipped to the hospital. The total process takes less than two weeks from the time the data is received to the time the implant is shipped.

Results

This self-contained production and supply chain are good news for the patient. The right implant shortens the duration of surgery, the patient recovers more quickly and the risk of infection is reduced.

Hospitals benefit and typical operating room rates run upwards of $60 per minute, so pressure is high to manage the costs of patient care. Scott DeFelice adds: "The new medical paradigm is about improving outcomes while reducing costs. That's what AM technology helps us accomplish."

After having successfully created and obtained FDA approval for their cranial implant, OPM is making plans to explore other implant opportunities throughout the body. DeFelice states: "EOS technology is capable of producing practically any shape geometry to match the precise needs of an individual patient. It lifts manufacturability restrictions. There is no region of the human skeletal anatomy that won't be touched by this technology. When the patient is on the operating table and the part shows up and doesn't fit, you're putting someone's life at risk. The first implant case was very large, measuring nearly six inches across, and large areas of critical tissue had to be exposed during surgery. So it was critical that the implant should fit perfectly. Every second is critical in that situation," explains Scott DeFelice. Medical engineering has very high standards: it demands the right material, the right process, the right quality system, and the right metrology. Together these elements are life-savers.

"EOS technology was by far the best choice because we produce low-volume parts with complex shapes. With the EOSINT P 800 we were a fairly early adopter of high-temperature laser fabrication, and we moved very quickly with the OsteoFab™ technology's entire development cycle. EOS supported us throughout the process."

Scott DeFelice,
President and CEO of OPM

EOS GmbH
Electro Optical Systems
Corporate Headquarters
Robert-Stirling-Ring 1
82152 Krailling/Munich
Germany
Phone +49 89 893 36-0
Fax +49 89 893 36-285

Further EOS Offices

EOS France
Phone +33 437 49 76 76

EOS India
Phone +91 44 28 15 87 94

EOS Italy
Phone +39 02 33 40 16 59

EOS Korea
Phone +82 32 552 82 31

EOS Nordic & Baltic
Phone +46 31 760 46 40

EOS of North America
Phone +1 248 306 01 43

EOS Singapore
Phone +65 6430 05 50

EOS Greater China
Phone + 86 21 602307 00

EOS UK
Phone +44 1926 62 31 07

www.eos.info • info@eos.info

Think the impossible. You can get it.

e-Manufacturing Solutions