ALPHAFORM

NOVAXDMA
DISPOSITIVOS MEDICOS AVANZADOS

Facts

Challenge

Development and manufacture of a precision-fit implant for the cranial area with particular permeability for liquids and heat dissipation.

Solution

Manufacture of a highly stable, yet porous, cranial implant using the EOSINT M 280.

Results

- Optimized: permeable for liquids, protects against heat
- Stable: large-scale implant despite porous structure
- Innovative: lattice structures support the attachment and in-growth of bone tissue

The porosity of the implant is 95%, so liquids can flow through with the least possible resistance and the bone tissue optimally coalesces with the outer edges (courtesy of EOS GmbH).

Improved Quality of Life Thanks to Cranial Implants Produced with Additive Manufacturing

EOS

Medical Product from Alphaform Offers Optimal Biomedical Characteristics for Patients

Short profile

Alphaform AG is a professional and innovative development and production partner for 3D printing technology, in particular for the manufacture of low-volume and niche products as well as series production.

Novax DMA specializes in the research, development, production, and marketing of innovative medical technologies. The company is represented in over 15 countries and since 1995 has developed medical implants for traumatology, orthopedics, and cranial surgery.

Further information

www.alphaform.de
www.novaxdma.com

Cranial implants need to meet the most stringent of criteria, with a large number of factors coming into play. This was the case with a patient in Argentina who required a particularly large implant after stroke-related surgery. The project called for a level of design for all relevant factors that was as close to perfect as one can imagine: from the highest degree of precision and compatibility to the integration of biological functions. The 3D-printing service provider Alphaform AG relied on EOS technology for the realization of this successful cranial implant which was developed by partner firm Novax DMA.

Challenge

If a person requires an implant in the skull area then external factors should serve to aid rather than hinder the healing process. This is particularly true of the implant itself. The most important factor here is that it should have the most perfect fit possible – a classic requirement of applications from the field of Additive Manufacturing. The layering production process, which utilizes a laser to harden the material – in this case titanium - piece by piece, offers the maximum degree of individualization in terms of both form and size.
The doctors provided the medical-technology experts from Novax DMA and Alphaform with further challenges to meet along the way. High on the list, due to the size of the hole in the bone structure, was the *integration of biological functions* and the lowest possible degree of heat dissipation in the cerebral tissue. Titanium actually conforms quite well with the human body. Nonetheless, the danger exists that, being a metal, it will lead to too much heat being generated inside the body in the event of high exposure to sunshine. Another factor is that a titanium structure would, of course, not be permeable for tissue fluid from the brain.

The additive manufactured implant made of a biocompatible titanium alloy was placed in the skull of a patient in Argentina who required it after stroke-related surgery (coutesy of Novax DMA).

In the requirement specification, the doctors also stipulated special post-manufacturing processes for the implant. Only controlled post-processing, particularly in terms of cleaning, would facilitate the utilization of the part in the medical sector. This is of vital importance because particles can separate from the body with the slightest movement, leading to the possibility of infections or of rejection. In addition, absolute sterility is a central criteria of a successful acceptance of the implant by the body.

Solution

Only a porous structure would be capable of meeting the required characteristics. A lattice-structured implant with integrated screw-in fixings all the way to the skull would facilitate both the passage of fluids through it and its fusion with the bone tissue of the skull itself. What's more, such a design would have an insulation effect such that the heat dissipation into the cranial cavity would be minimized. The dimensions of the pores themselves are approximately 1mm in size, while the cell-links are approx. 0.2mm thick.

Daniel Fiz, CEO of Novax DMA, remembers it well. "Time played an important role in this context. Patients should anyway be receiving their implants as quickly as possible. Once we had the information regarding the dimensions, we began immediately with the construction." For the 3D design of the implant they

employed the software from the company Within. "It allowed us not only to define the basic form quickly, but also the porous structure itself," explains Kaveh Mahdavi, Business Development at Within Ltd. As soon as the CAD work was completed, Alphaform took on the manufacture of the implant. For the actual production they used an EOSINT M 280 from EOS. The construction time was just a matter of hours.

"We had already successfully completed many products with the EOS system," says Christoph Erhardt, Director of Additive Manufacturing at Alphaform AG. "However, we are proud of this implant, not only because of the precise realization of the form, but above all because we were able to optimize the cleaning processes." Porous structures in particular, with their small interior hollow spaces, are extremely hard to clean. The process is relatively sensitive. Basically, Alphaform applied a multi-step process of abrasive and mechanical cleaning, rinsing, and ultrasound in order to arrive at the medically required level of purity. The development of this process alone took six months.

Results

The perfectly tailored implant meets the individual requirements of the specific clinical picture. The porosity level reached 95% which means liquids could flow through with the least possible resistance. In addition, the bone tissue was able to penetrate the outer edges of the implant and grow together with it. At the same time, the material is stable enough to return the patient the desired level of normality in everyday life. The structure, constructed in the form of a regular lattice, also provided the desired level of thermal conductivity – so the patient can also enjoy time in the sun.

Time played the most critical role in the process. If time to market is a key strength of Additive Manufacturing in the industrial context, then it is even more significant in the medical sector. The implant was in the operating theatre in just three weeks. The largest block of time was taken up in the transportation, which took a week. Preparation of the data, and then construction, were completed within just two and a half days. The remaining time was split among the various processes in the areas of logistics and coordination.
The two companies were also able to verify the purity levels through comprehensive measurements. Christoph Erhardt and his team carried out extensive tests, including particle and cytotoxicity testing. They also undertook a gas-chromatography analysis. "All of the analyses have confirmed that the implant produced through Additive Manufacturing fulfilled the necessary requirements to stabilize and protect the patient's skull. The one and a half hour surgery took place in May 2014, and went smoothly. The patient left hospital after two days and the wound was healed within three weeks. Since then, there have been no complications," confirmed the expert. The innovative technology from EOS has contributed significantly to ensuring that those who have suffered sickness or injury are able to live their lives without limits.

"We have been manufacturing medical implants since 1995. Additive Manufacturing represents a new milestone for patients. It offers optimal biomedical characteristics together with the highest levels of compatibility, thereby having a lasting effect on the improvement of quality of life. For these reasons we have applied the technology with success to other areas of the body. Alphaform has also manufactured jaw implants for us, as well as a hip joint and a spinal implant. For spinal implants we are currently considering a combined series production using Additive Manufacturing."

Daniel Fiz, CEO at Novax DMA

"For us, Additive Manufacturing and EOS amount to the same thing. Both ourselves, and our customers are continually amazed by the application possibilities and the high-quality production that can be achieved using the EOS systems. That was once again the case here. We were able to help a person to live a normal life – on an ongoing basis – despite them having suffered a very serious injury."

Christoph Erhardt, Director Additive Manufacturing at Alphaform AG

EOS systems are able to manufacture medical devices. However, EOS cannot offer any guarantee that these devices meet all requirements.

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