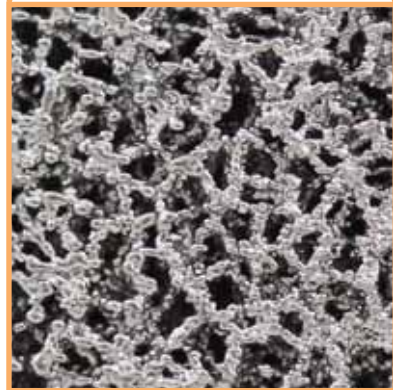
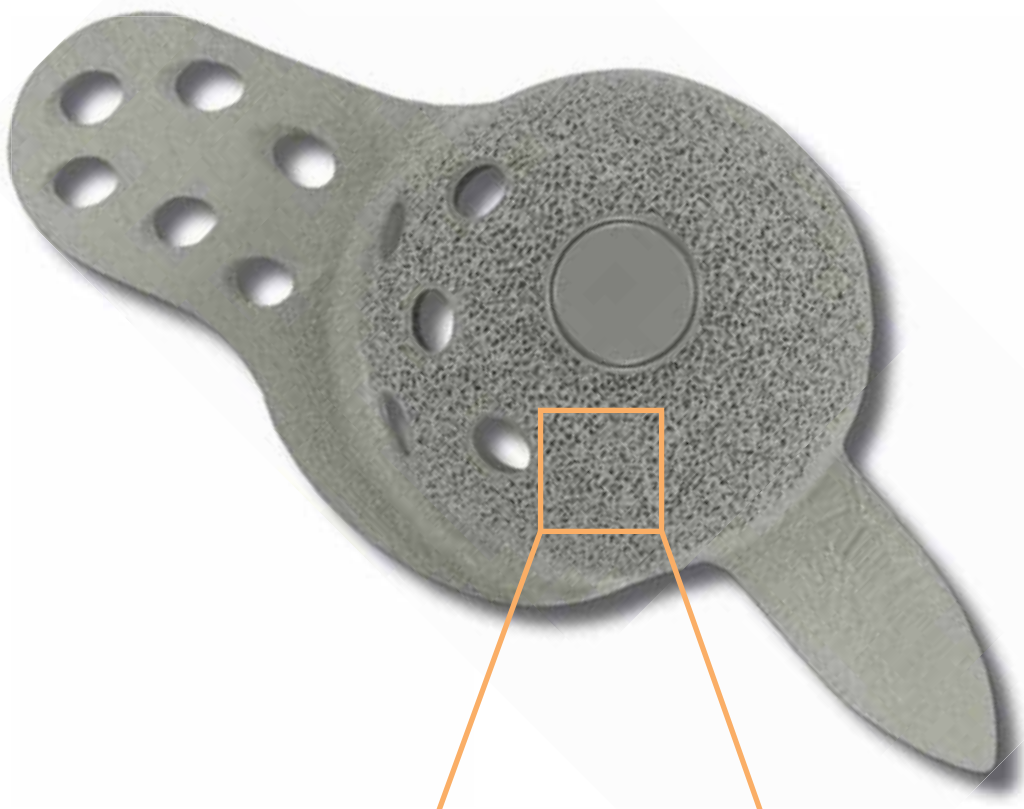


EPORE®

Highly Porous - Additive Manufactured Structures



implantcast





*Figure 1:
EcoFit® Cup EPORE®*



*Figure 2:
MUTARS® RS Cup*



*Figure 3:
EPORE® Acetabulum spacer*

Introduction

implantcast GmbH founded in 1988, is one of the world's leading manufacturers of tumour and revision endoprosthesis. Since implantcast GmbH foundation it has strived to utilize the latest new and innovative manufacturing processes available in medical technology. implantcast GmbH have pioneered the use of Titanium nitride coating in order to improve the potential longevity of the prosthesis, and Silver Coating in order to address high infection rates in tumour endoprosthesis. A new phase in implantcast GmbH pursuit to bring the very latest innovative technology to its product portfolio is EPORE®. A highly porous structure formed by Additive manufacturing technology, which allows the formation of highly complex structures at a cost that does not make it prohibitive to healthcare organisations.

A major goal of orthopaedics is to maintain, assist and restore a person's mobility. In some areas surgeons and patients are reliant on custom-made designs in order to achieve a satisfactory outcome. The challenge has always been to deliver high quality prosthesis to the very highest quality standards, in the most expedient way, while keeping the cost down to acceptable levels. implantcast GmbH investment in Additive Manufacturing will enhance its already well-established custom product service, allowing new solutions that were not possible prior to this exciting new technology, or too costly because of the limitations of previous manufacturing processes.

INDIVIDUALISATION

Conventional orthopaedic implants are made in a range of sizes, as human anatomy does not vary vastly even when considering race or stature differences. The principle adopted is a best fit process i.e. the implant is selected from a range which best matches the patient's individual anatomy. In some cases the use of standard implants would not be suitable, and custom prosthesis are then considered. The manufacturing of a custom prosthesis is a highly collaborative process, and this combined with former manufacturing limitations and manufacturing production time, meant that custom prosthesis were labour intensive and costly to produce. The advances in Imaging coupled to the development of software programs have led to the ability to digitize a patient's MRI or CT data, which can then be utilized in new ways to assist with

- Planning
- Production of patient specific cutting blocks, drill guides
- Custom Implants.

implantcast GmbH have invested in new computer software, that when used in combination with additive manufacturing will lead to greatly improved custom service options either in terms of custom implants, or planning and patient specific instrumentation.

COMPLEX TRABECULAR METAL GEOMETRIES

Mimicking of cancellous bone structure in metal would be extremely difficult to produce, and additionally carry a very high, prohibitive, cost using conventional manufacturing methods. Additive manufacturing uses a process that is computer design driven utilizing improved imaging data and combined with new software's program, that allows for unrestricted design permutations. The formation of such complex porous structures, such as cancellous bone, can now be achieved; this is the foundation of EPORE® implantcast GmbH new product coating/structure that will be the cornerstone of new primary and revision product line developments. EPORE® is designed to match natural cancellous bone structure which will lead to improved integration of the new prosthesis, and speed up the healing process, via a dynamic osseoprecipitation of the adjacent bone. The EPORE® is designed to be slightly compressive which stimulates the formation of new bone.

Introduction

COMPLEX MONOBLOC PRODUCTION CAPABILITIES

Currently complex prosthesis requires individual component parts to be made separately and then assembled at the end of the production process. This is not optimal in terms of performance of the prosthesis as the junction of where these modular components are joined can be considered a weak point of the prosthesis. Additive manufacturing allows the for complex structures to be formed in a monobloc fashion which increases the inherent strength of the prosthesis and additional it allows for cost reduction as complex assembly of component parts is no longer required.

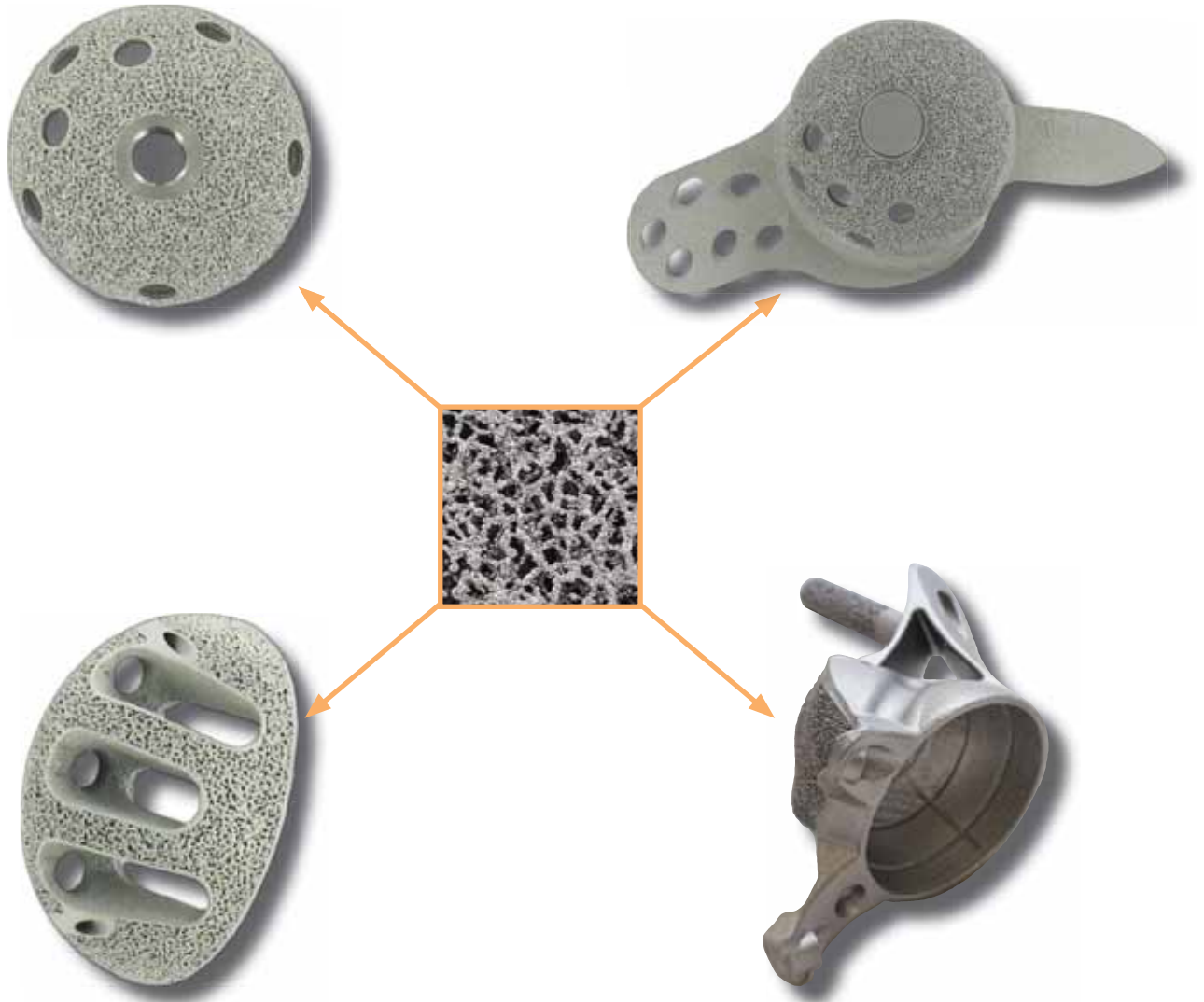
HEALTH CARE COST BENEFIT

A possible advantage of EPORE® is that it will enhance the healing process of the patient, which could lead to the faster rehabilitation and a subsequent cost saving to health care provider.



EPORE® - highly porous osteointegrative structure

The new manufacturing method of EBM® Electron Beam Melting used by implantcast GmbH offers a rapid, flexible and cost-effective production directly from the patients own 3D electronic data. This new innovative manufacturing process offers cost-effective, high-quality manufacturing of medical devices of almost any complex form. Additive manufacturing accelerates product production time scale for custom prosthesis offers design freedom and allows for a high degree of primary and secondary fixation.



<i>Mechanical properties EPORE®</i>	
<i>porosity</i>	60%
<i>rod thickness</i>	330 - 390 μm
<i>rel. modulus of elasticity</i>	3 GPa

EPORE® is a highly porous structure made of titanium alloy (Ti6AlV4). Titanium alloy is an excellent material for use as a porous in-growth structure as it is biologically inert, ductile, corrosion resistant and has a high fatigue strength. implantcast GmbH have designed EPORE® to have a high porosity and a low modulus of elasticity so it can enhance biological in-growth. The structure is characterized by rods of 330-390 μm thickness which are arrayed in a way that mimics cancellous bone structures.

Production process steps of additive manufacturing

implantcast GmbH additive manufacturing process uses a powder-bed-based method which is then turned into solid form using an electron beam melting EBM®. The beam speeds up the manufacturing process considerably by providing multiple melting points to the under construction prosthesis

3D-CAD DESIGN

First a three dimensional model of the component to be manufactured is designed on a computer by using a CAD software. implantcast GmbH uses special software which enhances the design capability. It is the base point for the additive manufacturing process.

SLICING OF THE 3D DESIGNED COMPUTER GENERATED PROSTHESIS

The model is virtually cut on the PC into individual slices, each corresponding to the height of a layer's thickness of the additive manufacturing process.

POWDER APPLICATION

A uniform powder layer is applied. The amount of the powder layer corresponds to the previously generated slice thickness, which is approximately 50 µm.

MELTING

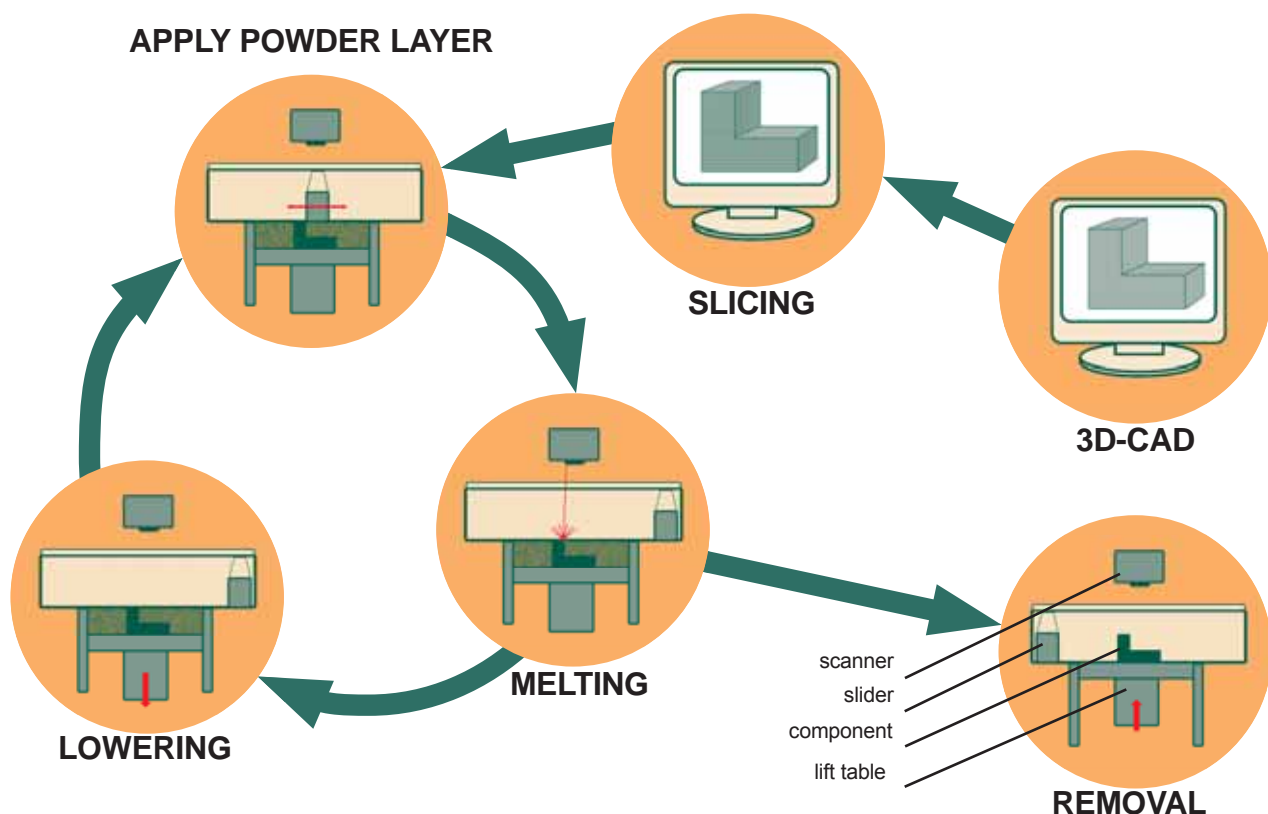
By using a radiation source, the powder is exposed locally and melted. The melted powder solidifies and bonds with the underlying layer to form a solid homogenous metal structure, as per the 3D CAD design.

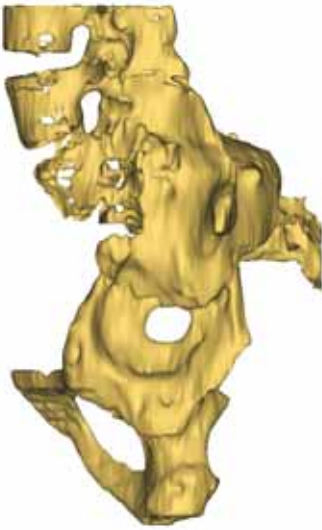
LOWERING

After each melting cycle the work platform is lowered by the exact height of the powdered layer, this then allows for a uniform new application of powder, and the process is repeated until the prosthesis is constructed.

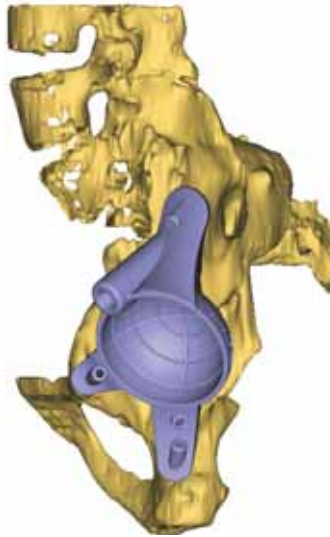
REMOVAL

The component is removed. Non exposed powder is recycled.





*Figure 4:
exported bone*



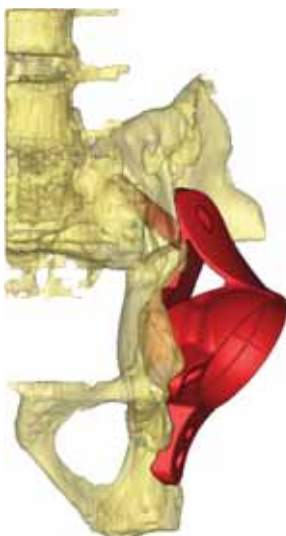
*Figure 5:
PSI drill guide*



*Figure 6:
individual prosthesis*

The need for individual prosthesis in revision and tumour arthroplasty is increasing. Some complicated bone defects created after revision or large tumour resection cannot be treated adequately by standard prosthesis alone and therefore a custom prosthesis is required. implantcast custom service has been improved by the addition of additive 3D printing technology and the investment in special software. It is now possible to create a 3D model from high-resolution MRI or CT data of the reconstructed bone / joint. This 3D model is now the base for the individual prosthesis, and our highly experienced bio engineers work closely with the clinician to plan and produce a prosthesis based on their specifications and the patient's requirements.

This enables exact positioning of the implant to the residual anatomical defect contour. Additionally the hyper accurate 3D planning can suggest additional bone resections sites that would improve the sitting of the prosthesis, and can produce patient specific cutting block templates that facilitates the creation of screw holes or additional stabilizing primary fixation options. This additional planning minimizes the amount of bone to be resected and reduce the amount of surgery time for the patient. The processing time for such an individual prosthesis is approximately 4 weeks.



*Figure 7:
individual prosthesis
preoperatively*



*Figure 8:
individual prosthesis
postoperatively*



*Figure 9:
individual hip cup*



*Figure 10:
PSI drill guide*

Advances in imaging and manufacturing technology have now made it possible to be able to deliver orthopaedic implants in a more optimal way. The hyper accurate Patient Specific Instruments [PSI] allows the surgeon to accurately implant standardized orthopaedic implants more quickly without comprising on any aspects of the patients care and as the instrumentation are patient specific usually with a much better alignment to the patient's own anatomy. This same technology used differently can provide custom made prosthesis in that allow for complex designs, which would not have been viable for technical or cost reasons before.

implantcast GmbH have invested in this new technology in order to be able to bring the very latest in cutting edge technology to its product range and custom specific prosthesis for the overall benefit of the surgeon and patient alike. The new technology once fully integrated would allow significant improvements in long term outcomes, as they will improve delivery and performance of the prosthesis, which in turn will improve the financial burden of healthcare providers.



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