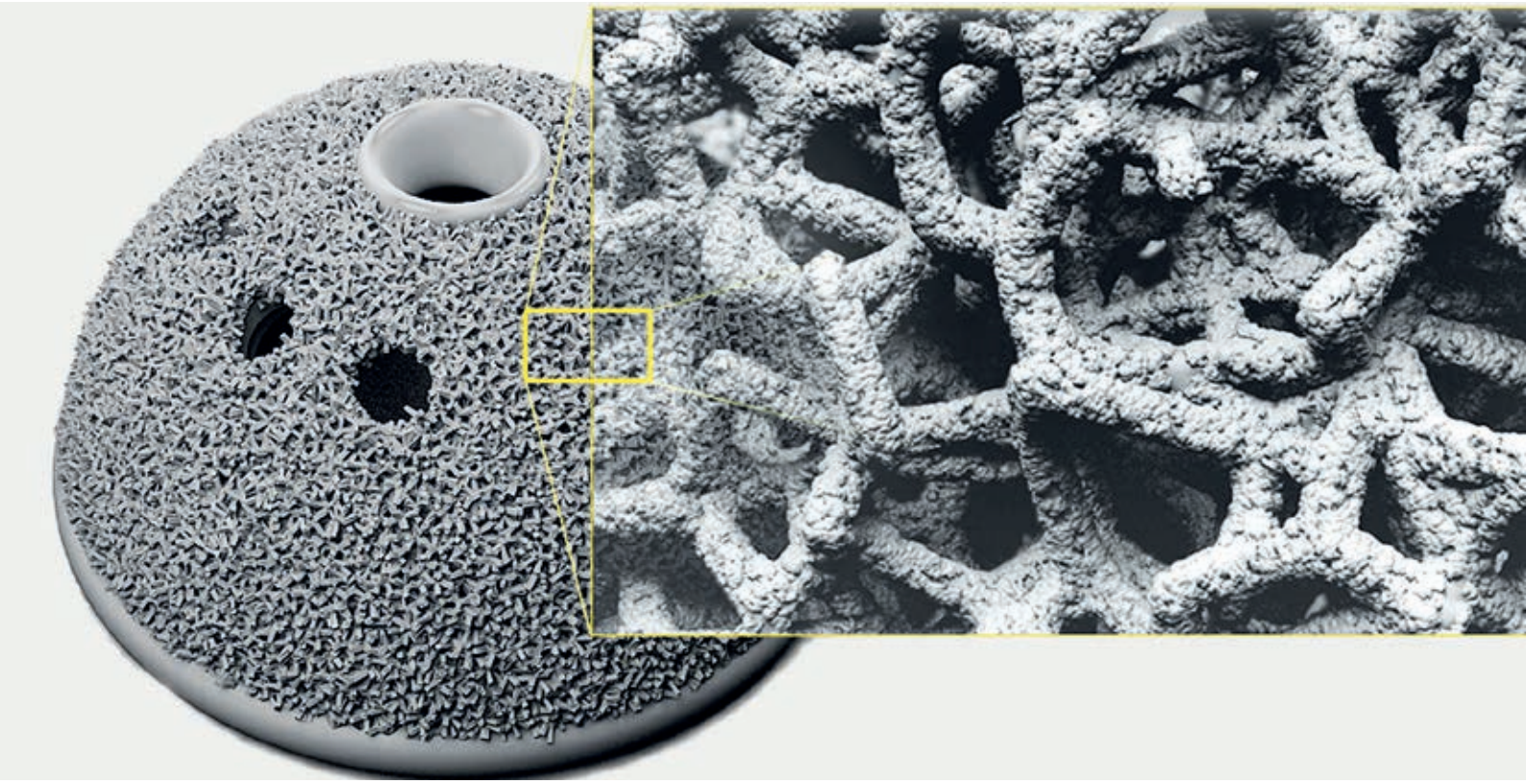

Hip implant with lattice structures for improved osseointegration. Additive Manufacturing in a single step using EOSINT M 280 (Source: Within)

Additive Manufacturing in the Medical Field

e-Manufacturing Solutions

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Finger implants
(Source: Within)

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(Source: Within)

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(Source: FHC, Inc.)

Challenges in the Medical Field

One aim of medical technology is to maintain, assist or restore a person's mobility. In many areas doctors and patients are reliant upon custom-made designs or individualized small series for the production of medical devices. Both the materials and workmanship of the devices have to meet high quality standards. Products must also be quickly available, and preferably at an economical price.

- **Individualization**
  Often the making of a customized prosthetic can involve a long and stressful adaptation phase for the patient before an optimum result is achieved. This, together with the patient's wish for a personalized product design, often involves high (extra) costs.

- **Complex geometries**
  Free-form structures are difficult to produce using conventional manufacturing methods such as milling, turning or casting. At the same time, there is a growing desire to replicate the successful models used by nature and, for example, to make implants based on bionic principles. The objective is to accelerate the patient's healing process.

- **Functional integration**
  Most medical devices that fulfil one or more functions require extensive assembly work after manufacture. The aim of product development and manufacture is therefore to cover multiple functions with as few components as possible.

- **Reduced costs**
  Innovative products accelerate the healing process, thereby reducing the strain on both healthcare system and patient. The better a patient is cared for, the lower the financial outlay for the hospital stay and for follow-on treatment.

- **Rapid availability**
  Often years are needed for a medical innovation to reach the patient. The sooner a medical device can be applied and used, the better it is for the patient. Accelerated product development processes and quicker manufacture are therefore becoming increasingly important.

Benefits of Additive Manufacturing (AM)

Fig. 4:
Spinal implants,
material:
EOS Titanium Ti64
(Source: Within)

EOS translates these requirements into tailor-made solutions. The Additive Manufacturing method, which includes systems, materials and applied solutions, enables EOS to support its customers in all relevant phases of the development and manufacturing process.

EOS – the world leader in Additive Manufacturing
Founded in 1989, today EOS is the world leader in technology and innovation in the area of Additive Manufacturing of plastic and metal parts and a provider of design-driven, integrated manufacturing solutions for industrial applications. The generative manufacturing method of laser sintering offered by EOS makes for rapid, flexible and cost-effective production directly from 3D electronic data: layer by layer and based on an array of plastic and metal materials. This groundbreaking Additive Manufacturing technology paves the way to a paradigm shift in design and manufacturing: it facilitates fast, cost-effective and high-quality manufacturing of medical devices in almost any complex form, which would hardly be possible using traditional methods. Additive Manufacturing accelerates product development, offers design freedom, optimizes part structures and allows for a high degree of functional integration. In this way EOS gives its customers significant competitive advantages and offers a complete solution portfolio: spanning systems, applied know-how, software, parameters, materials and their further development as well as comprehensive support services such as maintenance, application consulting and training.

Additive Manufacturing – Patient Specific Implants

Fig. 5: Hip implant with lattice structures for improved osseointegration. Additive Manufacturing in a single step using EOSINT M 280

Animation of lattice structure design (Source: Within)

Please scan in the QR Code with a Smartphone app such as Scanlife, www.scanlife.com

The key challenge in orthopedics is that although every human body is different, the implant should ideally fit perfectly, be quickly accepted by the body and thereby enhance the patient's long-term quality of life. However, as far as individual patient histories are concerned, standardized orthopedic solutions often fall short. At the same time, there is a lot of pressure on costs as well as the need to be able to react quickly to specific or changing requirements. The orthopedics sector is increasingly using the EOS Additive Manufacturing method in the production of implants, as this offers a number of advantages.

"We have been using Additive Manufacturing for years now for the design of spinal, hip and other metallic implants."

Dr. Siavash Mahdavi, project stake-holder and Managing Director, Within Technologies

Additive Manufacturing – Benefits for Patient and Hospital

Improved patient care

By using Additive Manufacturing it is possible to produce lattice structures that significantly accelerate the healing process following the implant in the body. A large, rough surface area, which can be defined in the manufacturing process, promotes better integration of the implant and therefore better bone ingrowth. Customized implants can be made based on 3D CAD data of the patient. This means that treatment can be optimized, hospital stays shortened and any unpleasant side-effects for the patient minimized.

Cost-effectiveness for the hospital

Patient-customized implants must accommodate the needs of both patient and hospital. Despite the need for individualization, unit costs need to be economical. Additive Manufacturing allows small quantities to be produced at reasonable prices. At the same time, this manufacturing method offers a high degree of flexibility, since an implant based on 3D CAD data can be quickly optimized and adapted.

Fig. 6: Finger implants, material: EOS Titanium Ti64 (Source: Within)

Additive Manufacturing –
Patient Specific Disposable Instruments

Fig. 7:
Stereotactic platform, STarFix fastening with two target areas, material: PA 2200 (Source: FHC, Inc.)

The field of surgery requires devices and instruments that are made with maximum precision. For complicated operations surgeons are increasingly using patient-specific disposable surgical instruments, manufactured with Additive Manufacturing methods based on 3D CAD data. Often the deciding factor is the speed of response to doctors' requirements, since Additive Manufacturing can greatly shorten the lead time.

"The trend in medical devices is to create customized products. EOS technology provides us with patient-specific product manufacturing while enabling us to control costs as we speed delivery to our surgical customers."

Ron Franklin, Chief Technology Officer, STarFix™

"We anticipate even greater product improvement opportunities from the switch to laser sintering as we go forward. Having the flexibility of a technology that can create patient-specific solutions rather than one-size-fits-all can result in both hospital economies and better patient outcome."

Fred Haer, FHC CEO and STarFix™ President

Additive Manufacturing – Benefits for Patient, Surgeon and Hospital

Improved patient care

A surgical instrument that is perfectly tailored to a specific patient and operation ensures that the patient spends less time in the operating room and so requires less anaesthetic. Individualized instruments allow an implant to be placed more precisely, thereby minimizing the probability of a further operation and a protracted rehabilitation period. In contrast to operations performed with conventionally manufactured, standardized instruments, an operation with patient-specific instruments can often be performed with minimal invasion, reducing overall stress for the patient.

Precision for surgeons

Operations performed with surgical instruments produced specifically for the patient are easier for the surgeon: The instrument design can be optimized to suit the specific operating situation, and its functionality can be enhanced.

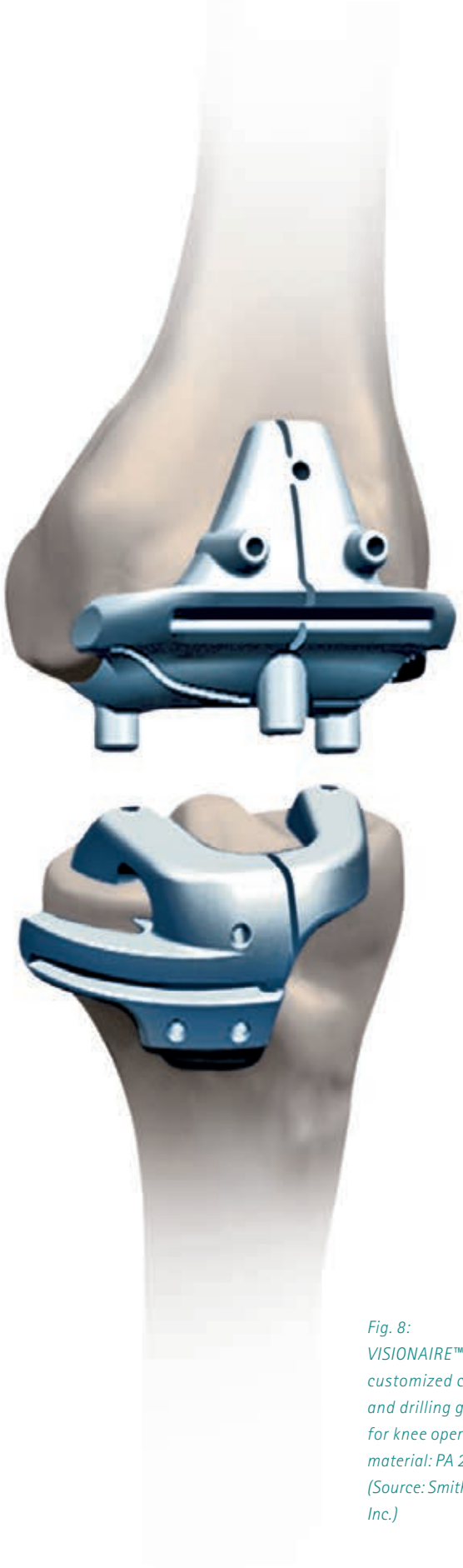

Fig. 8:
VISIONAIRE™, patient-customized cutting and drilling guide for knee operations, material: PA 2200 (Source: Smith & Nephew Inc.)

The surgeon can work with greater precision and therefore shorten the operating time considerably. This also reduces the risk of errors, complications or infection during the operation.

Cost-effectiveness for the hospital

Conventionally manufactured instruments are usually standardized and thus associated with additional sterilization and storage costs, which can be considerably reduced by using disposable instruments produced by EOS technology. Despite customization, higher productivity and lower unit costs can be achieved in production than with conventionally manufactured instruments. In this way the surgeon is supplied with a tailored, high quality product that meets the rigorous standards for medical applications.

Additive Manufacturing – Patient Specific Prostheses and Ortheses

The combination of Additive Manufacturing and orthopedic technology produces improved prosthetics and orthotics. A new generation of prostheses can be produced by combining new manufacturing technologies with innovative simulations. Due to the material properties of the plastics, Additive Manufacturing technologies easily meet the ISO standards applicable to prosthetics, ensuring that high quality standards are observed.

Improved patient care

The key is the design of the prosthesis as a whole, not only the functioning of its individual parts. Both the function of the parts and the design of the entire prosthesis are important. The prosthesis is designed to reproduce the volume of the whole leg instead of imitating it. This creates a totally new aesthetic, the mark of a prosthesis produced by generative manufacturing processes that cannot be achieved using anyother method.

Weight reduction

The process enables tailor-made, functional and highly-technical products to be developed and manufactured on the basis of 3D data and bionic models. Due to the geometric freedom of the production process, it is possible to produce complex geometries and internal structures. This minimizes weight and increases patient comfort.

Cost-effective manufacturing

Additive Manufacturing offers the convincing benefits of rapid and flexible production and efficient component manufacture at low material costs.

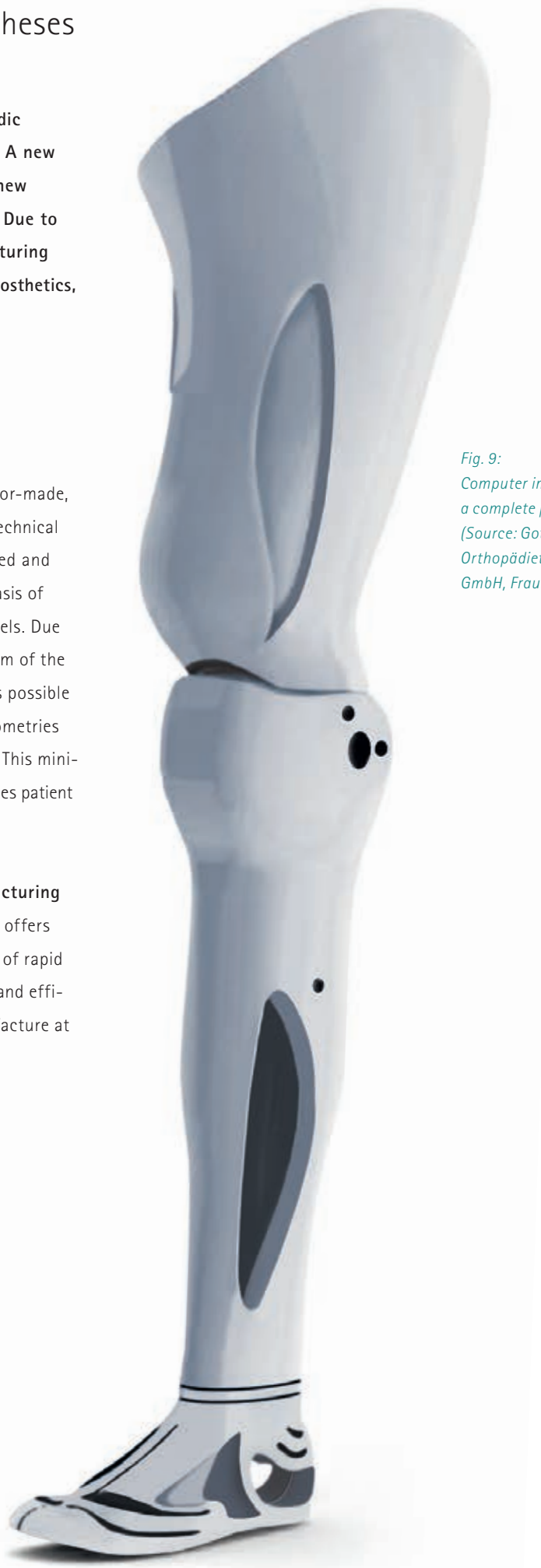

Fig. 9: Computer image of a complete prosthesis (Source: Gottinger Orthopädietechnik GmbH, Fraunhofer IPA)

Additive Manufacturing – Serial Production of Medical Devices

Many medical devices and items of laboratory equipment are not only costly and complex but are also niche products produced in small series. Conventional manufacturing often requires expensive tools, the cost of which must be reflected in the product price. In contrast, laser sintering technology works without tools, thus allowing components to be manufactured economically in smaller series or even as single units. Medical technology companies such as Andreas Hettich GmbH have recognized the high profitability of this method and are changing over to Additive Manufacturing. The centrifuge manufacturer uses the process in product development and production and has thus managed to enhance the value of its products while reducing manufacturing costs at the same time.

Fig. 10/11: Cell washing system for blood group serology, series production using EOSINT P 380, material PA 2200 (Source: Hettich)

Typical production volumes for these centrifuges are between 10 and 1,000 units per annum. Hettich invented and patented a new form of centrifuge, which combines the sedimentation and separation of blood components in a single device. The ROTOMAT comprises a drum motor with six boxes and drip trays. The boxes have a complex geometry and are subject to high rotational speeds with acceleration forces of 1,200 x gravitational acceleration. Conventional manufacture of the box components requires complex tools and involves time-consuming assembly. After carrying out a comprehensive technical evaluation, the sector specialist decided to change its method for manufacturing the centrifuge housing. He now uses the EOS Additive Manufacturing method to produce its components.

Cost-effective manufacturing

Production of the modified components by laser sintering was only slightly more expensive, but saved the costs of a set of tools. There were also further cost savings on assembly and logistics. Furthermore, laser sintering can be used "on demand". If necessary, additional changes to the design or product variants can be implemented quickly and at minimal cost. For example, different versions can be made for different blood bags.

Functional integration

The switch also improved product functionality. The toolless production method for the boxes and the potential for integrating functions increased the product value, while reducing production costs.

EOS Partners

WITHIN – EOS partner in the design process

WITHIN, a young design consultancy based in London, offers tools which constantly push the boundaries of the possible in the world of Additive Manufacturing. At the core of their technology lies a powerful optimization engine which takes as its input parameters such as desired weight, maximum displacement and stiffness. It is able to custom-design optimized lattice structures and surface skins to meet exact specifications. Products are then manufactured using AM. WITHIN's suite of technologies can enable products that exhibit properties that were previously unachievable. It is therefore a powerful tool for patient-specific instruments and implants.

IMDS – EOS partner in the medical field

IMDS (Innovative Medical Device Solutions) supports its customers in the preparation of contracts as well as in the development and production of medical devices. The company focuses on innovation and rapid introduction to the market. IMDS provides products improving the quality of life and the level of care for patients.

The EOS Principle:
The Big Picture in Every Detail

The EOS Additive Manufacturing method paves the way for improved individual patient care. For the best solution for your individual requirements, EOS offers you much more than the materials and systems necessary for the manu-facturing process. With its thorough understanding of the market and knowledge of the specific development sequences in the medical sector, EOS works together with a strong network of partners. The result: EOS delivers comprehensive and reliable advice and support through the entire development and production process, whether for building a prototype or series manufacture. Thus you are guaranteed a safe, thoroughly tested and high-quality manufacturing process.

You are unique

EOS technology offers you a cost-effective manufacturing process, right from the very first batch. It enables you to run test series, create prototypes and produce individual items for patients profitably.

You are free

Unlike conventional manufacturing solutions, the producibility of your designs is never an issue. You are free to concentrate on innovative functionalities without worrying about the limits of the process.

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

Selected Customers and Partners

FHC

Fraunhofer IPA

GOTTINGER

Hettich ZENTRIFUGEN

imds

smith&nephew

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