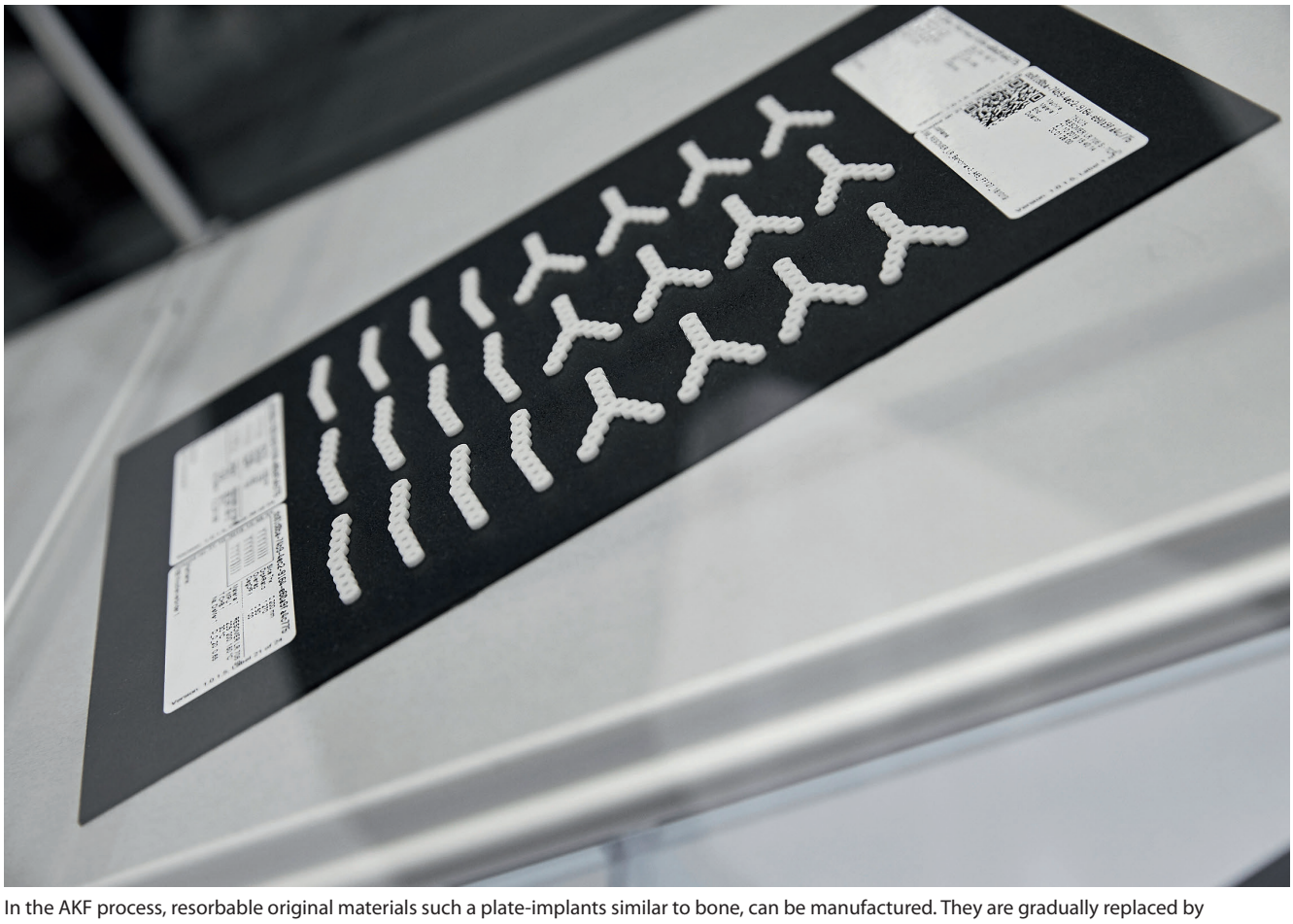
New Possibilities for Use in the Human Body

Medical Product Manufacturers Are Processing Original Materials Using the Freeformer

Arburg Plastic Freeforming is predestined for the additive manufacturing of medtech components. The associated Freeformer-type additive manufacturing systems process the same plastic pellets that are used in injection molding. That makes the open systems very economical to use. They can also process, among other things, biocompatible, resorbable and sterilizable, as well as FDA-approved original materials. This also opens up new possibilities for applications in the human body.



In the AKF process, resorbable original materials such a plate-implants similar to bone, can be manufactured. They are gradually replaced by endogenous tissue © Arburg

As has now been widely demonstrated in practice, the APF (Arburg Plastic Freeforming) process now permits even challenging medtech applications that are not feasible by any other process. Thus, implant plates of the resorbable, FDA-approved original material Resomer LR 706 – a composite of poly(L-lactide-co-D,L-lactide) and β-TCP (manufacturer: Evonik Nutrition & Care GmbH, Essen, Germany) – can be manufactured, which can be used directly in the body on bone fractures (**Title figure**). The polymer composite imitates human bone and contains 30% ceramic additives based on »

Fig. 1. The medical-grade TPE Medalist MD 12130H can be used to manufacture flexible, individually tailored hand orthoses © Arburg

Fig. 2. Hans Keller, Director of R&D Productions at Aesculap, sees the potential of the Freeformers e. g. for additive manufacturing of prototypes, trial implants and drilling templates © Arburg

β-TCP (tricalcium phosphate). The component is thereby more stable, and also releases calcium to promote bone growth. After a predetermined time, the implant dissolved completely. The example shows how such applications are increasingly approaching the individual requirements of human medicine.

The Freeformer is available in sizes 200–3X and 300–3X, and builds up components layer by layer from extremely small plastic droplets. Its users can process their own original materials and perform their own process control optimization. Alternatively, they can access the database of the machine manufacturer (Arburg GmbH + Co. KG, Lossburg, Germany), where they can select and process the certified plastic pellet stocks that are also used in injection molding. Such materials, such as ABS (acrylonitrile-butadiene-styrene copolymer), amorphous PA (polyamide) and PC (polycarbonate), elastic TPU (thermoplastic polyurethane) and semicrystalline PP (polypropylene), but also PLLA (poly-L-lactide) and other original materials especially for medical applications.

Functional MedTech Parts with Anti-Inflammatories

Resorbable cranial, cheek and finger bones of medical PLLA (type: Purasorb PL18, manufacturer: Corbion NV, Amsterdam, Netherlands, or Resomer LR 708, Evonik) have the advantage that they do not need to be surgically removed after healing. In addition, the plastic pellets can be loaded with, e. g., anti-inflammatories to minimize rejection problems. In order for the material to dissolve in the body at the right time, it is very important to select the correct material grade. In addition, permanent implants, e. g. of PCU (polycarbonate urethane) are also manufactured by the AKF process. They are suitable, e. g., for use in spinal surgery.

Additively manufactured functional components are also finding growing applications not only in the body. The process is also predestined for medtech equipment and accessories. In 2018, Arburg presented the first ever processing of a medically approved elastomer (SEBS, styrene-ethylene-butylene-styrene, type: Cawiton PR13576, manufacturer: Wittenburg BV., Zeewolde, Netherlands), with a hardness of 28 Shore A. The very soft material is leaktight and tear resistant, and is suitable, e. g., for manufacturing functioning bellows.

The Freeformer is the only additive manufacturing system available to date that can process the FDA-approved TPE Medalist MD 12130H (manufacturer: Teknor Apex; hardness 32 Shore A), for example for flexible hand orthoses (**Fig. 1**) or for customizable respirator masks, whose seal conforms to the patient's face contour. The degree of filling of the component can be selectively varied while retaining constant parameters, and the mechanical properties of the parts thereby modified. In the case of TPE, this results in e. g. different Shore hardnesses. Different material densities can also be adjusted within one and the same part.

With minor adjustments, all Freeformers are suitable for use in cleanrooms. They feature low emissions and are almost dust-free, and their build chamber is generally made of stainless steel. An optional robot interface allows additive manufacturing to be automated and the machines to be integrated into IT-networked manufacturing lines. The process quality can be reliably documented and the parts clearly traced if necessary.

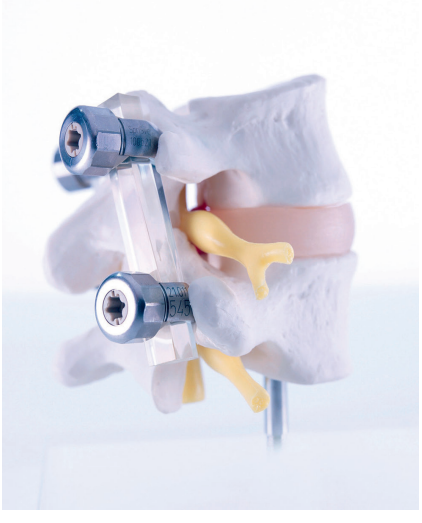


Fig. 3. With the Freeformer, Samaplast has additively manufactured a permanent spinal implant e. g. from FDA-approved PCU, for stabilization in the event of a slipped disk © Samaplast

Aesculap: MedTech Products "in the Blood"

Typical examples of a medtech accessory are sawing templates of PA, which are used as customized operation aids. Aesculap AG in Tuttlingen, Germany, a subsidiary of B. Braun Melsungen AG, has already been using additive part manufacturing in medtech since 1993. The company has been working with a Freeformer 200–3X since February 2018. The Freeformer offers us clear advantages: processing of medically approved, resorbable PLLA; high-quality parts thanks to extremely thin layers and the option of manufacturing hard/soft combinations," says Hans Keller (**Fig. 2**), Director for R&D Productions at Aesculap.

There is ever greater demand for specially adapted bone components and implants for individual patient treatment. Not least for reasons of cost, ever more medical products, such as sawing templates or trial implants, are being made of plastic. According to Hans Keller, "While the special materials cost us up to EUR 200 per kilo, the Freeformer allows us to process commodity plastic pellet stock, at only a fraction of the costs."

Samaplast: Permanent Spinal Implant

Samaplast AG, a manufacturer of medtech and technical products with headquarters in St. Margrethen, Switzerland, uses a Freeformer 200–3X to manufacture extremely small series down to batch size of one. It also produces combinations from a prototype project through to OEM manufacturing. With the AKF process, it manufactures implants of FDA-approved PCU and resorbable materials such as polylactide or components of two materials with special geometries.

Thomas Mösli, assistant CTO at Samaplast, describes their first experiences with the Freeformer as follows: "We manufactured prototypes for our customers on injection-molding machines in the past. We now offer additive manufacturing of components with the Freeformer in addition, particularly in the medical sector." For example, a permanent implant for the spinal region (**Fig. 3**), which is used to stabilize a slipped disk, was made from an FDA-approved PCU (type: Bionate; manufacturer: DSM Biomedical B.V., Geleen, Netherlands) in the various Shore hardnesses 90A, 80A, 55D, 65D.

Fig. 4. Frank Reinauer, Head of Innovation and Production Biomaterials at Karl Leibinger Medizintechnik, welcomes the new possibilities that the Freeformer offers for manufacturing implants

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Other tests involved parts made from two materials. For example, a spiral sheathed with a second polymer, two rods of different hardnesses combined or a resorbable polylactide manufactured.

All the trials clearly highlighted the advantages of the Freeformer. According to Thomas Mösli, "We can test new materials as well as unusual geometries rapidly and at low cost, without needing to develop and construct expensive »

Fig. 5. Jens Harmeling (left) and Dr. Axel Höfter head the new Röchling Direct Manufacturing Center. In the global additive manufacturing center, Röchling also employs a Freeformer 300–3X
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injection molds. There is also the fact that implant materials are expensive. With the Freeformer, we can manufacture test products with low material consumption from commercially available, qualified injection moldable plastics. That makes us much more flexible."

Karl Leibinger: Bioresorbable Implants for the Facial Area

Karl Leibinger Medizintechnik GmbH & Co. KG of Mühlheim an der Donau, Germany, a member of the KLS Martin Group, is a leading innovator in medtech. Since December 2017, the company has worked with a Freeformer to manufacture custom parts and implants at short notice. Different polylactides and polymer-metal composites are processed, to manufacture, for example, tensioning rods, prototypes and functional components. With the Freeformer, they are able to selectively influence the part properties, process their own plastics and optimize the process control themselves. Arburg's material database immediately provides the necessary key data.

This is where the specialists at Karl Leibinger Medizintechnik can also see the particular strengths of the industrial additive manufacturing system. Frank Reinauer (**Fig. 4**), Head of Innovation and Production Biomaterials, says, "The possibility of processing a wide range of original plastic pellet stocks and using their properties for medical products makes our production just as flexible as the Freeformer."

One product area is bioresorbable implants for the mouth, jaw and facial areas. They are used for osteosynthesis (surgical fixture to bone) and for reconstruction, and they degrade in the body over a period of up to 24 months. Such complex geometries can also be economically manufactured in small quantities on the Freeformer. The quality of the parts is comprehensively assured by means of geometrical and chemical analysis. Since personalization is becoming increasingly important in health care for implants directly adapted to the patients, Karl Leibinger, with the Freeformer, sees itself particularly well positioned here.

Röchling: Center for Additive Manufacturing

The Röchling Direct Manufacturing Center (RDMC) in Waldachtal, Germany, focuses on industrial additive series manufacturing and services such as design for 3D-printing. "Additive manufacturing has long achieved an industrial standard. With the RDMC, we are expanding our 3D printing expertise for the entire Röchling Group", notes Dr. Axel Höfter (**Fig. 5**), one of the two managing directors of Röchling Direct Manufacturing GmbH. They want to manufacture new, complex geometries additively and equip new products with advanced functions. The focus here will be on industrial additive manufacturing of fully functional prototypes in series, as well as on design that is appropriate to the production process.

Summary

The AKF process is particularly suitable for additive manufacturing in medtech. Geometrical freedom combined with the wide material selection opens up entirely new plastic applications, including for applications in the human body. A focus of the Freeformer manufacturing system: the additive manufacturing of custom orthoses, implants from biocompatible standard pellet stocks and auxiliary means for surgical preparation. The machine can also be integrated into fully automated manufacturing lines. ■

The Author

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