Fraunhofer
IFAM

FRAUNHOFER INSTITUTE FOR MANUFACTURING TECHNOLOGY AND ADVANCED MATERIALS IFAM

BUSINESS SEGMENT
MEDICAL TECHNOLOGY AND LIFE SCIENCES

CONTENT

TECHNOLOGY FOR PEOPLE AND FOR THE ENVIRONMENT

THE FRAUNHOFER-GESELLSCHAFT

The Fraunhofer-Gesellschaft promotes and carries out applied scientific research and development work. Founded in 1949, the work of the Fraunhofer-Gesellschaft is geared to the needs of industry and society. Our contract partners and customers are companies in the manufacturing and service sectors as well as public organizations. The Fraunhofer-Gesellschaft currently operates 72 institutes in Germany and employs more than 25,000 people, most of whom are scientists and engineers.

The various institutes within the Fraunhofer-Gesellschaft collaborate as groups or come together to form flexible alliances, depending on the specific demands of the projects. In order to develop specific and customized solutions the Fraunhofer Institute for Manufacturing Technology and Advanced Materials IFAM, is involved in the Fraunhofer Group "Materials and Components – MATERIALS", as well as in 10 other alliances and the Fraunhofer Academy.

FRAUNHOFER IFAM

Fraunhofer IFAM is one of the leading independent research organizations in Europe in the fields of "Adhesive Bonding Technology and Surfaces" and "Shaping and Functional Materials". The focus of all our R&D activities is to provide customers with effective, application-oriented solutions. Most of the products, processes, and technologies we develop are for sectors where sustainability is particularly important, namely for the aviation industry, automotive sector, energy and maritime technologies, medical technology and life sciences. The solutions developed at Fraunhofer IFAM are, however, also used in various other branches of industry including machinery and plant construction, electronics and electrical engineering, shipbuilding, rail vehicle manufacture, the packaging industry, and the construction sector.

Fraunhofer IFAM has a highly qualified workforce of more than 650 people, organized into project teams and business segments covering specific topics. These topics include materials, shaping, joining technologies, surface functionalization, and the development of complete components and complex systems. This means that Fraunhofer IFAM covers the whole value chain from the development of materials and product design up to the integration into industrial production – including pilot trials and customized workforce training in new technologies.

MEDICAL TECHNOLOGY AND LIFE SCIENCES

In the medical technology and life sciences sector, Fraunhofer IFAM is working on technical or biological materials that interact with humans or the environment. In this sector a successful development requires the consideration of the entire process chain, beginning with custom-made materials and material combinations, manufacturing technology and surface functionalization as well as the complete characterization of the product and its properties. Our scientists will link the institute's specific core competencies for maximum customer benefit.

Fraunhofer IFAM possesses specific knowledge in the field of biological evaluation of medical products according to DIN EN ISO 10993 and has established essential testing according to this standard in Bremen in order to accelerate product introduction (time-to-market). These services offered can be complemented by the realization of regulatory requirements and quality management according to DIN EN ISO 13485.

ORIENTED TOWARDS SCIENCE AND SOLUTION

We think analytically and we create solutions
The emphasis of our service is the development of practical solutions for practical demands. For specific tasks a team of experts will be put together according to your needs.

We work together in partnership
We listen, we show the way forward and we take responsibility for achieving the shared goals. As an institute we are independent, neutral and, if necessary, committed to confidentiality.

We bring in our knowledge and impart it
Our expertise, our many years of experience and our highly developed equipment are the basis for creating a successful and applicable solution to your problem. We conduct permanent preliminary research to provide an in-depth understanding of materials and processes while creating strategic partnerships for the development of complex tasks. For the transfer of knowledge and technology we offer a number of customizable options.

We stand for technological progress
We are on top of technological developments and we possess the know-how to implement these in products. We manufacture everything starting with the prototype to the small series and we will also accompany you for the long term during any further development of your products.

We stand for future with quality
All relevant departments of the institute are certified according to DIN EN 9001 or DIN EN ISO/IEC 17024, or are accredited according to DIN EN ISO/IEC 17025.

WE ARE HERE FOR YOU

The scope of our R&D-services ranges from feasibility studies to market-ready concepts or products. If required wewill provide a technology or know-how transfer including workforce qualification.

Analyzing markets
- Observing trends in technology
- Performing feasibility studies and economical analyses

Optimizing existing processes
- Demonstrating and implementing potentials
- Establishing new technologies

Developing products
- Manufacturing processes
- Prototyping and production of small series

Improving products
- Increasing performance
- Improving cost efficiency

Characterizing, testing and certifying
- Modern testing facilities
- Evaluating results and certifying

Providing licenses
- Using the results of preliminary research
- Acquiring a license and exploit it effectively

Qualifying for the future
- Transfer of technology
- Professional training

MEDICAL TECHNOLOGY AND LIFE SCIENCES

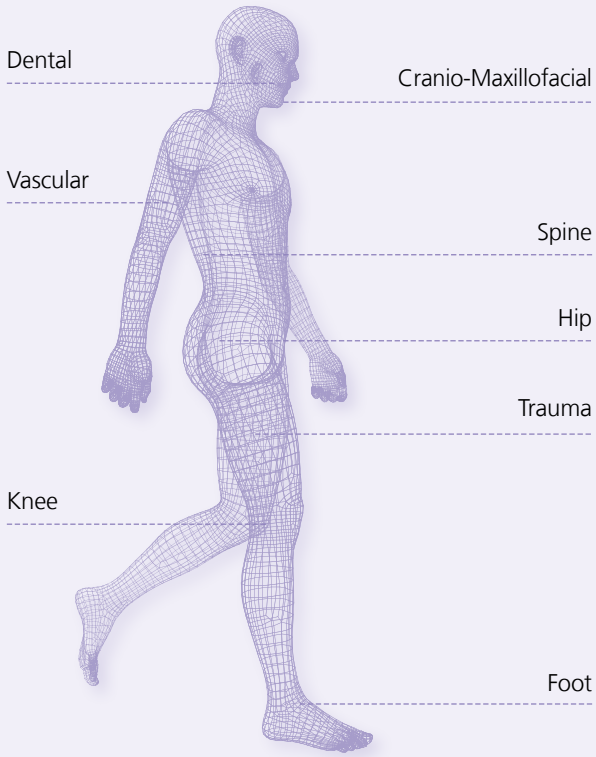
CONTACT

Dipl.-Ing. (FH) Kai Borcherding MBA RWTH
Phone +49 421 2246-678

Dr. Sebastian-Boris Hein
Phone +49 421 2246-261

medilife@ifam.fraunhofer.de

SELECTED AREAS OF APPLICATION OF FRAUNHOFER IFAM TECHNOLOGIES



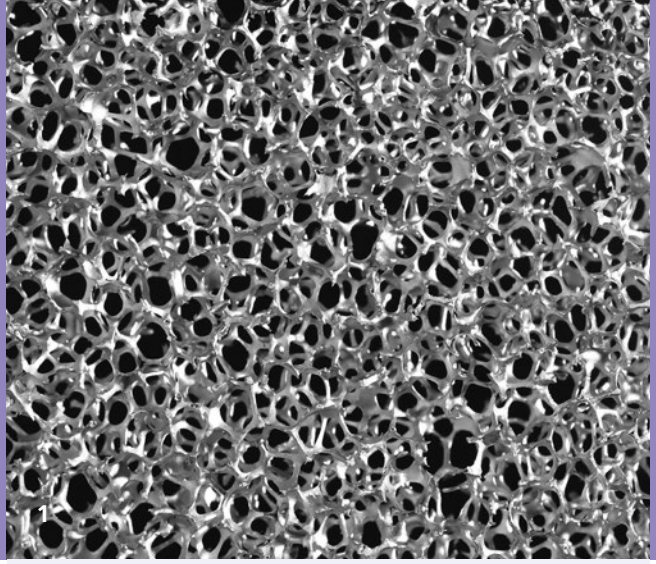
Our team of specialists, consisting of engineers, chemists, biologists and external medical practitioners, individually develop concepts and technical solutions for the entire process along the product creation chain. We are there for our customers from the beginning of the preliminary research to market alignment, technology development and technology transfer, relevant staff qualification and final certification.

In this business field Fraunhofer IFAM specifically addresses suppliers, developers and manufacturers of life science and medical products. Main attention of our research and development is directed to materials, the methods of component production, functionalization technologies and comprehensive analyses in order to develop a more comprehensive understanding and for quality control purposes.

The focus in the medical technology sector is on implants, instruments, adhesives and functional surface coatings, taking into consideration the final application of the product, the materials used, the requirements of the customer and any relevant regulatory issues.

In life science applications the emphasis is on functional surfaces and sensors while the central aspects are the interaction of biological and technological systems and their monitoring. At Fraunhofer IFAM a biomimetic approach is often used, whereby the analysis of a natural example leads to the technical implementation of the functional principle involved.

MATERIALS



At Fraunhofer IFAM metallic materials, adhesives and functional coatings have traditionally been the focus of developments in medical technology. In conjunction with this, our experts have over the last few years been involved with stainless steels, cobalt-chromium alloys, titanium and titanium alloys as well as the joining of various materials through adhesive bonding and the development of special adhesives. Examples of products include artificial heart valves or stents made of titanium, which are manufactured using powder technology. Functional surfaces are realized as antimicrobial coatings on catheters, among other products. The adhesives developed at Fraunhofer IFAM are also used in diagnostic or therapeutic equipment and in prostheses or implants.

Recently there has been increasing demand for new materials in the medical technology and life sciences sector. Examples include composite materials, for example in the form of highly filled polymers, bioceramics and bio-inspired materials or composite materials made of ceramics and metals. Form and function also play an important role during the development. The materials can be implemented as full-density or porous materials, in the form of surface coatings or as printed structures for sensors. Under consideration of their functions, the materials are optimized for applications in medical technology, for example as degradable implants, for MRI compatibility, as medicinal adhesives or for cell growth management.

Materials in the life sciences sector that are in direct contact with biological systems often have a natural origin or are bio-inspired. These materials include proteins or peptides, which are used in hybrid materials, such as the biomimetic mussel adhesive. However, technical materials are also continuously being developed for bionic applications, enabling them to fulfill a function that follows a natural model. The shark skin lacquer, for example, minimizes flow resistance and is used in a variety of applications.

1 *Open-porous metal foam.*

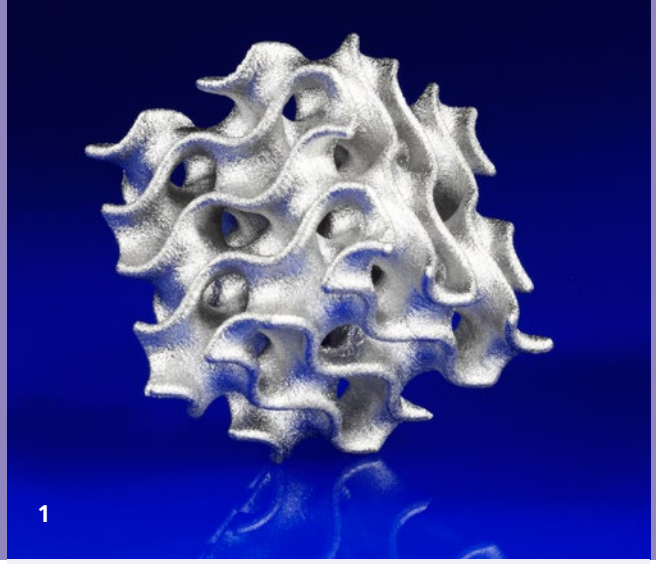
MATERIALS

Metals
- Stainless steels
- Co-Cr-alloys
- Titanium and titanium alloys
- Magnesium
- Precious metals

Ceramics
- Oxide ceramics
- Bioceramics
- Carbides, nitrides, borides

Polymers
- Technical/synthetic polymers
- Biopolymers
- Plasma polymers
- Adhesives

Composites
- Fibre composite materials
- Polymer composites
- Metal-ceramic composites
- Polymer-peptide hybrids
- Nanocomposites



1

PRODUCTION OF COMPONENTS

MANUFACTURING PROCESSES

Shaping processes
- Injection molding
- Powder injection molding (PIM)
- Pressing
- Cold isostatic pressing (CIP)
- Extrusion
- Investment casting
- 3D-screen printing
- Sintering
- Spark plasma sintering (SPS)

Additive manufacturing
- Laser beam melting (LBM)
- Electron beam melting (EBM)
- Binder jetting
- Fused filament fabrication (FFF)
- Continuous photopolymerization

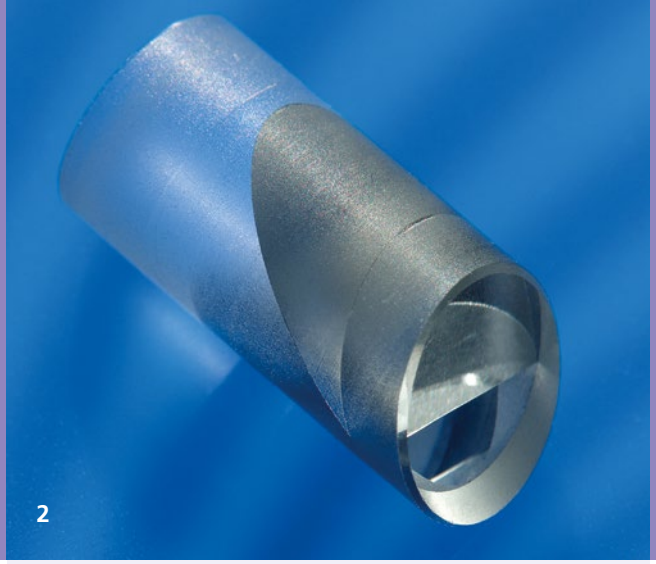
Printing technologies
- Aerosol jet printing
- Inkjet printing
- Pad printing
- Screen printing
- Dispensing

During the development of new products or the improvement of existing products the emphasis is on the manufacture of the product itself. The manufacturing process significantly influences the quality of the product and thus its performance throughout its application. Therefore we pay great attention to the manufacture of components, with a focus on molding processes, additive manufacturing, joining processes and surface modifications.

With shaping processes the geometry of a component is defined by a given mold, which can be a molding or injection molding tool or the extruder nozzle of an extruding die. This enables the manufacture of both simple and complex components, as well as semi-finished parts. For medical products injection molding is often used as it is well-suited for complex components that are produced in high numbers. At Fraunhofer IFAM this process has been developed for use in, for example, the processing of degradable composite materials.

Powder injection molding (PIM) enables components to be produced from almost all metals, as well as from many ceramics and composite materials of both material classes. In the PIM process the components undergo a sintering step after shaping, sintering the powder particles in a controlled manner and compacting them. Through the use of temporary place holders porous components can be selectively produced.

Additive manufacturing encompasses a variety of processes requiring no mold for the production of components, building them instead in layers directly from digital data. At the institute LBM (Laser beam melting) and EBM (electron beam melting) processes are used for metallic materials, binder jetting is used for powdered materials and FFF (Fused filament fabrication) is used for thermoplastic polymers and highly particle-filled feedstocks, similar to the PIM approach.



2

In the medical technology sector we offer, for example, the process development of patient-specific implants and very complex or customized instruments, depending on your choice of material and process.

The implementation of sensors is feasible in the manufacture of functional components. At Fraunhofer IFAM RFID chips are integrated into processes for this purpose, such as the injection molding or the additive manufacturing processes, while various printing technologies have been developed for sensor applications, including inject printing, aerosol jet printing, the dispenser process and screen printing.

During manufacture the modification of surfaces and the joining of components also represent important steps in the process. Particularly in medicine and medical technology a number of inert materials are used that are difficult to work with or join. At the same time there has been an increase in the variety of materials, the miniaturization of instruments and the demands on resilience during sterilization. Therefore, the development of manufacturing processes using adhesive bonding technology for the medical sector represents a particular challenge.

Examples of our activities include the precise integration of optical components in endoscopy, the design of sterilization resilient adhesives and their implementation in the manufacture of adhesively bonded composites as well as the development of processes for the synthesis of nanocomposites for use in dental materials.

Surfaces play a key role particularly in the combination of biological and technical materials. Numerous wet and dry chemical processes offer customized solutions in the field of medical technology. An integral part of our work is the consideration of component development and its later application during production.

1 *Component manufactured by using binder jetting.*

2 *Adhesively bonded endoscopelense.*

MANUFACTURING PROCESSES

Surface technology

- Atmospheric pressure plasma
- Low pressure plasma
- VUV-excimer-technique
- Laser treatment
- Flame treatment
- CO_2-snow blasting
- Vacuum suction blasting
- Wet chemical primer

Coating technology

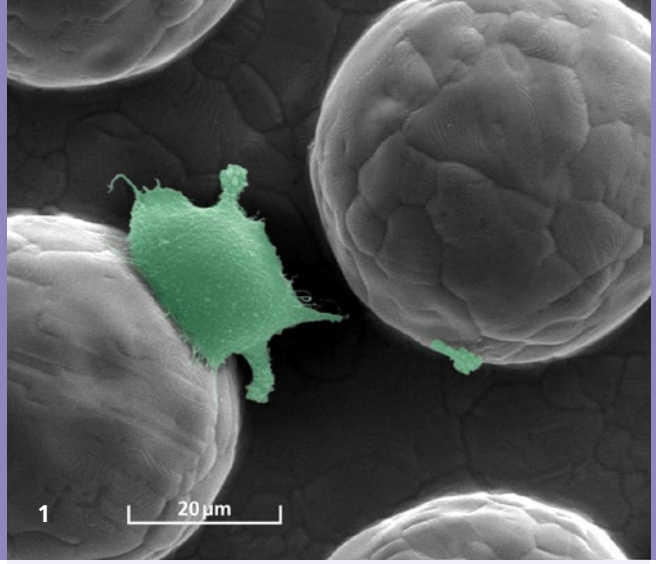
- Coating application
- Powder coating
- Sol-gel systems

Simulation

- Finite element method (FEM)
- Computational fluid dynamics (CFD)
- Molecular modeling

Adhesive technology manufacture

- Adhesive formulation and synthesis
- Catalysts and inhibitors
- Hybrid joining processes
- Micro manufacture



1

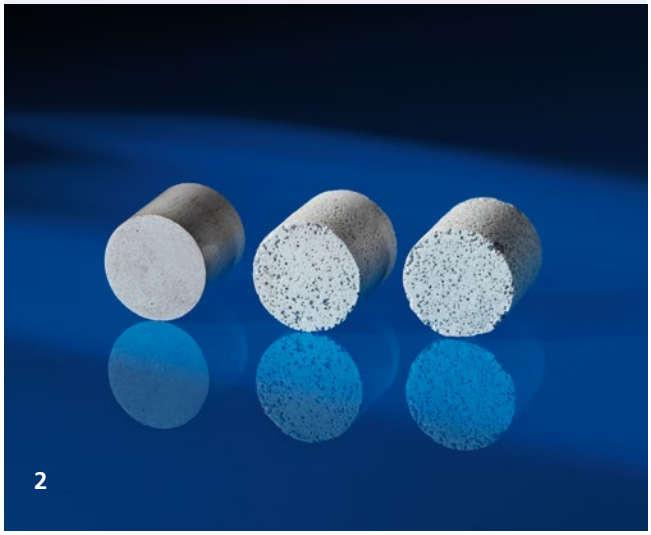
FUNCTIONALIZATION

TECHNOLOGIES

Surface structuring
- Cell growth behavior
- Tribologic characteristics
- Adhesive properties

Porous materials
- Adaptation of density, Young's modulus, strength
- Vascularization
- Material transport
- Lightweight construction
- Material reduction

Surface modification | functional coatings
- Preliminary treatment
- Cleaning
- Activation
- Antimicrobial properties
- Biocompatibility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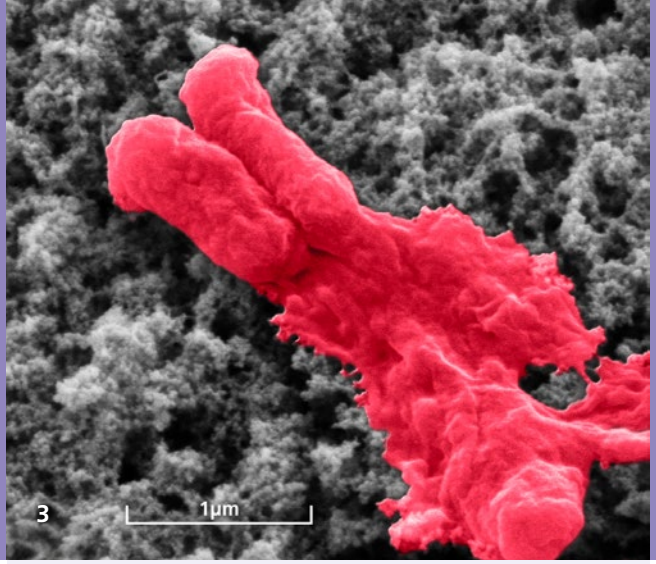
The functionalization of components can occur during the manufacture of a component or during a downstream process. During shaping, for example, surface structures can be applied locally or comprehensively and pore structures can be precisely set. Downstream processes in the production of surface modifications and coatings are used for functionalization. Thus, the characteristics of a material can be purposefully changed and additional materials can be integrated into the components, enabling specific functions. This can be in the form of coatings or as sensors.

Functionalization in the field of medical technology encompasses a number of aspects at Fraunhofer IFAM. A surface applied during manufacture can be used to control or manage the growth behavior of bone to an implant. Porous areas in components enable, for example, the vascularization of implants, which benefits new tissue growth.

A surface coating can also be used for a specific purpose: examples include biofunctional surfaces for the control of cell adhesion or to prevent any unspecified adsorption of biomolecules such as proteins. This process can also be reversed, to promote a coupling of functional groups if necessary. A surface activation manipulates the surface energy so that a hydrophobic surface becomes a hydrophilic surface. Such an adaptation significantly influences cell adhesion.

Coatings can be used in a variety of ways, from color-coding on implants that prevent mix-up of products to bioactive coatings for the optimization of bone cell growth and furthermore to antibiotic storage layers. Fraunhofer IFAM has extensive experience in the field of antimicrobial, biocompatible and non-cytotoxic surface coatings.



3

In addition, surface technologies can be combined and act synergistically. One example is the combination of metallic particles and antibiotics on implants to generate a local synergistic effect for preventative or therapeutic uses against implant associated infections.

Another example is the treatment of polymer implants with titanium or titanium oxide to increase biocompatibility. Beside this surface coatings can be used for corrosion and mechanical protection on medical devices.

Surface modifications and functional coatings are useful in the life science sector for such purposes as corrosion protection, anti-fouling coatings or anti-ice layers. A number of developments implement a bionic approach. Anti-freeze proteins are used to decrease ice formation. Biocide-free anti-fouling concepts, adhesives made of mussel proteins and antimicrobial coatings consisting of peptides are also being developed.

Sensors are used in the medical technology sector for a number of purposes. RFID chips enable identification and tracking, which can be important e. g. for surgical instruments in an operating theater. Structural Health Monitoring (SHM) sensors can monitor the stress placed on components such as prostheses or load-bearing implants. They are also relevant in the life sciences sector, guaranteeing the functionality of technical systems that are in long term contact with biological systems.

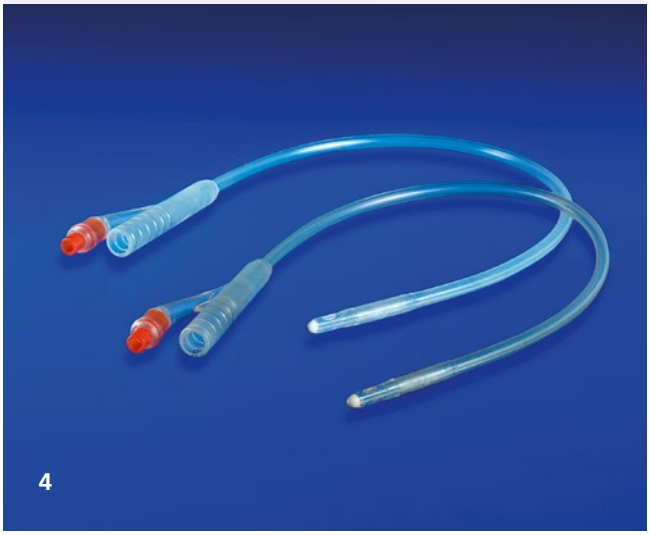
TECHNOLOGIES

Coatings

- Antibiotic release coatings
- Color layers
- Anti-corrosion
- Friction and drag resistance
- Barrier layers
- Anti-icing
- Anti-fouling
- Dirt-repellent surfaces

Sensors

- Expansion sensors
- Temperature sensors
- Biosensors
- Gas sensors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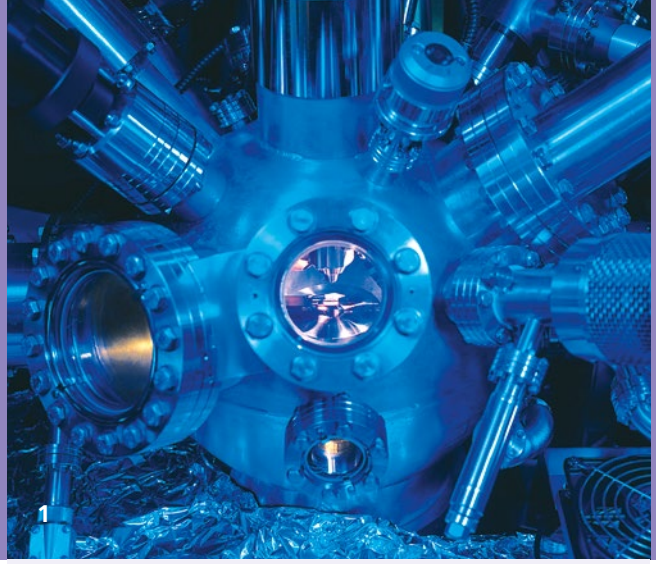
1 *Hemispheres made by metal powder injection molding for cell growth management on implants.*
2 *Composites made of calcium phosphate and polylactic acid for bone implants with a variety of porosities.*
3 *Antibiotic coating lyses bacterium (E.coli).*
4 *Antimicrobial coating created with plasma technique, seen here on a catheter.*



ANALYTICS AND QUALITY CONTROL

Biological evaluation of medical devices
- DIN EN ISO 10993-5 Tests for in-vitro cytotoxicity

Imaging processes
- Electron microscopy
- Computer and X-ray tomography

Chemical composition and structure
- Spectroscopy and spectrometry
- X-ray diffraction
- Chromatography
- Element and trace element analysis

Electrochemical characterization
- Impedance spectroscopy, noise analysis potentiometry

Surface analysis
- Spectroscopy and spectrometry
- Reflectrometry
- Colorimetry
- Contact angle measurement

Physical analysis
- Rheology, tribology, magnetic measuring

Powder measurement technology
- Particle and powder analytics

Thermal analysis
- Gravimetry, calorimetry, dilatometry, dynamic analysis

Materials and components testing
- Mechanical and non-destructive assays

Especially in the medical technology sector materials must fulfill a variety of demands regarding their area of use. They must be cleanable, long-lived and possess good mechanical characteristics. There are also high demands on the long term stability and reliability of these products, in addition to standardization issues, regulatory limitations and pressures on cost.

Fraunhofer IFAM offers services in analytics and quality assurance within the scope of research and development projects, as well as in service analytics. A wide variety of highly developed methods and technologies is used to characterize the material or the component. Manufacturing and functionalization processes can be monitored, evaluated and purposefully optimized. Through our comprehensive knowhow our customers will be supported in the development of customized quality assurance concepts according to their needs.

Since 1995, Fraunhofer IFAM has been certified to DIN EN ISO 9001 in the sectors of product-oriented development of materials, processes and production technologies for adhesive bonding technology, surface technology and paint/lacquer technology, characterization and simulation of materials and technologies, adhesives development, metallography, thermal analysis, powder measurement technology and trace analysis.

The test laboratories conducting material testing, corrosion testing, paint/lacquer technology, materialography and analysis in Bremen have since 1996 been additionally accredited according to DIN EN ISO/IEC 17025. The test laboratory in Dresden is accredited according to DIN EN ISO/IEC 17025 for powder metallurgy, special tests for the characterization of inorganic powders and sintered materials as well as for the material testing of metallic materials.

1 *The X-ray photoelectron spectroscopy (XPS) analyzed the chemistry of surfaces and interfaces.*

LOCATIONS AND DEPARTMENTS

Institute Directors
Prof. Dr.-Ing. habil. Matthias Busse
Prof. Dr. Bernd Mayer

Fraunhofer Institute for Manufacturing Technology and Advanced Materials IFAM
Wiener Strasse 12
28359 Bremen | Germany
Phone +49 421 2246-0
info@ifam.fraunhofer.de
www.ifam.fraunhofer.de

Winterbergstrasse 28
01277 Dresden | Germany
Phone +49 351 2537-300
info@ifam-dd.fraunhofer.de

Marie-Curie-Strasse 1–3
26129 Oldenburg | Germany
Phone +49 441 36116-262
info@ifam.fraunhofer.de

Ottenbecker Damm 12
21684 Stade | Germany
Phone +49 4141 78707-101
info@ifam.fraunhofer.de

Hermann-Münch-Strasse 1
38440 Wolfsburg | Germany
Phone +49 421 2246-126
info@ifam.fraunhofer.de

LOCATIONS AND DEPARTMENTS

BREMEN
- Adhesion and Interface Research
- Adhesives and Polymer Chemistry
- Adhesive Bonding Technology
- Business Development
- Casting Technology and Lightweight Construction
- Chemistry of Fiber Composite Materials
- Electromobility
- Materials Science and Mechanical Engineering
- Paint/Lacquer Technology
- Plasma Technology and Surfaces
- Powder Technology
- Smart Systems
- Workforce Training and Technology Transfer

BRAUNSCHWEIG*
- Fraunhofer Project Center for Energy Storage and Systems

DRESDEN
- Cellular Metallic Materials
- Energy and Thermal Management
- Hydrogen Technology
- Sintered and Composite Materials

OLDENBURG
- Electrical Energy Storage Systems

STADE
- Automation and Production Technology

WOLFSBURG
- Fraunhofer Project Center for Electromobility and Lightweight Design

Under construction.

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