

INSTITUTE FOR IMPLANTTECHNOLOGY AND
BIOMATERIALS E.V. - ASSOCIATED INSTITUTE
OF THE UNIVERSITY OF ROSTOCK

Medical Technology for Life

INTRODUCTION



Sustainable and well-paid jobs in our country are the key to mastering global challenges.

Representatives from politics, business, science and administration have therefore jointly developed visions for the future to maintain and improve our prosperity and want to support their implementation. The Mecklenburg-Vorpommern Industrial Policy Concept and the Regional Innovation Strategy for Intelligent Specialization Mecklenburg-Vorpommern 2021 to 2027 are therefore also part of the current coalition agreement. The aim is to strengthen the innovation and competitiveness of the economy in the state for the benefit of the people.

The three designated fields of action include medical technology and biotechnology, renewable energies and mechanical and plant engineering. Medical technology and biotechnology have great potential on international markets of the future. However, access to these markets is only possible with innovative products and processes that meet the requirements of current demographic and medical technology developments.

In addition to economic power and prosperity, medical technology progress is also hope for a better quality of life for many people. However, progress needs innovative, competitive products, which do not occur out of nowhere. In addition to outstanding ideas, targeted research and development are particularly important.

The framework conditions for such research and development have been improved continuously over the last years by the government of Mecklenburg-Vorpommern.

With the collaborative research funding established in the state of Mecklenburg-Vorpommern, regional companies can make even better and more targeted use of the existing scientific potential of universities, and non-university research institutions, for the development of their own innovative marketable products and processes. As a center of competence for medical technology the IIB e.V. has proven to be a reliable partner for industry in terms of collaborative research. With its focus on the regional biomedical economy, the Institute is a recognized competence carrier of research and transfer activities in Mecklenburg-Vorpommern.

The Institute carries out excellent research work in numerous joint projects with companies from Mecklenburg-Vorpommern that leads to internationally competitive products. This is essential for strengthening the economic power of the regional economy.

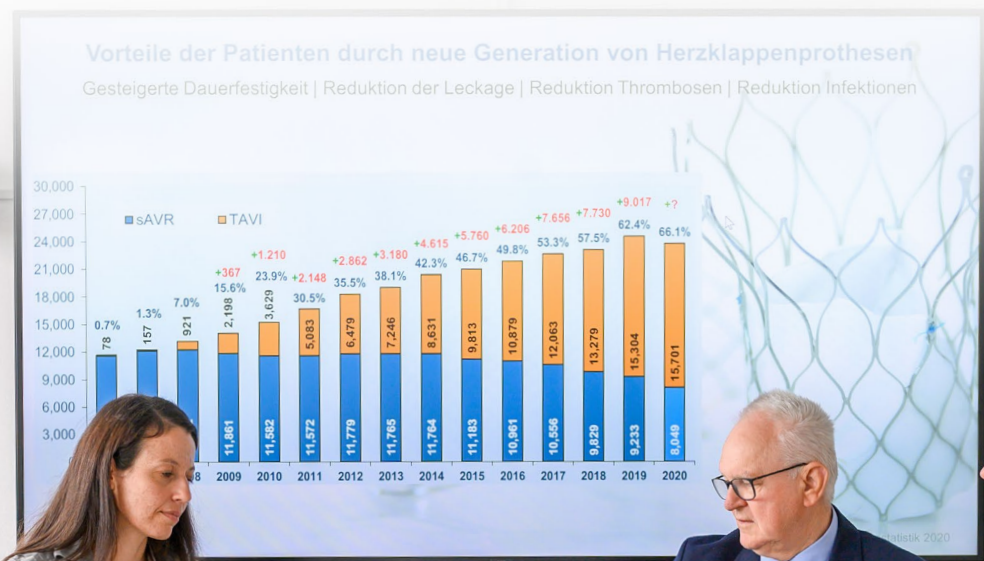
This brochure provides you with comprehensive information on the performance spectrum of the IIB e.V. The existing infrastructure and the human potential, that masters the relevant methods, provides stimuli and offers opportunities for joint innovations. Take advantage of the possibilities that are offered by the IIB e.V. The Ministry of Economic Affairs, Infrastructure, Employment and Tourism of the State of Mecklenburg-Vorpommern offers the best possible support in implementing innovative ideas for the future through the state's own funding for research and development.

A handwritten signature in black ink, reading "Jochen Schulte". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Jochen Schulte

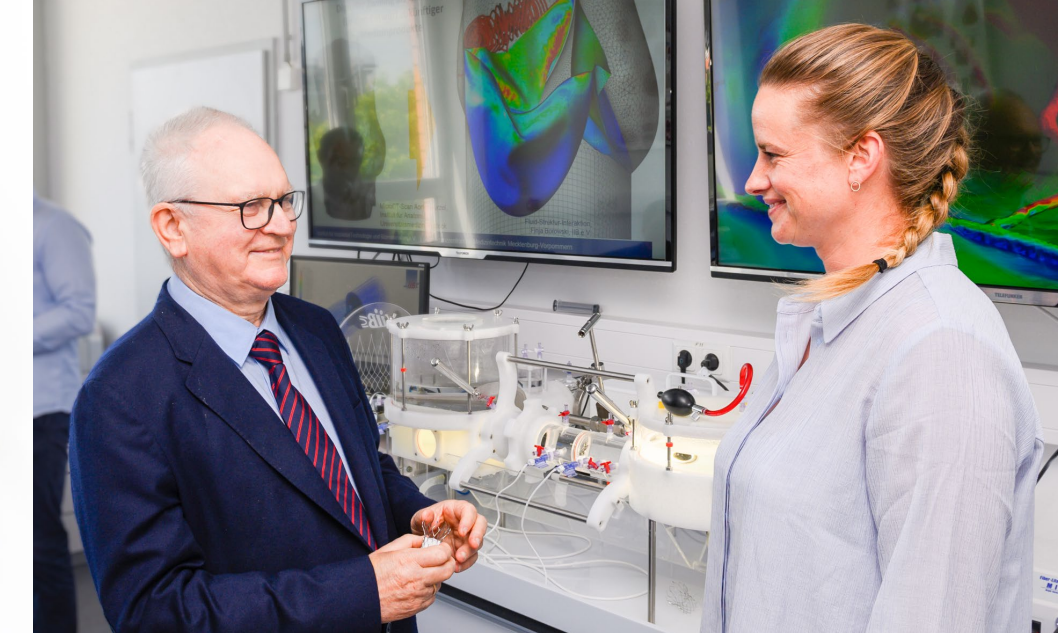
*State Secretary of Economics, Infrastructure,
Tourism and Labour Mecklenburg-Vorpommern*

The management of the IIB e.V.: Institute Director Prof. Klaus-Peter Schmitz, Managing Director Dipl.-Soz. Verw. Andrea Bock as well as the heads of the departments »Research & Development« Dr. Michael Stiehm and Technology & Transfer« Dr. Stefan Siewert support research partners and companies in transferring their medical technology innovations to clinical application.



Over **25** years of IIB e.V.

The goal: Creating structural change through the transfer of medical innovation and technology into clinical practice, as a powerful research and development partner for science and industry in Mecklenburg-Vorpommern and Germany.



Prepared for the Future by Tradition

Health technology, especially medical technology, constantly demands the highest standards from people and technology. Today more than ever, it is essential to develop innovative ideas and combine competencies in order to realize visionary solutions to improve patients' lives. Science and technology are the most valuable building blocks of our knowledge-based economy.

Since 1996, the Institute of ImplantTechnology and Biomaterials (IIB e.V.) is established as a research and development partner, but also as a service provider for the medical technology industry as well as for companies and research institutions in related high-tech fields.

We are delighted to address the industry's needs and challenges in the development of innovative medical products and technologies. By supporting regional industry and working closely with universities, we actively contribute to the sustainable development of Mecklenburg-Vorpommern as a forward-looking technology center in Germany with international recognition.

Prof. Dr.-Ing. Klaus-Peter Schmitz
 Director of the Institute for
 ImplantTechnology and Biomaterials e.V.

Dipl.-Soz. Verw. Andrea Bock
 Managing Director of the Institute for
 ImplantTechnology and Biomaterials e.V.

THE INSTITUTE FOR IMPLANTTECHNOLOGY
AND BIOMATERIALS E.V.

Heading for Science and Business

Medical technology cluster
Rostock-Warnemünde with
extensive laboratory and
equipment facilities
at IIB e.V.

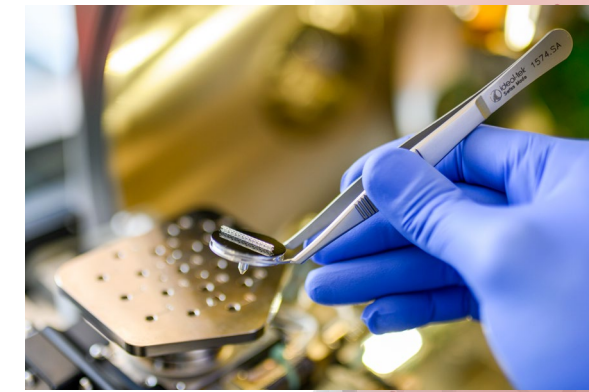


Center of Competence Medical Technology Mecklenburg-Vorpommern at IIB e.V.

The IIB e.V. is an associated institute of the University and University Medical Center Rostock in the legal form of a non-profit research institute. As the Center of Competence for Medical Technology in Mecklenburg-Vorpommern, the IIB e.V. is an efficient partner for regional and trans-regional companies in the field of medical technology as well as other high-tech areas. The structures within the IIB e.V., the interdisciplinary orientation and the extensive technology and laboratory equipment enable the IIB e.V. to react flexibly to current trends in research and development in order to support regional and national companies.

Comprehensive Range of Expertise

The IIB e.V. supports medical technology innovations from early idea stage up to their application on the patient. The work is focused on the development of smart and safe medical devices to treat common diseases in a minimally invasive manner. As a competence partner for medical technology, we work at the interface between science, industry and hospitals. With our unique expertise, we help medical technology companies to improve their competitiveness.



Fluid and structure simulations
of heart valve prostheses

Comprehensive Range of Competencies at IIB e.V.

- Fluid and structural simulations of heart valve prostheses
- Development of innovative medical devices
- Development of new testing equipment and methods for medical devices under consideration of physiological loads and parameters
- Processes and technologies for the manufacturing of medical devices
- Biomechanics and biofluid-mechanics
- Biomaterial testing and general materials testing
- Structural analysis, microscopy and materialography
- Metrology and sensor systems in medical technology
- Digitalization and artificial intelligence in medical technology
- Method development for pre-competitive research and development in medical technology
- Implementation and strengthening of the testing activity for companies, considering the EU legislation for the approval of medical devices.

Implants for Life

Stents and Heart Valve Prosthesis for the Treatment of Cardiovascular Diseases

Cardiovascular diseases are characterized by a significant epidemiological prevalence and a substantial demand for technology-driven innovations. The international markets for such innovations are extensive, with growth rates above the average. In Germany alone, over 800,000 patients with vascular diseases (including coronary heart disease and myocardial infarction) and approximately 100,000 patients with heart valve diseases are diagnosed and treated annually.

The IIB e.V. demonstrates a strong commitment to advancing these specific areas, primarily through close collaborations with various clinical partners. Noteworthy successes in this regard include the fruitful scientific collaboration with Prof. Dr. Alper Öner from the Cardiology Department at Rostock University Medical Center.



The close collaboration between research, science, and clinical practice facilitates the development of innovative medical products. This approach forms a valuable foundation for highly effective cardiovascular therapies and successful treatment concepts at the forefront of medical advancement.

Prof. Dr. med. Alper Öner
Clinical Director IIB e.V. | Senior Deputy Director and Chief Physician of Cardiology, Clinic for Internal Medicine, Rostock University Medical Center

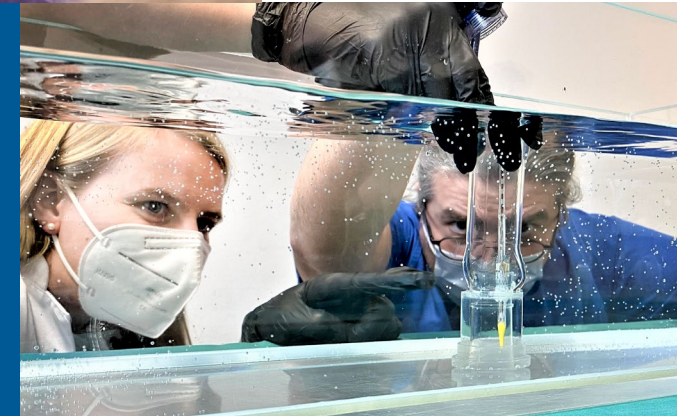


Optical microscopic analysis of stents and their coating as quality control

Close cooperation with the clinic during the implantation of a transcatheter heart valve prosthesis under the guidance of qualified cardiologists in a laboratory test

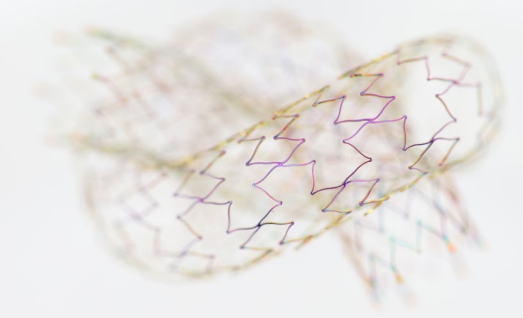
Best-in-Class Stent Technology

IIB e.V. represents a rich tradition in the field of stent development. These experiences are leveraged to advance the development of new generations of stents and simultaneously extended into new research areas.



Our innovative Research Approaches for Stent Development

- Optimization of stent designs for enhanced flow and structural mechanics, particularly for specialized applications like bifurcation stenting
- Utilization of advanced process technologies for manufacturing and surface structuring
- Pioneering biodegradable drug-eluting stents (DES) designed for vascular intervention. These stents are based on magnesium alloys and polymers and hold the potential for complete vascular regeneration
- Research and evaluation of drug-releasing coatings and other surface functionalizations in conjunction with implant-tissue interactions



Development of new polymeric and metallic stents for coronary and peripheral applications



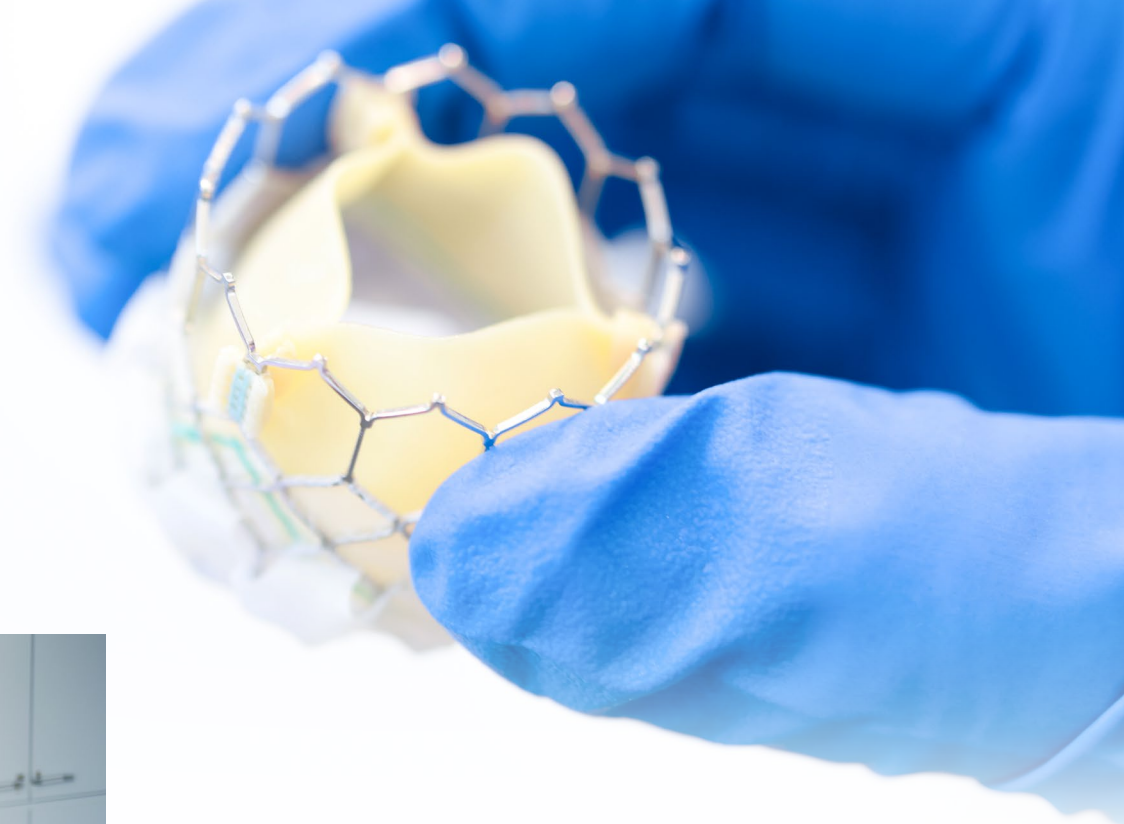
Life-Saving Prosthetic Heart Valves and Repair Implants

In the field of heart valve prosthetics, the IIB e.V. primarily concentrates on transcatheter aortic valve replacement, with additional emphasis on mitral valve repair devices.

The overarching objective is to create enduring implants for the treatment of structural heart diseases. Ensuring the long-term functionality of these implants is paramount, particularly for their potential use in younger patients, as this helps to mitigate the risks, stress, and cost associated with recurring operations.



Prototypes of a transcatheter aortic valve prosthesis based on a metallic stent-frame combined with pericardium tissue as the leaflet material



Our Innovative Research Approach

- Utilization of numerical structural-mechanical simulations for the analysis of heart valve structures, aiding in the development of cutting-edge therapy methods
- Assessment of implantation strategies through virtual simulations of mitral valve repair implants
- Creation of innovative implant designs through coupled structural and fluid mechanics simulations
- Experimental examination of fluid mechanics in heart valve prostheses and mitral valve repair implants under conditions mimicking physiology
- Conduction of standard-compliant tests for heart valve prostheses in accordance with ISO 5840.
- Comprehensive investigations aimed at reducing the thrombogenicity of heart valve prostheses
- Development of sealing concepts to prevent paravalvular leakage (PVL) in transcatheter aortic valve replacement (TAVR)

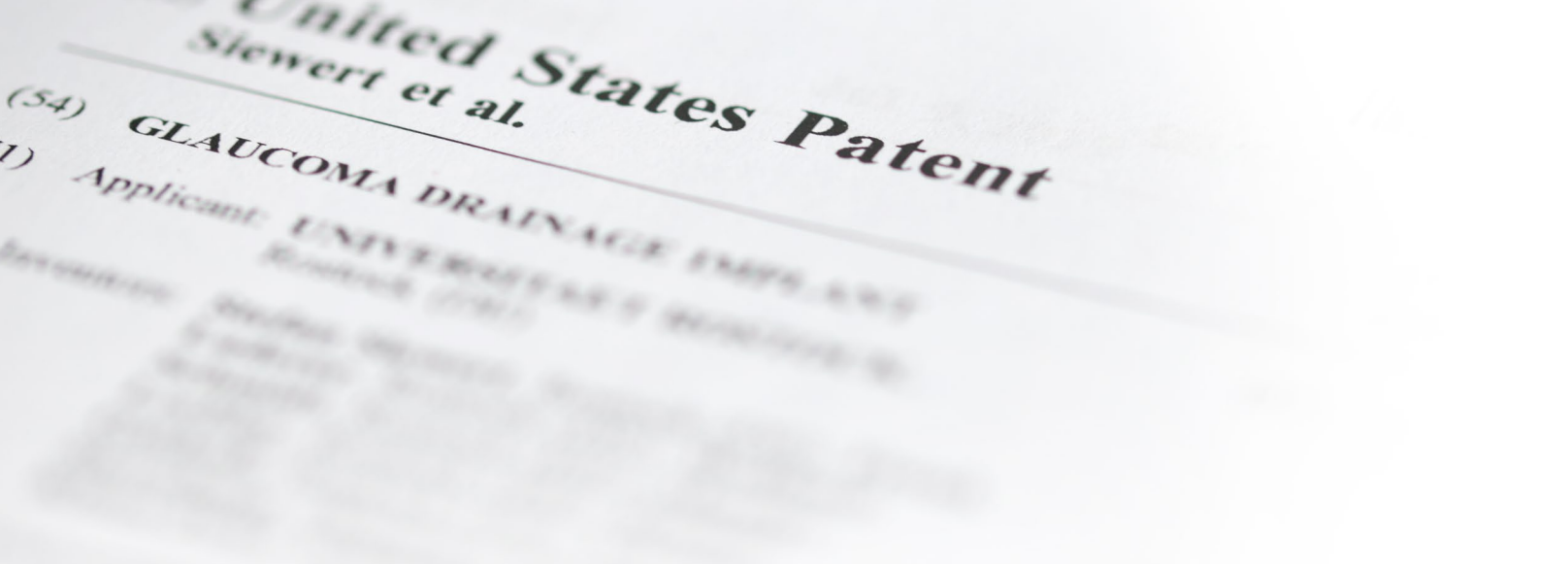


Implant device for the minimally invasive mitral valve repair



The development of implants for treating structural heart diseases is a profoundly exciting and challenging endeavour. We can only successfully bring new implants to market with the support of robust interdisciplinary teams that combine expertise from engineering and the natural sciences.

Dr.-Ing. Michael Stiehm
Head of Research and Development IIB e.V.



Transfer of Innovative Stent Technologies into Various Medical Areas

The utilization of cutting-edge stent technology opens up unprecedented possibilities for success across various medical applications. Under the guidance of Prof. Klaus-Peter Schmitz, there is currently ongoing development of a drug-eluting microstent for ophthalmology, featuring dimensions in the sub-millimeter range.

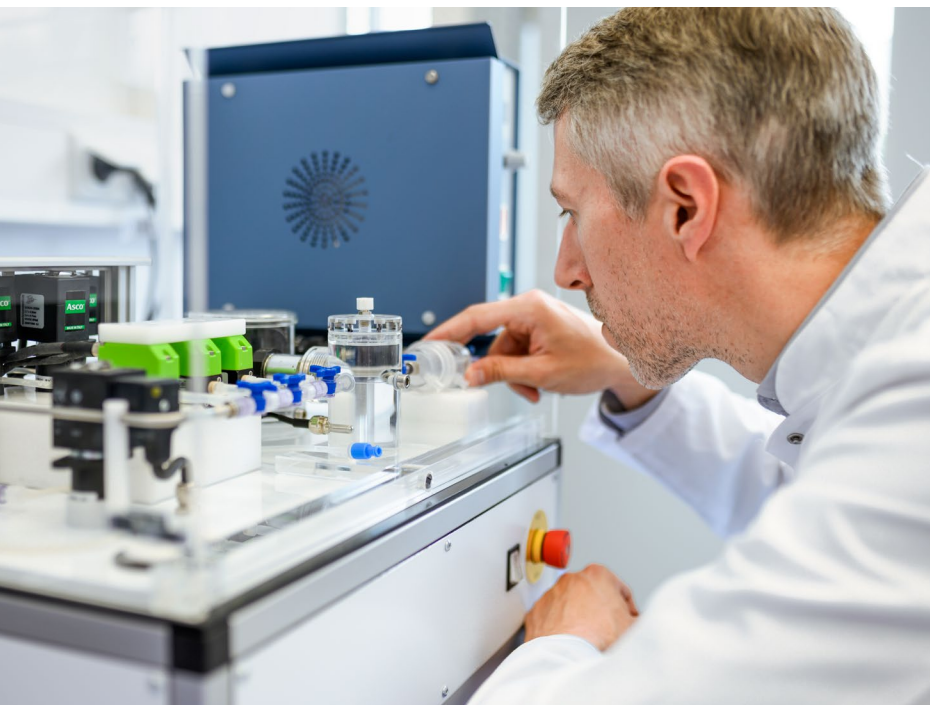
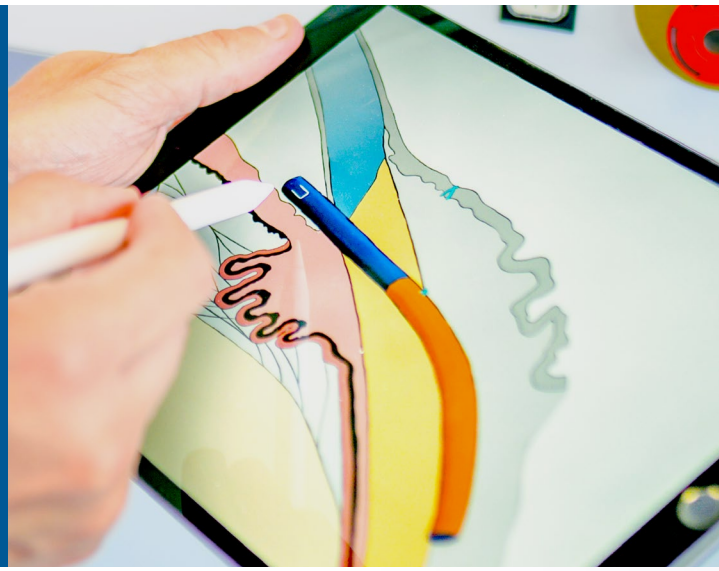


Our drug-eluting microstent provides completely new possibilities in glaucoma therapy. We hope to improve patients' quality of life in the future with this implant-based »fit and forget« approach.

Dr.-Ing. Stefan Siewert
Head of Technology and Transfer IIB e.V.

With an Eye for the Fundamentals – Implant-Based Adaptive Concepts for Minimally Invasive Glaucoma Therapy

Glaucoma represents the leading cause of irreversible blindness globally. To mitigate the damage caused by glaucoma, it is crucial to employ specialized therapy methods aimed at reducing intraocular pressure to a defined, patient-specific target level.



Laboratory testing of the safety of glaucoma microstents



Prototype of a glaucoma microstent and associated applicator for minimally invasive implantation

Unique Selling Points of the Innovative Drug-Eluting Microstent for Glaucoma Therapy

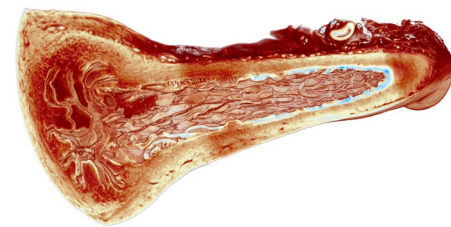
- Consistent regulation of intraocular pressure within physiological boundaries via a microvalve
- Controlled local drug release to ensure sustained efficacy
- Patient-friendly, minimally invasive implantation procedures

Position of the glaucoma microstent in the eye





Prototype of a bioresorbable fallopian tube microstent device



Micro-computed tomography image depicting an implanted microstent prototype within a porcine fallopian tube

For the Miracle of Life – Biodegradable Microstents for the Treatment of Fallopian Tube Occlusions

Prof. Klaus-Peter Schmitz and Andrea Bock are pioneering the adaptation of stent technology from cardiology to gynecology.

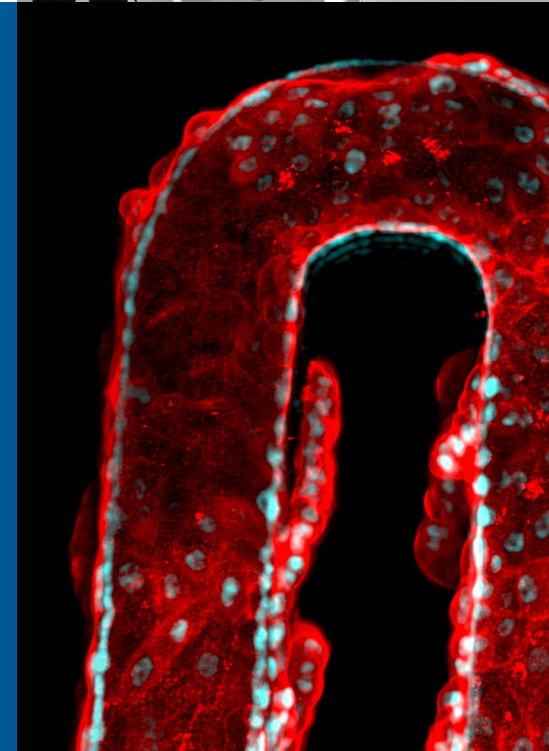
In Germany, one in ten couples faces the distressing challenge of infertility. Traditional treatments for addressing female infertility typically involve costly artificial insemination procedures or pose surgical risks. Furthermore, these methods often result in relatively low pregnancy rates below 50%. Through the development of our innovative biodegradable microstent, we aim to provide an alternative to expensive artificial insemination and enable natural conception in the future.



Our groundbreaking fallopian tube stent leverages proven innovation know-how from coronary stent technology and applies it to modern gynecology. Our goal is to bring joy to many patients by paving the way for natural fertilization in the future.

Prof. Dr. med. Marek Zygmunt
Gynecological Clinic and Polyclinic and Obstetrics |
University Medicine Greifswald

Implant development is interdisciplinary teamwork from the fields of technology, natural sciences and medicine



Fluorescence micrograph of fallopian tube epithelial cells on a microstent prototype

Our Innovative Research Approach

- The collaboration between IIB e.V. and University Medicine Greifswald introduces an innovative approach with a biodegradable microstent for minimally invasive treatment of fallopian tube occlusions, marking a significant technological breakthrough. This therapy facilitates the recanalization of fallopian tubes by employing a biocompatible, self-expanding, and degradable micro-support structure. This approach minimizes patient risks and costs while enabling natural fertilization.
- Our primary focus lies in the development, production, and rigorous testing of prototypes, with careful consideration of the physiological and anatomical requirements for an implant intended for fallopian tube recanalization. Structural-mechanical simulations represent an integral part of design optimization, and simulated applications in technical models play a pivotal role in preparing for clinical implementation.

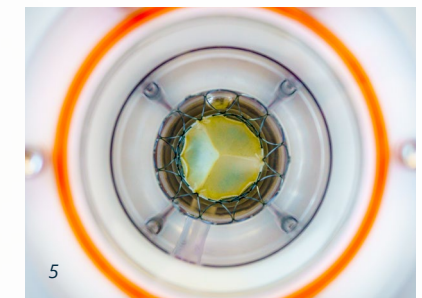
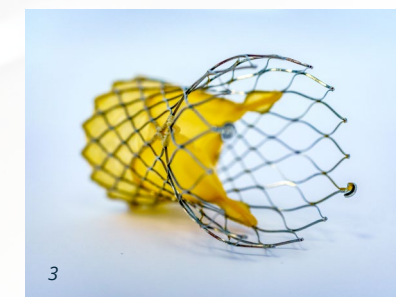
DEVELOPMENT, PROTOTYPING AND TESTING OF MEDICAL DEVICES

The World of Innovation at IIB e.V.

Bundling competencies, focusing on expertise: Through the collaborative efforts of IIB e.V. with stakeholders from the realms of science, medicine, and business in the field of medical technology, the development of new medical products is efficiently shepherded along the entire translation chain. This collaborative approach significantly accelerates forward-looking innovation processes.



Teamwork in the hydrodynamic characterization of heart valve prostheses



- 1 Left atrial appendage (LAA) occluder
- 2 Prototyping using femtosecond laser technology
- 3 Transcatheter aortic valve prostheses
- 4 Pacemaker and their leads
- 5 Heart valve prostheses in durability testing
- 6 Polymeric microstents for different fields of application

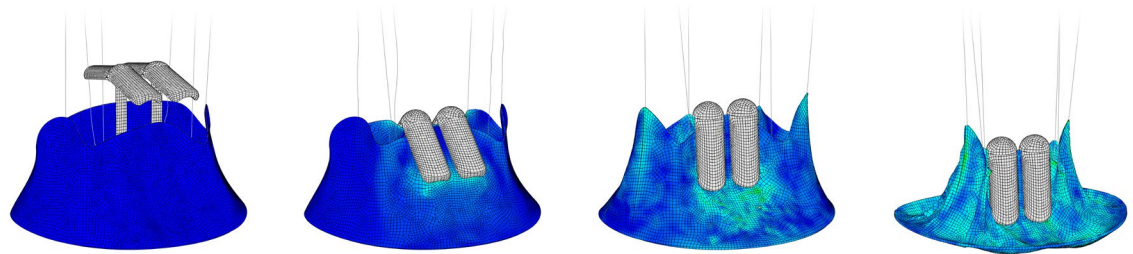
Concept and Design for Innovative Implants

The foundation for the development of innovative implants and other medical technologies lies in anatomical studies and clinical analyses. These studies establish a clear set of requirements regarding the performance and safety of the implants.

To achieve this, IIB e.V. maintains close collaboration with the Institute for Anatomy at Rostock University Medical Center and other clinical partners. This collaborative effort ensures that the anatomical and physiological prerequisites for innovative implants,

as well as their clinical significance, are carefully considered during the development process.

To adhere to these rigorous quality standards, IIB e.V. and its partners and customers have access to a wide array of technologies, ranging from imaging to production to testing, which can be employed in the development of various implants.



Evaluation of clinical implantation strategies using virtual implantation of mitral valve repair implants

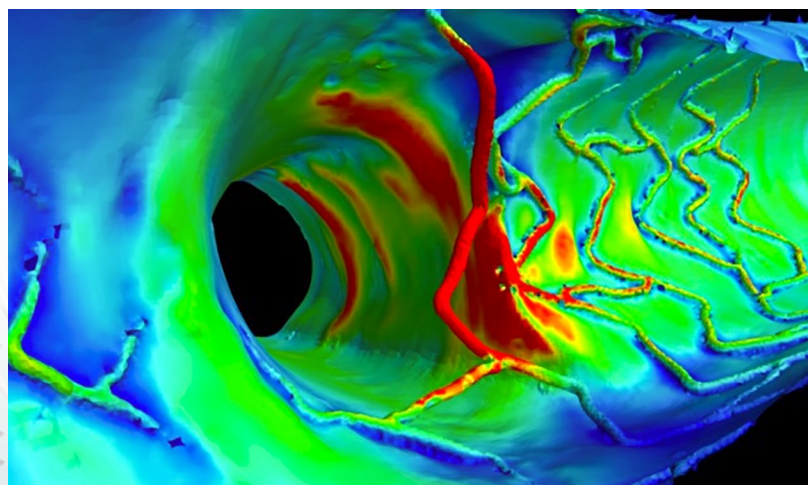
Design and Simulation

At IIB e.V., we specialize in the development of innovative implants and systems for minimally invasive applications based on structural and fluid mechanical simulations. The development of implant designs relies heavily on structural mechanical simulations.

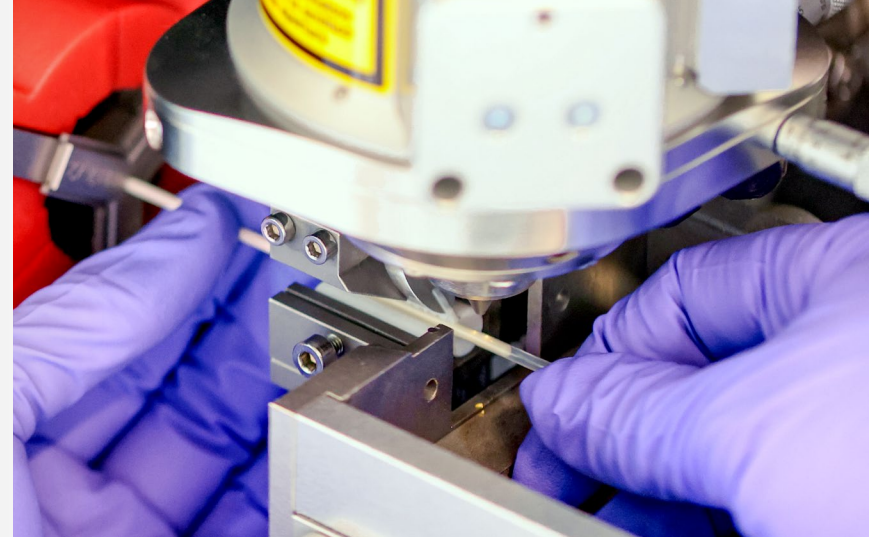
These investigations provide insights into the biomechanical behavior during implantation and under physiological conditions. They enable the

prediction of fatigue properties and support risk mitigation through worst-case analyses.

Numerical fluid flow simulations are employed to identify critical elements in implant designs, forming the basis for fluid mechanical design optimization. One of our objectives is to minimize the thrombosis risk associated with vascular stents or transcatheter heart valve prostheses.



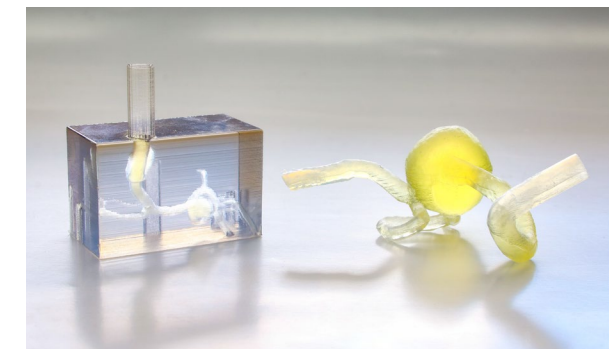
Simulation of the flow through a coronary bifurcation (branching of the coronary arteries) for the evaluation of implantation techniques



Cutting and microstructuring of polymers and metals using femto-second laser technology



Prototype of a stent system »made by IIB e.V.«

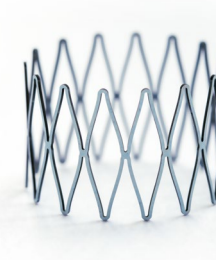


Additively manufactured models of intracranial aneurysms

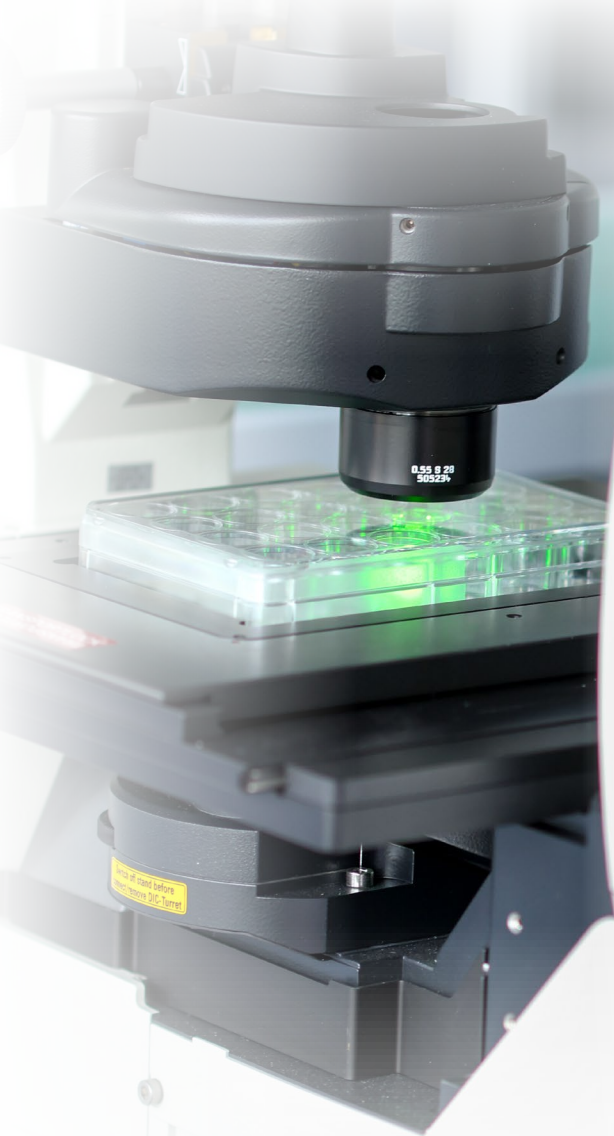
Prototyping of Implants

IIB e.V. has access to a diverse range of methods for the production and prototyping of implants and other medical devices. These include techniques for microstructuring (femto-second laser cutting system) as well as generative manufacturing (stereolithography or PolyJet 3D printing) of polymer and metallic prototypes.

Based on structural mechanical simulations, we design and manufacture annealing tools that allow for the expansion of laser-cutted stent structures to achieve the desired final outer diameter in multiple steps. Additionally, our inhouse experimental workshop is equipped to produce medical products using conventional manufacturing methods.



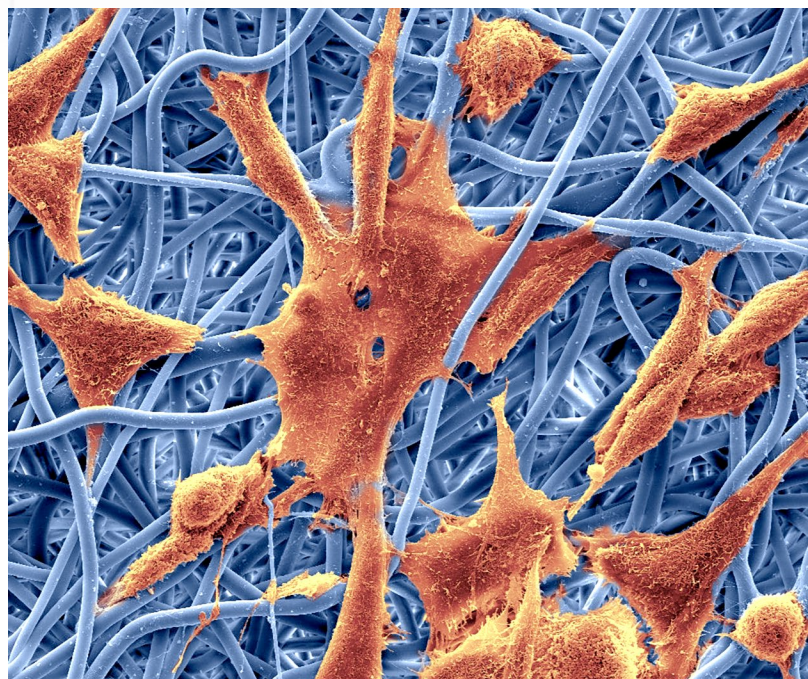
Process steps in the manufacturing of stent structures using femto-second laser cutting – from cutting the raw tube materials to mechanical post-processing and shaping through thermal treatment



Fluorescence microscope for analyzing cellular parameters of biological samples

Biology and Surface Analytics

In addition to implant development and testing, the investigation of mechanical competence and implant-tissue interaction plays a decisive role. The focus here is on the tissue reaction and the degradation behaviour of implants. In order to specifically influence the implant-tissue interaction, possibilities of surface functionalization are being developed. The spectrum ranges from the design of the surface topography to diffusion-controlled local drug release and stimulus responsiveness of the implant coatings.



Mouse fibroblasts on nanofiber nonwoven (stained scanning electron microscope image)

Test setup for multi-axial fatigue testing for characterization of the isolation properties of pace maker leads or peripheral stents, respectively; an internationally recognized in-house development of the IIB e.V.



Development of Test Methods and Test Setups as well as Development-Related Tests of Medical Devices

IIB e.V. guides medical technology based innovations from the idea all the way through to application in patients. It acts as a pioneering research institute at the interface between medical technology, industry and clinic.

Due to permanent increasing demands on modern implants, IIB e.V. in cooperation with partners, continuously develops innovative test methods. These test methods are used during product development as well as approval and guarantee a maximum degree of safety and efficacy.

Furthermore, in collaboration with the state government of Mecklenburg-Vorpommern, a Medical Device Regulation (MDR)-Center is established at IIB e.V. for consultancy of companies. A fundamental part for medical device approval is the independent testing of the newly developed implants.



Accompanying visual inspection to every mechanical testing of pace maker leads

OUR EXPERIENCE FOR YOUR SAFETY –
COMPETENCE, PRECISION, QUALITY

The Accredited Testing Laboratory at IIB e.V.

Modern medicine is inconceivable without innovative medical devices. The quality and safety of the medical devices and consequently the patient's safety are paramount. As a result, accurate testing at the testing laboratory for medical devices is an inherent part of daily functioning of our institute.



Competence, Precision, Quality – our Experience for Your Safety

Since the 1990s our testing laboratory performs independent investigations of medical devices. The focus is physical testing of stents and stent systems. The essential tests are subject to international standards, e.g. ISO 25539-2 or various standards of the American Society for Testing and Materials (ASTM).



Within our testing services we work discretely, independently, impartially and transparently. Due to this, and due to our competence within the field, healthcare experts, patients, authorities and the medical device industry places trust in us.

Dr.-Ing. Wolfram Schmidt
Head of the accredited
testing laboratory at IIB e.V.

Testing can be offered for:

- medical device approval
- comparative testing of commercially available products for scientific understanding of product function (benchmark testing)
- formulation of development goals

Playing Safe Nationwide and Around the World

The testing laboratory already worked for many medical device manufacturers from Germany, other European countries, the USA, South America and Asia.

Simultaneously, the IIB testing laboratory serves as a reliable contact and service provider for regional companies and research institutes.

Standards and Milestones

The accreditation (from the German Accreditation Authority, DAkkS) and recognition as a test laboratory for medical products (Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices, ZLG), in accordance with DIN EN ISO/IEC 17025, represent the basis for high quality and acceptance of our services.

It is a particular achievement, when customers used the test results from our independent testing laboratory to achieve CE approval or approval from non-European notified bodies (USA – FDA, China CFDA, Japan – PMDA etc.).

Test methods, as well as test setups, are permanently adapted or even redeveloped in consideration of current medical or technical evidence, respectively, in order to cope with the rapid pace of new innovative devices.



For a Strong Regional Industry

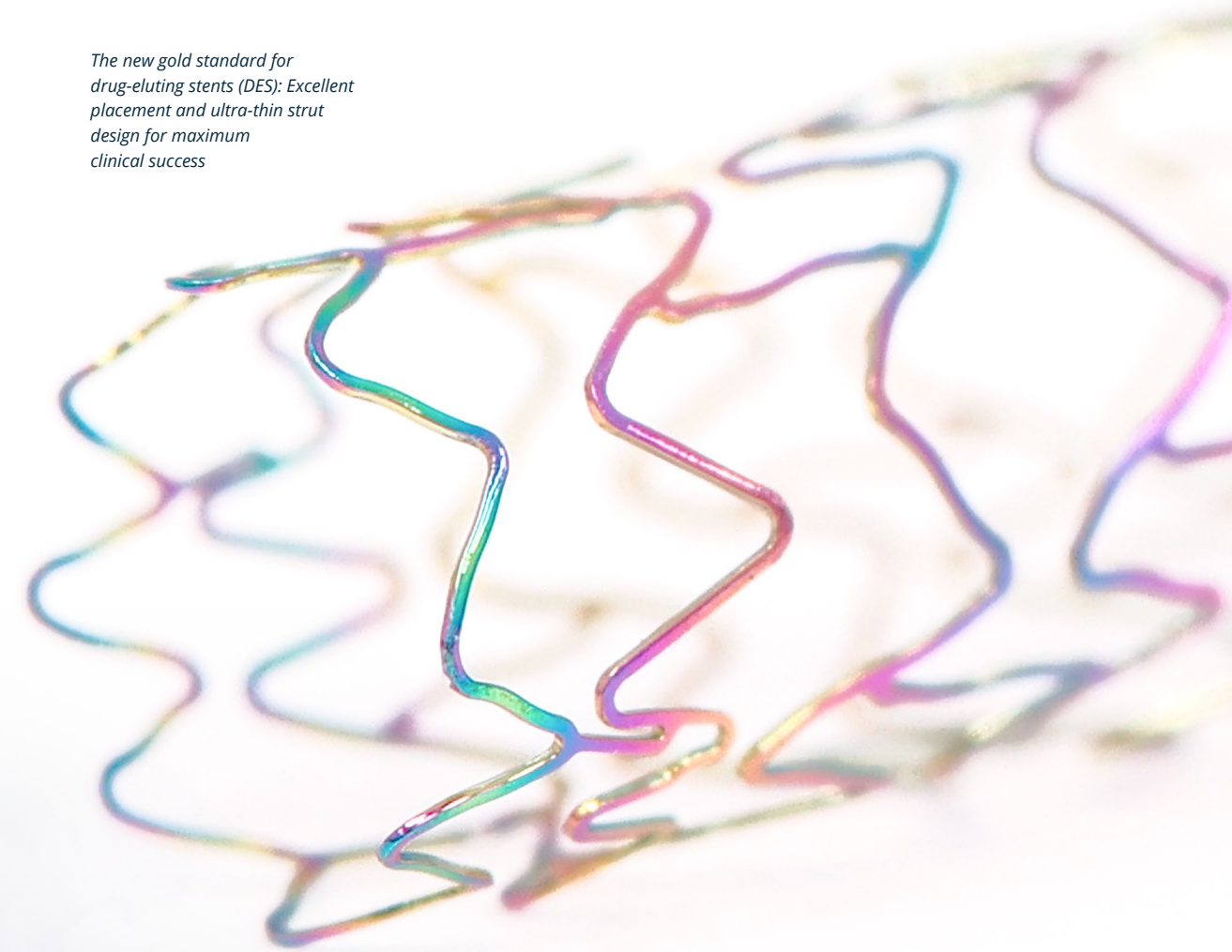
The IIB e.V. supports in particular small and medium-sized medical technology companies in Mecklenburg-Vorpommern. As a partner, we support them in developing their unique selling propositions, becoming technology leaders and expanding their product portfolios. In this way, we strengthen their innovative power and thus their competitiveness. In the course of this, IIB e.V. is building up a regional innovation network in biomedical technology and biomaterials research. The technology transfer between science and industry strengthens the innovative region as a research and development location.



The innovative health industry has a significant role to fulfill for Mecklenburg-Vorpommern. The IIB e.V. helps to shape the process of structural change in the state in a sustainable way. Last but not least, we are able to create future perspectives for the people in our state. This makes us very proud.

Dipl.-Soz. Verw. Andrea Bock
Managing Director of the Institute for
ImplantTechnology and Biomaterials e.V.

The new gold standard for drug-eluting stents (DES): Excellent placement and ultra-thin strut design for maximum clinical success



Drug-Eluting Stent Technology – A Lighthouse Project

One of the World's Leading Stents is Made in Warnemünde

In a network meta-analysis published in JACC Cardiovascular Interventions at the end of 2020, BIOTRONIK's Orsiro Stent was ranked as the best drug-eluting stent in the world.

The Orsiro Stent was developed in close cooperation with the University of Greifswald (Prof. Heyo Kroemer), the University Medical Center Rostock (Prof. Niels Grabow, Dr. Katrin Sternberg) and the IIB e.V. (Prof. Klaus-Peter Schmitz).

Currently, more than 6 million stents have been manufactured by CORTRONIK in Rostock-Warnemünde and sold by BIOTRONIK worldwide.

A real success story for cooperation between science and economy.

Strong Network with Partners in Cutting-Edge Research

Connected with International Partners

IIB e.V. has a strong and structured network of national and international cooperation partners based on past and currently funded, coordinated research projects.

In the scientifically and technically demanding environment of medical technology, the IIB e.V. offers an attractive research infrastructure for regional development. The continuation and strengthening of existing structures as well as the development of new areas of competence with high innovation potential represent the goal for the future development of the IIB e.V. as a recognized and application-oriented research institute.

The foundation is strong strategic cooperation with associated clinics, institutes and facilities from the areas of cutting-edge research at the universities of Mecklenburg-Vorpommern, Hannover Medical School, Charité Berlin as well as at international universities and research facilities.



University of Greifswald



University of Rostock



University Medical Center Rostock

National and International Research Projects

The IIB e.V. is a partner in national and international research projects and is supported within the framework of publicly funded projects of the state and federal government as well as financed by the EU.

In addition, IIB e.V. conducts business-oriented research and development while presenting itself internationally at high-quality scientific conferences and expos.

Funding sources include:

- Ministry of Economics, Infrastructure, Tourism and Labor Mecklenburg-Vorpommern
- Ministry of Science, Culture, Federal and European Affairs
- Federal Ministry of Education and Research
- Federal Ministry of Economy and Climate Protection
- European Union



Graduation of scientific young talents – PhD-seminar with Prof. Dr. Klaus-Peter Schmitz at the IIB e.V.

Attractive Research Hub and Employer at the Baltic Sea

Technology-oriented and well-paid jobs are crucial to the structure and well-being of regional development. As an associated institute of the University of Rostock and the University Medical Center, the IIB e.V. offers high potential for the future of Rostock and Mecklenburg-Vorpommern as a first-class medical technology cluster, and as a research institute at the interface between science, business and clinical practice.

The connection between research and education also plays an important role at the IIB e.V. Our research is incorporated directly into the interdisciplinary Bachelor's/Master's degree program »Biomedical Engineering«, of the Institute for Biomedical Engineering at the University and University Medical Center Rostock. In addition, the IIB e.V. is intensively dedicated to the training and further education of specialists and executives, e.g. in the form of PhD theses or habilitations.

INTERNATIONALLY CONNECTED

From Warnemünde to the World



Paris
attendance at European-
leading cardiology-conference in
Paris »EuroPCR«



San Francisco
TCT-conference



San Diego
The IIB e.V. at the world's largest
symposium for cardiology
»Transcatheter Cardiovascular
Therapeutics - TCT«.



I have a motto: »Medical technology must become clinical practice.« We aim to inspire young people to improve the treatment of diseases with innovative medical technology and improve the quality of life and life expectancy of patients. Our worldwide network offers exciting topics and opens doors around the globe. From Warnemünde to the world – that is part of our daily practice.

Prof. Dr.-Ing. Klaus-Peter Schmitz
Director of the Institute for ImplantTechnology and Biomaterials e.V.

CONTACT

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Gerhard Sekunde (Treasurer)
Prof. Dr. med. Hermann Dittrich, Member
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Curatorium

State secretary Jochen Schulte, Chairman
(Ministry of Economics, Infrastructure, Tourism
and Labor)
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