

## IN PROFILE

The Translational Center in Würzburg develops new cell-based tissue models and test systems, scalable production processes, applications, and biological vascularized implants up to prototype level. The aim is to speed up the implementation and/or combination of results from current materials research, tissue engineering and regenerative medicine in preclinical and clinical applications, in close cooperation with partners from medical technology, biotechnology and pharmaceutical companies. Within this framework, we perform contract-based research for companies as well as for hospitals, diagnostic laboratories and research facilities. Creativity and capability have us head in new directions to design novel high end products.

Due to our application-oriented research we serve customers from numerous industrial companies and are in a position to gain public funding. For the development of innovative enabling technologies, we cooperate with several universities and non-university research facilities worldwide. As a Translational Center for Regenerative Therapies we take pride in offering an exceptionally broad and versatile range of services, starting from risk assessment of compounds, the product development of new cell-based transplants and medical products, continuing with preclinical studies and reaching up to manufacturing authorization.

## HOW TO REACH US

To further foster the effective translation from material development for implants and medical devices into new therapies, the Fraunhofer Translational Center Regenerative Therapies, headed by Prof. Heike Walles, has joined the Fraunhofer Institute for Silicate Research ISC as of August 2017. Fraunhofer ISC traditionally develops medical devices like OR-MOCER®-based dental restoration materials, e. g. the Admira® product line from VOCO GmbH, Cuxhaven, or a silica-based wound dressing, certified under CE Marking of Conformity for Medical Devices, Number 2106976CE01 and EC Notified Body Identification Number 0344.

### HOW TO REACH US

#### By car

Approaching on the A3 Frankfurt-Munich motorway, or A81 from Stuttgart (approx. 10 km/15 min from motorway exit):

- Please exit “Würzburg-Heidingsfeld” and follow signage “Würzburg-Zentrum” on federal highway B19 (5.9 km).
- Take exit “B8/B27/Marktheidenfeld/Fulda/Congress-Centrum” and follow signage “Congress-Centrum” to junction B8 (4 km).
- Follow the right lane and turn right into direction “Congress-Centrum”, continue on B8 500 m, reaching Röntgenring 11 on the right side.

Approaching on the A7 Kassel-Ulm motorway, or the A3 Munich-Frankfurt motorway (approx. 9,5 km/15 min from motorway exit):

- Exit “Würzburg-Estenfeld” to B19 direction “Würzburg” or exit “Rottendorf” to B8 direction “Würzburg”, following signage “Hauptbahnhof” (main station).
- Passing main station you reach Röntgenring 11 after 500 m on the left side.

#### By rail

(Approx. 800 m by foot)

- Arriving at “Würzburg Hauptbahnhof” (main station) exit the station building to the right and follow the park path parallel to the main street Röntgen-Ring.
- After approx. 700 m you reach a crosswalk on the left, cross the Röntgen-Ring, turn right and follow the street to Röntgen-Ring 11.

#### By air

- Nearest international airports are Frankfurt (FRA), Nürnberg (NUE) and Munich (MUC), with frequent connections by train to Würzburg.
- ICE or IC train to “Würzburg Hauptbahnhof”, then accordingly as above.

## CONTACT

#### Fraunhofer Institute for Silicate Research ISC

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#### Translational Center Regenerative Therapies

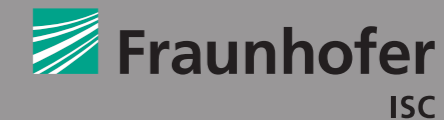
and  
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Röntgenring 11  
97070 Würzburg

#### Head of Translational Center and TERM

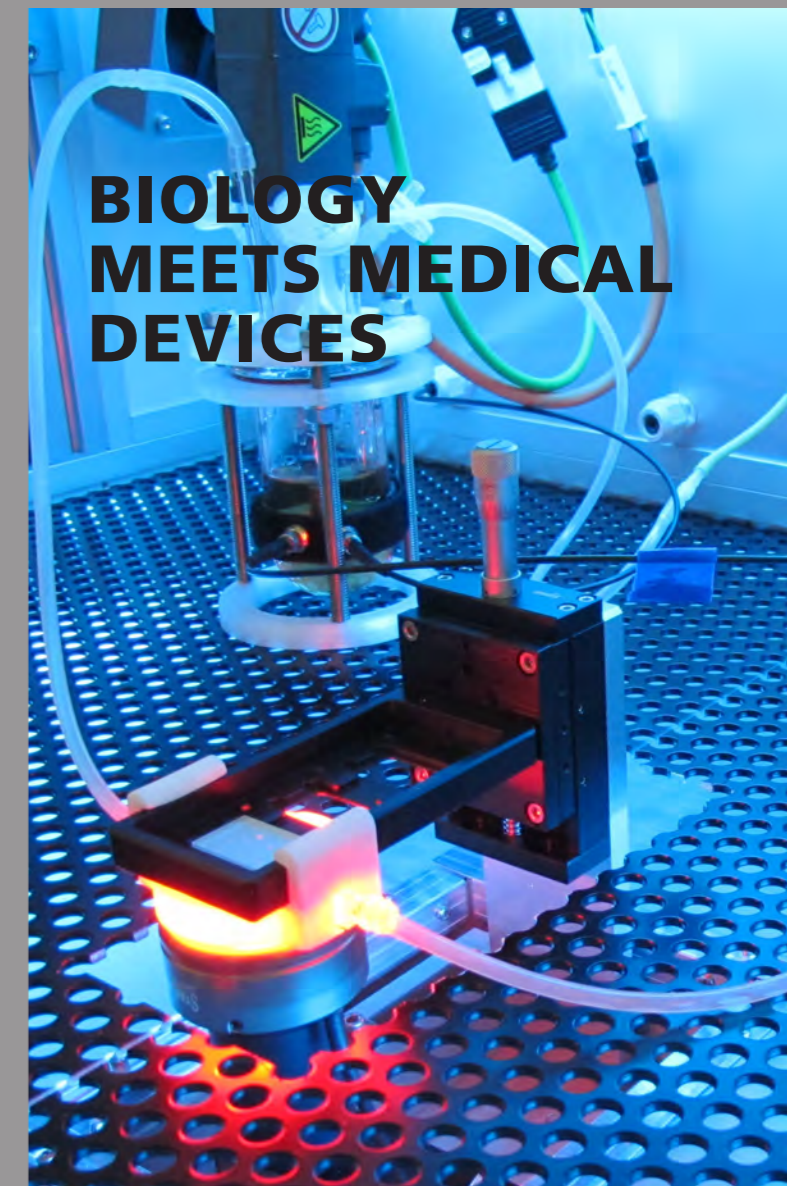
Prof. Dr. Heike Walles

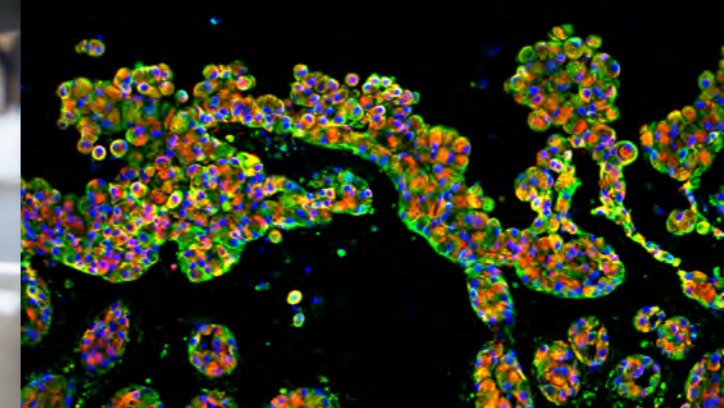
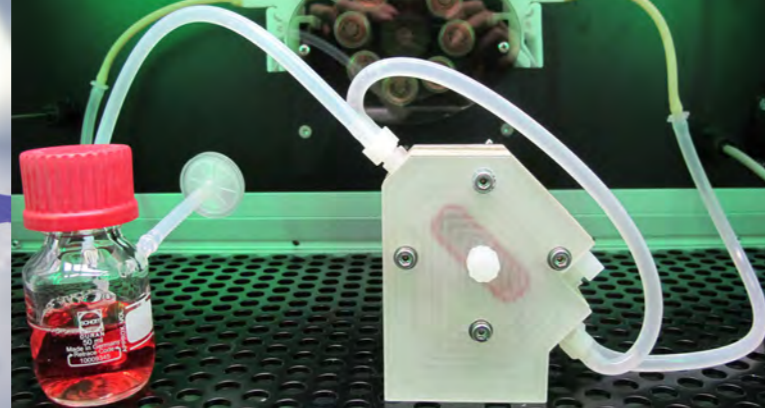
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FRAUNHOFER TRANSLATIONAL CENTER  
REGENERATIVE THERAPIES





## BIOACTIVE MATERIALS

Smart bioactive materials can diagnose, monitor, stimulate and control physiological processes. One of the core tasks of the Fraunhofer ISC's Health unit is to develop these materials and to find suitable ways of processing and integrating them into existing systems together with our customers. Current research and development activities concern biohybrid, biodegradable and other biocompatible materials with biofunctionalization, biologized surfaces or controlled drug release properties. The Fraunhofer ISC provides both the infrastructure for and the experience in processing and manufacturing biofunctional materials on a pilot scale. Customized development of innovative dental restoration and regeneration materials completes the supply.

## MATERIALS AND DEVICES

Our portfolio includes the development of materials and devices for tissue engineering and regenerative therapies and diagnostics. In this, we focus on biological as well as synthetic materials for preclinical and clinical applications including the evaluation of cell-material interactions, incubators and bioreactors for the long-term culture of different cell types and tissues under physiological conditions. Furthermore we develop non-invasive detection methods to control the viability and differentiation state of the human tissues. Our technologies enable highly efficient and personalized therapy accompanied by in-vitro and in-vivo diagnostics or even combine diagnosis and therapy in situ.

## CHARACTERIZATION

Exact analyses and characterizations are key elements in the efficient R&D of materials and their processing. Owing to an excellent equipment and infrastructure, the Fraunhofer ISC is able to offer a broad portfolio of advanced analytical services. High-definition electron microscopy, quantitative and qualitative chemical analysis, physical and mechanical characterization regarding biological needs as well as the specialized particle analysis and characterization contribute to a full investigation of the material properties. Special tasks include the analyses of biological interactions between living cells and material surfaces and/or active drug substances.

## TISSUE MODELS

The Fraunhofer Translational Center develops 3D in-vitro test systems based on human cells that can be used as an alternative to animal experiments, for a reliable and rapid evaluation of new active ingredients as well as for the testing of medical and pharmaceutical products. In addition, several tissue test systems exist as disease models to study human pathogen infections or are developed as tumor models to identify new treatment strategies in oncology.

## REGENERATIVE THERAPIES

Innovative products for therapeutic uses in or on humans are subject to complex regulatory requirements. We advise and support you in the planning and implementation of preclinical and clinical trials for medical devices, drugs, ATMPs (cell-based drugs for novel therapeutic products), combination products (ATMP plus medical device). These can either be initiated by the user (IIT) or commercially. Together with the Center for Clinical Studies (ZKS) in Wuerzburg, we are developing strategies that ensure the implementation of preclinical and clinical testing according to internationally recognized quality standards (GLP, GCP).

## SERVICES

- Materials development and manufacture on a pilot scale for implants, wound care, regenerative medicine, dental restoration and regeneration
- Particle development and manufacture for diagnostics/theranostics
- Biofunctionalization, 2D and 3D structuring
- Additive manufacturing/3D printing

## SERVICES

- Evaluation of material and medical device – cell/tissue interactions
- Custom-based bioreactor and incubator development for 3D tissue engineering
- Support in laboratory and process automation
- Development of therapy supporting diagnostics (Theranostics)

## SERVICES

- Product development accompanying analysis and characterization
- Production monitoring and failure analysis
- In-vitro testing
- Cell-based assays
- Live Cell Imaging
- Material-based consulting

## SERVICES

- Risk assessment and efficacy testing of biological, synthetic or pharmaceutical substances
- Infection studies with bacteria and viruses
- Safety and efficacy studies
- Mode of action of new drugs, e.g. immune therapies
- Validation of new endpoints in risk assessment

## SERVICES

- Cell therapy development and GMP manufacturing for advanced therapeutic medicinal products (ATMPs)
- Implant development and GLP safety assessment of cell-based and medicinal products
- Advice and setup of pre-clinical (GLP) and clinical studies (GCP) of ATMPs and medical devices
- Support in the preparation of an Investigational Medicinal Product Dossier (IMPD)