From ideas to innovative MedTech products

EMPA
Materials Science & Technology

MedTech & Advanced Therapeutics

Empa's Research Focus Areas (RFA)

The RFA «Health and Performance» consists of 5 Research Modules one of which is «MedTech & Advanced Therapeutics»

Prof. Dr. Harald Krug

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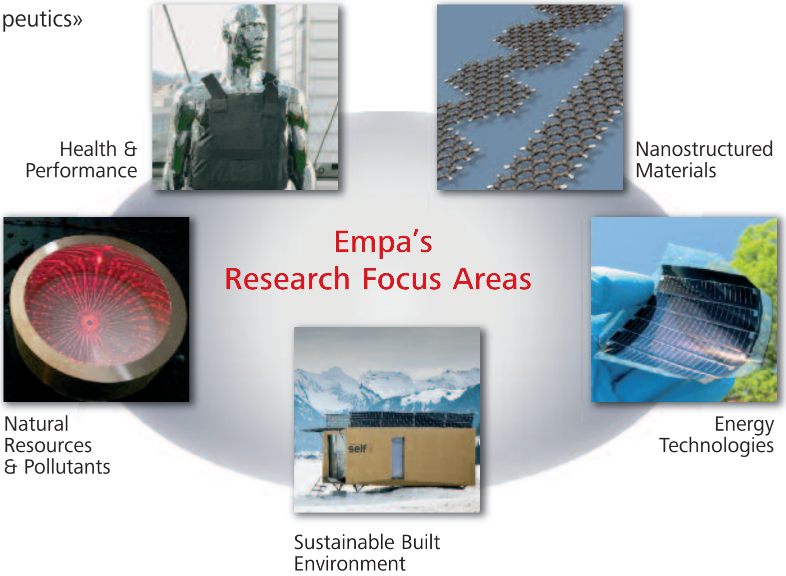
Head RFA



Empa's medtech activities are concentrated in the research module «Medtech & Advanced Therapeutics». The module combines the expertise and superior infrastructure of more than 10 Empa labs in the field of implant production and development, implant and surface design, material characterisation and in vitro biological evaluation. Thus the in-house multidisciplinary competences and approaches enable to tackle a broad variety of medtech challenges.

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Head module

Bernhard Weisse

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Deputy head module

Objectives of the Module

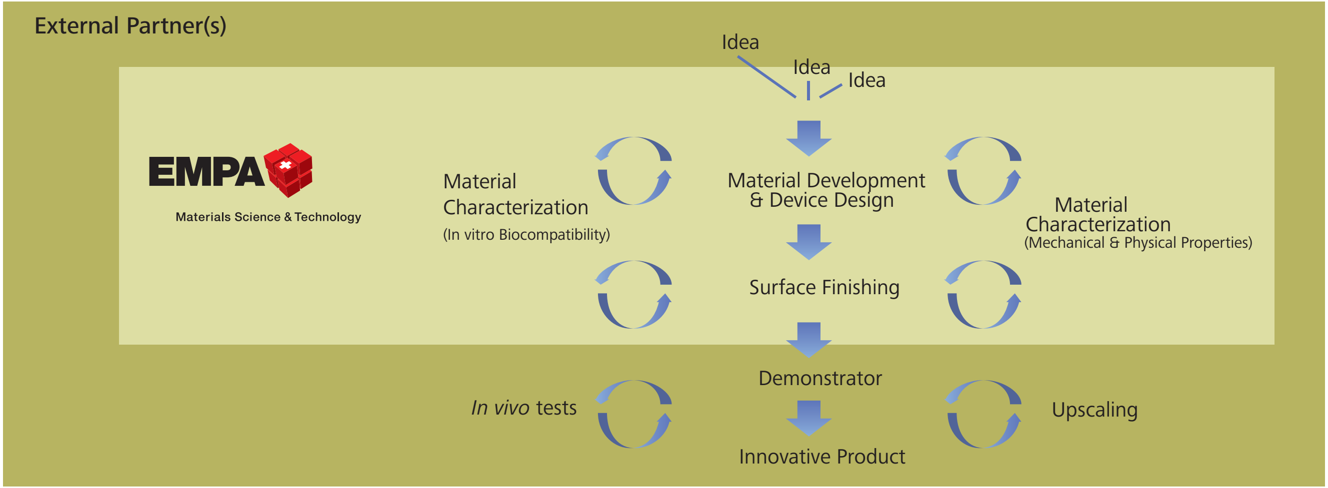
- Supporting and strengthening the Swiss medtech industry by making use of our multidisciplinary expertise to optimise existing and to develop new medtech products
- As a result our knowledge is steadily improving. This will help current and future partners to even better define their next generation medtech products

"Switzerland is among the global hotspots for MedTech."

(Swiss MedTech Report 2010)

→ We want to contribute to assure Switzerland's leading role in the future.

From ideas to innovative products. Interactions and support by Empa



Material Development & Device Design

Material Development

New polymers

Biopolymers

Thermo-responsive polymers

Electroactive polymers

Processing

Various spinning plants

Bi-component melt-spinning

Electro-spinning

Fabric Design

Integration of functional polymers and electronic/optical components

Device Design/ Biomechanics

Compliant systems

Finite element modelling

Rigid body modelling

Joining & Interphase Technology

Brazing, soldering, metal-ceramic joining

Material Development & Device Design. Many Issues, one Partner!

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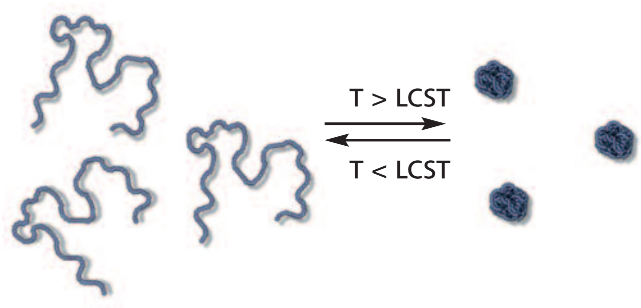
Various steps are needed to turn an idea into a first product prototype at macro scale:

- Definition of the materials of interest
- Processing of the material
- Design of the product

Empa has expertise in all fields along the development chain and supports partners in realizing their ideas.

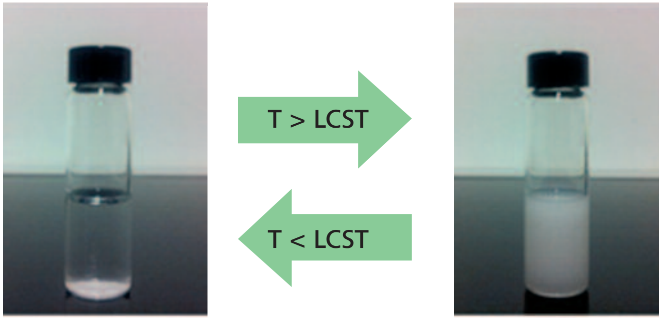
Material Development & Device Design

A nanoscale change (at molecular level)….



LCST: *Low Critical Solution temperature*

Triggers a macroscopic effect



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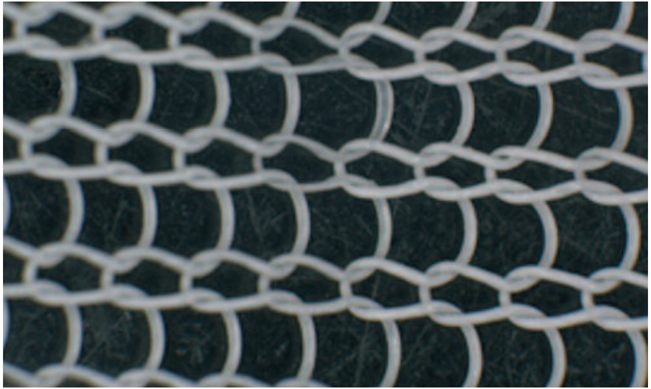
Thermo-responsive Polymers

We synthesize new polymers that can change their conformation in response to different environmental conditions. These smart macromolecules find applications in:

- Drug delivery devices
- Membranes and textiles with enhanced comfort properties
- Surfaces for tissue engineering

Material Development & Device Design



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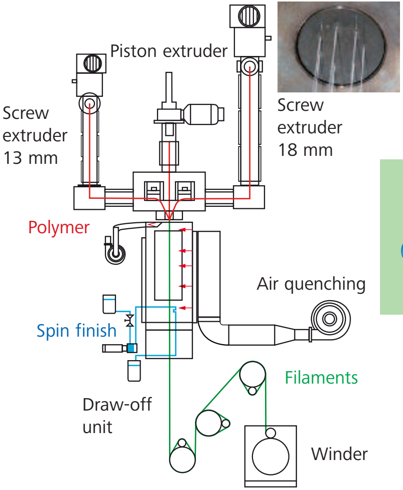
Material Development & Device Design. Biopolymers

We synthesize, functionalize and process conventional and new biodegradable polymers to tailor the properties of the final product. The obtained materials can be applied as:

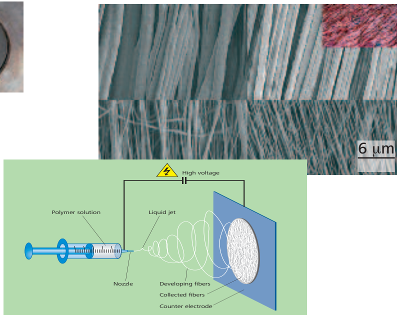
- Scaffolds for drug delivery
- Coatings for protection of biomaterial surfaces and enhanced drug release
- Fibre-based structures for sutures and meshes
- Microparticles and films for in vitro and in vivo tissue engineering

Material Development & Device Design

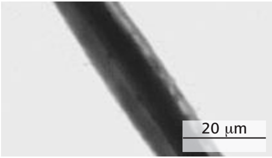
Pilot bicomponent melt-spinning plant



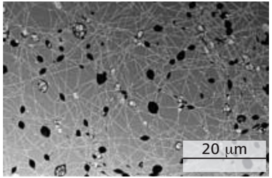
Electrostatic spinning



Bicomponent nanofibers with drug-loaded core



Beaded nanofibers with liquid core



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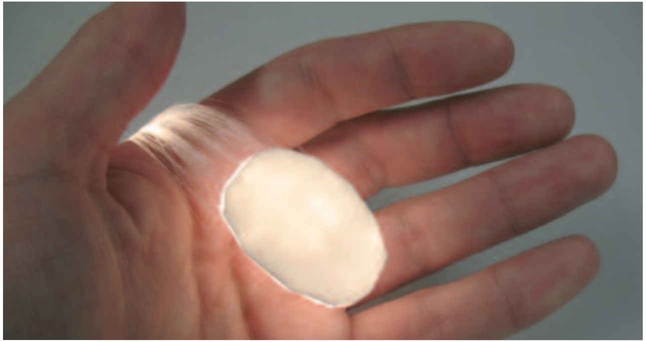
Material Development & Device Design. Processing e.g. Electrospinning

We aim at developing functionalized medical textiles for use as wound dressings, as substrates for tissue engineering or as sensors. Therefore, we apply selected processing procedures such as electrostatic or melt spinning to fulfil the requirements of the devices regarding surface, mechanical and morphological properties.

- Electrostatic spinning
- Melt spinning
- Characterization of the fibre and fabrics

Material Development & Device Design

ECG breast-belt



Textile-based light diffuser

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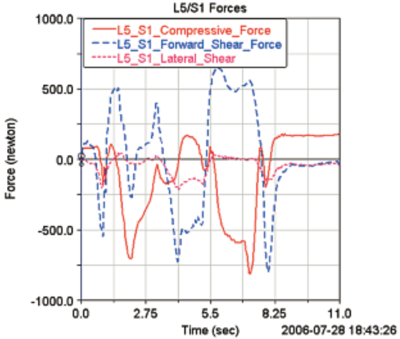
Material Development & Device Design. Fabric Design

We develop textile-based sensors using either light conductive fibres or electrically conductive fibres. Flexible polymer optical fibres are developed using the in-house pilot melt spinning plant. These are among others used for:

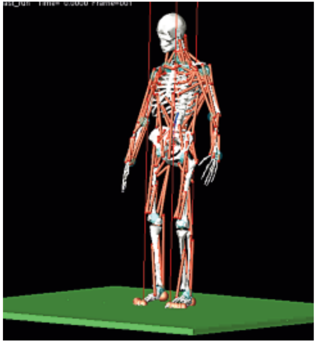
- Production of luminous textiles for the photodynamic therapy or as sensing device for the measurement of arterial oxygen saturation of haemoglobin
- Elastic polymer optical fibres for strain or pressure sensors

By combining the electrodes with an additional water dispensing pad, ECG monitoring can be performed with nonsweating subjects (e.g. elderly people).

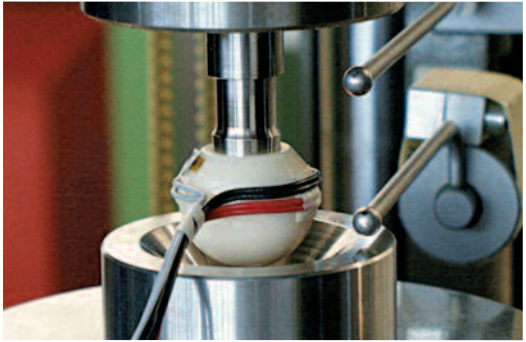
Material Development & Device Design



Reaction forces in spinal disc L5 - S1



Musculoskeletal system model



Mechanical Testing of medical devices (e.g. hip joint ball head)

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Material Development & Device Design. Biomechanics

Two aspects of biomechanics are addressed at the Empa.

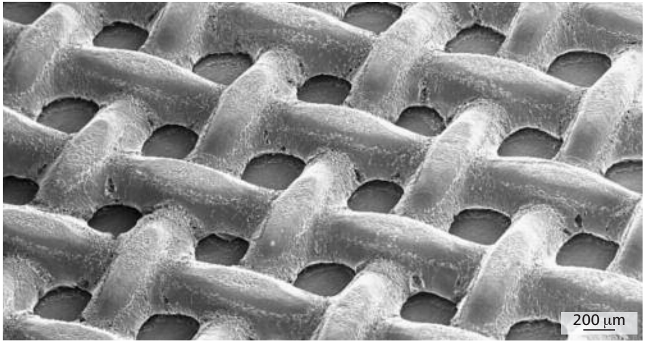
Numerical simulation:

- Simulation of the human musculoskeletal system (using a multi-rigid body model)
- Finite Element Analysis of medical devices (trauma/dental implants, instruments, joint replacements, bones and soft tissues)

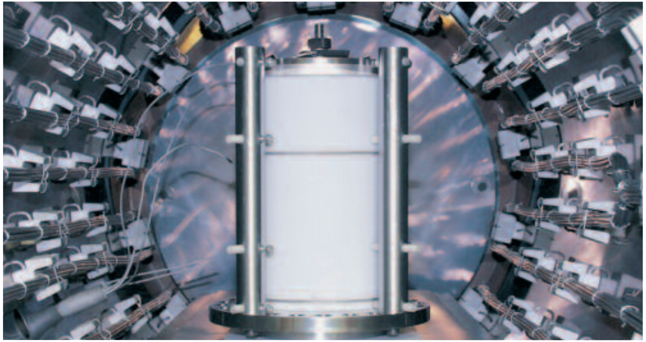
Mechanical testing:

- Static and Fatigue tests incl. deformation and strain measurements: Implants may be tested in physiological solution at 37°C in order to simulate in vivo conditions. The laboratory is accredited in accordance with DIN EN ISO/IEC 17025: Mechanical testing of metallic materials, structural components and constructions (STS053).

Material Development & Device Design



Ti mesh on Ti substrate, diffusion bonding



Brazed Ti-Al_2O_3 component in high-vacuum furnace

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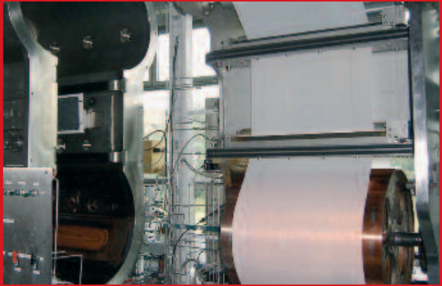
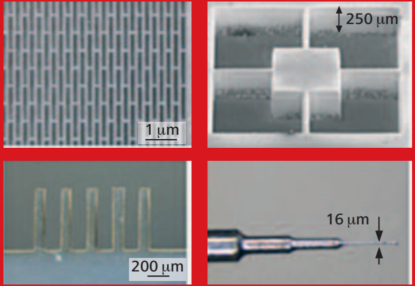
Material Development & Device Design. Advanced Joining Technologies

Biomedical applications typically rely on the controlled fabrication of joined components (constituted of e.g. Ti and Al_2O_3 ceramics). Important requirements for the applied materials in the assembly are a high biocompatibility and a high corrosion resistance. We offer services in advanced joining technologies (i.e. soldering, brazing, solid state and transient liquid state diffusion bonding), including:

- Computer-assisted joint design (using the Calphad method)
- The development and optimization of novel joining processes
- Experimental and theoretical studies of the integrity and durability of joined assemblies under extreme loading conditions (e.g. high temperatures, corrosive environments).

Surface Finishing





Surface Coating Techniques

- Functional polymer film with Ag nanoparticles
- DLC coating
- Metal coating

Surface Erosion Techniques

- Laser treatment

Surface Finishing – Different surfaces, one Partner

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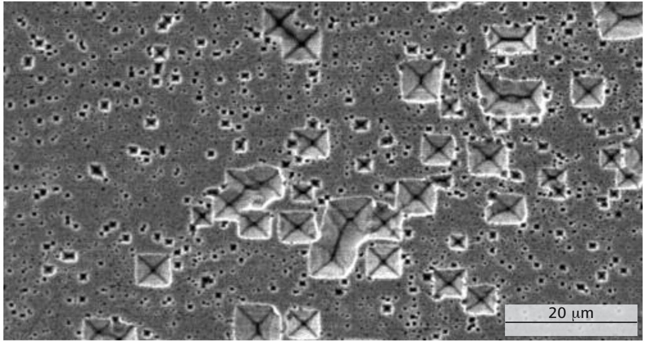
After setting of the macroscale structure of the first product prototype as a next step its surface should be defined. This can be done by:

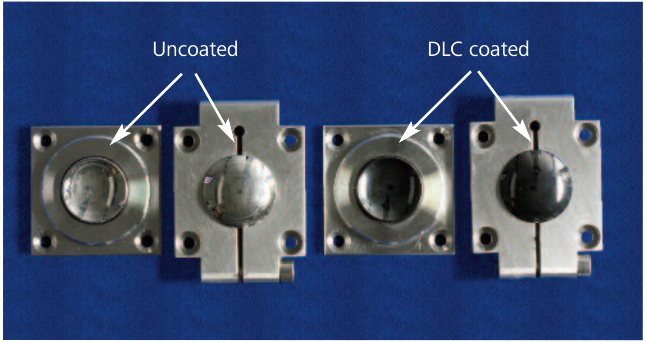
- Addition of materials giving it its structural and chemical characteristics (coating)
- Removal of surface until the envisioned surface structure is obtained (abrasion, erosion)

Empa has a broad expertise in both kind of techniques and the required high standard equipment

Surface Finishing



In vitro corrosion investigation
- Crevice corrosion of interlayer material



Simulator Testing
- DLC coating is not generating wear particles

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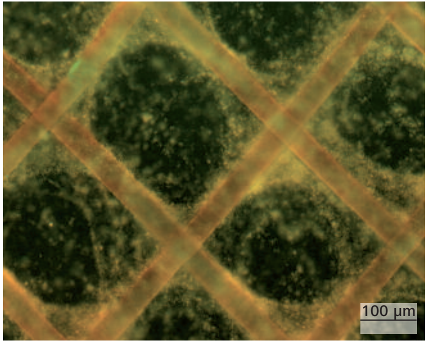
Surface Finishing. DLC Coating

Extra-hard coatings made of diamond-like carbon (DLC) extend the operating lifetime of tools and components. What could be more logical than to apply DLC to medical implants such as artificial joints. Advantages are:

- No Implant degeneration due to wear
- Prevents wear particle generation in joints
- Prevents allergic reactions triggered by metal or polyethylene wear
- Interface reaction monitoring ensures long term film adhesion
- Special in-vitro test predicts coating adhesion lifetime
- Prediction of nano-corrosion processes in vivo

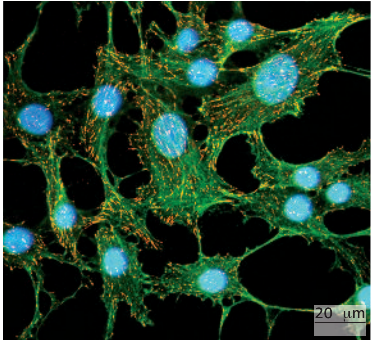
We have the expertise in DLC coating. Our DLC control corrosion at interfaces in the nano-meter range.

Surface Finishing



Antimicrobial plasma coating

…yet cell growth
supporting



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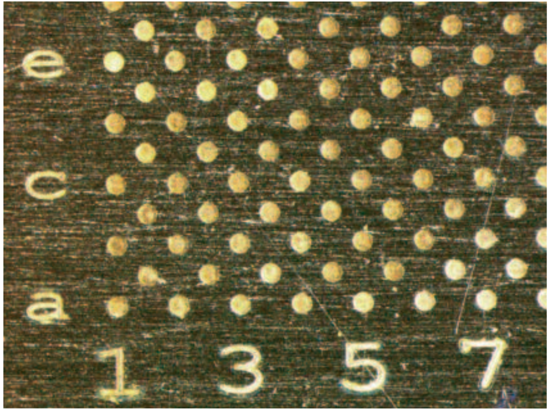
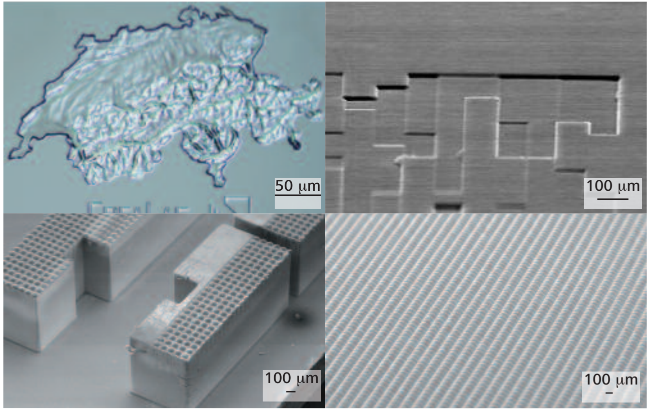
Surface Finishing. Plasma Coating

Empa's Plasma & Coating group develops plasma-based processes to functionalize surfaces. Cold plasma enables the treatment of sensitive, flexible substrates such as membranes, fabrics, fibres, (electrospun) nonwovens, foils etc. in a broad field of application such as:

- Biocompatible coatings
- Non-fouling surfaces
- Controlled drug release
- Conductive fibres
- Sensors

Surface Finishing





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Surface Finishing – Many parameters, one Partner

Laser ablation processing of materials is accept laser a tool-free micromachining process. Any material can be machined with the adequate choice of the laser and the laser parameters. Direct laser processing at Empa can be carried out by lasers with picoseconds to microsecond pulses for following applications:

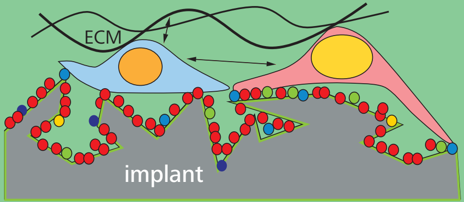
- cutting
- grinding
- polishing
- scribing

The choice of the laser does very much depend on specific requirements. In Empa's Excimer Laser center large flat surfaces (1.9 x 1.4 m^2) can be microstructured with the single shot of the laser. In Empa Dübendorf "cold" micromachining of various materials can be performed by laser with picosecond pulses. The materials can be structured with the lateral resolution in the micrometer scale and the depth resolution of several tens of nanometers.

Material Characterization

In vitro biocompatibility

- In vivo niche mimicking in vitro tests using human cells



Mechanical Characteristics

- Impact tests
- Creep & relaxation tests
- Static & dynamic tests according to ASTM, ISO. New developments
- Wear, fatigue, creep, tribology tests

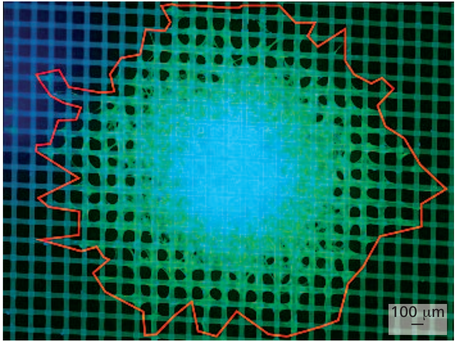
Corrosion Characteristics

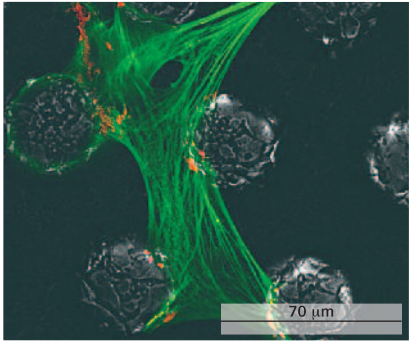
- Surface reactivity

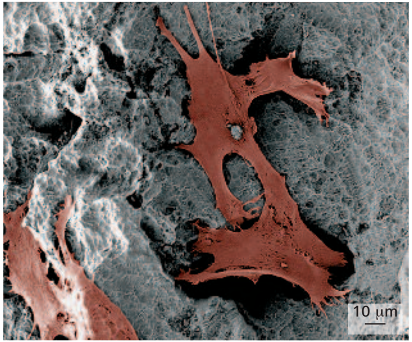
Material Properties/Imaging

- Focused ion beam (FIB)
- X-ray photoelectron spectroscopy
- X-ray microtomography
- Ultrasonic diagnostics
- Electronic speckle pattern interferometry

The optimization of prototypes at the various scale length is not possible without parallel evaluation of the characteristics of each prototype aspect regarding its *in vitro* biocompatibility (*in vitro* cytotoxicity and bioactivity), mechanical and material properties including imaging and corrosion aspect. In all of these aspects research is performed at the Empa to optimally support their partners.







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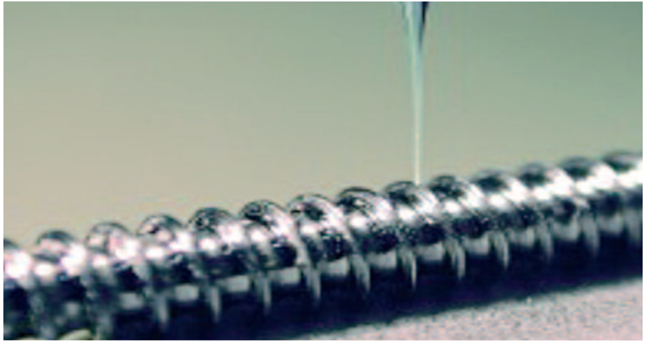
Material Characterization. *In vitro* Biocompatibility

Biocompatibility is defined as the ability of a biomaterial to induce appropriate response with respect to its function and, as a result, is not a general characteristic but defined by the locations and envisioned function of the device material. Empa investigates cellular responses to (nano)materials using cell cultures. The following is evaluated:

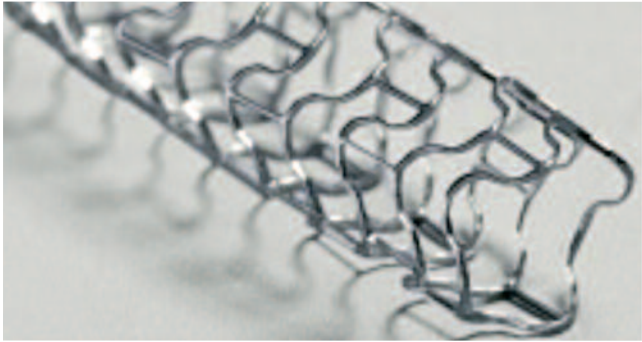
- Assessment of cytotoxicity according ISO10993-5
- Assessment of bioacceptance (i.e. support of cell ongrowth and colonization) and bioactivity (steering cell functionality) using cell types which in vivo will be in contact with the (nano)materials

We focus our research in developing in vitro systems which mimic the biological environment (niche) at the implant surfaces in order to greatly improve the prognostic value of these in vitro investigations regarding which type of tissue will be formed at the material tissue interface.

Material Characterization



Microcapillary based electrochemical characterization



Biodegradable Mg-Alloy stent

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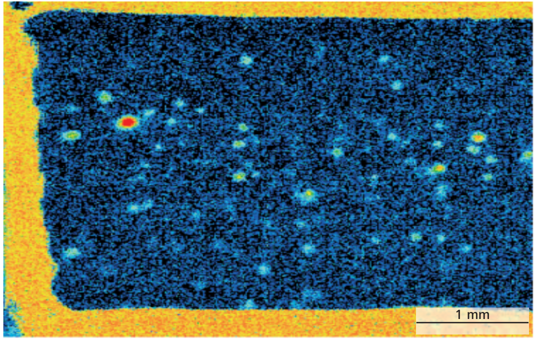
Material Characterization. Corrosion

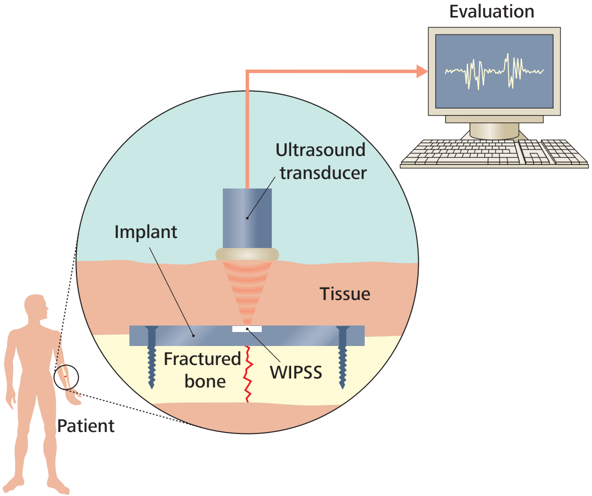
Metal implants are subject to electrochemical reactions at their interfaces with the surrounding body fluid and tissue. This can lead to localized corrosion attacks and the accompanied release of “toxic” ionic species.
We offer high-end services in the bio-functionalization of metal and alloy surfaces, including:

- In-vitro investigations of localized corrosion processes and biocompatibilities of metallic implants in electrolytic solutions (with or without proteins) by advanced surface-analytic techniques
- Design and construction of experimental setups to investigate crevice and galvanic corrosion processes of complex implant geometries and joint assemblies
- Tailoring of the stability and degradability (i.e. time-dependent dissolution) of metallic implants
- Surface functionalization of reactive metal and alloy surfaces by microstructural design of the surficial oxide film

Material Characterization



Ultrasound image of pores in ceramic material



Wireless implantable passive strain sensor and its ultrasound-based data read out-unit

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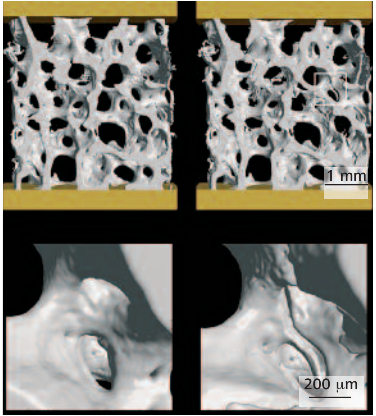
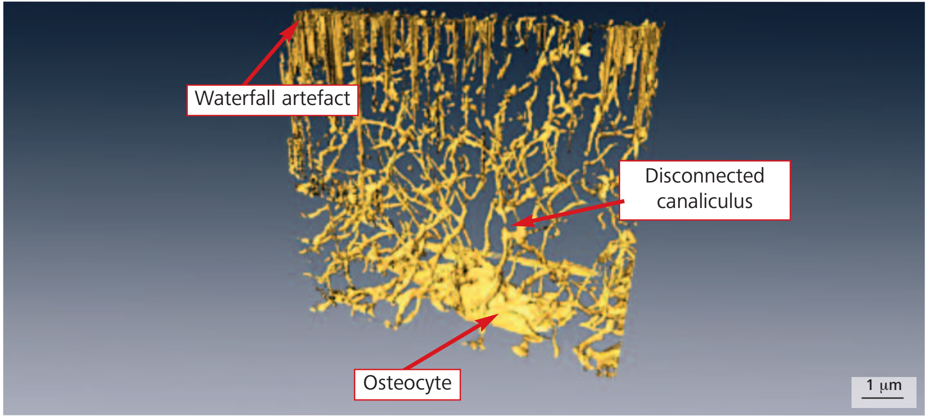
Material Characterization. Ultrasonic Diagnostics

Ultrasonics is a non-destructive method to detect and image flaws in materials and devices. Delaminations, cracks, pores and other irregularities may be found in base material as well as in glued, welded and brazed joints. Furthermore, material characteristics such as elastic moduli can be measured. Ultrasound waves may also be used for non-invasive data read-out for implantable passive strain sensors attached on orthopedic implants.

Material Characterization

before failure after failure





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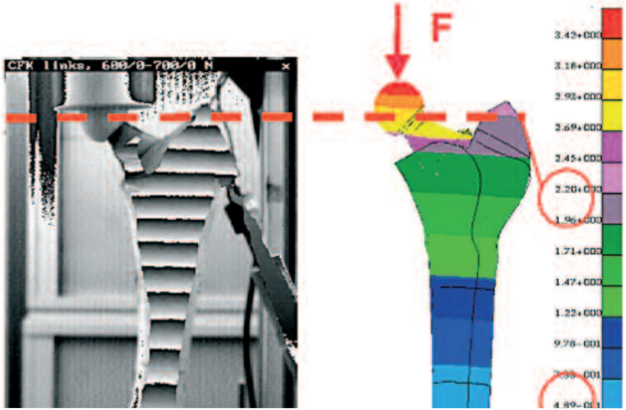
Material Characterization. X-ray and Focused Ion Beam Microtomography

Micro tomography enables 3D imaging of biological and technical micro structures:

- X-ray Computed Tomography (CT) offers non-destructive 3D imaging at different scales (static or under mechanical load) using micro focus X-ray sources or synchrotron radiation
- Focused Ion Beam (FIB) tomography allows 3D analysis and visualization of bone structures with a spatial resolution down to 20 nm (destructive)

Empa has developed an in situ mechanical loading device for the non-destructive investigation of fatigue, elastic and plastic behavior, micro crack formation and fracture mechanisms of biological and technical micro structures with a resolution of 1 µm in all dimensions by using synchrotron radiation tomographic microscopy at PSI's Swiss Light Source (SLS).

Material Characterization



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Material Characterization. Electronic Speckle Pattern Interferometry

Hip prostheses are designed to transfer load from the pelvis to the leg. Finite Element (FE) model calculations help to predict the deformation of the bone for different mechanical designs. The results from FE simulations must be validated experimentally during the optimisation of the implant design. We characterised the mechanical behaviour of a bone-endoprosthesis-compound by Digital Speckle Pattern Interferometry. This is an imaging laser technique to measure minute surface deformations with a resolution of a few tens of nanometres. By illuminating the object from several directions deformations and strains can be calculated.

Empa. Bridging Research and Applications: Recent Empa Spin-off's compliant concept AG; inventing smart bed systems

Materials Science & Technology

Pressure ulcers are one of the most serious problems in day-to-day care. They are the most frequent cause of death for bedridden paraplegic persons. There is one solution to this problem; prevention. However, prevention is extremely costly in terms of nursing effort. The Empa/ETH spin-off company “compliant concept” (www.compliant-concept.ch) has developed a unique care solution that includes a revolutionary risk detection tool and unassisted prevention, enabling an advanced pressure ulcer prevention at lower costs than today's practice. “compliant concept” was granted several awards, among them, the Swiss CTI MedTech Award 2010.

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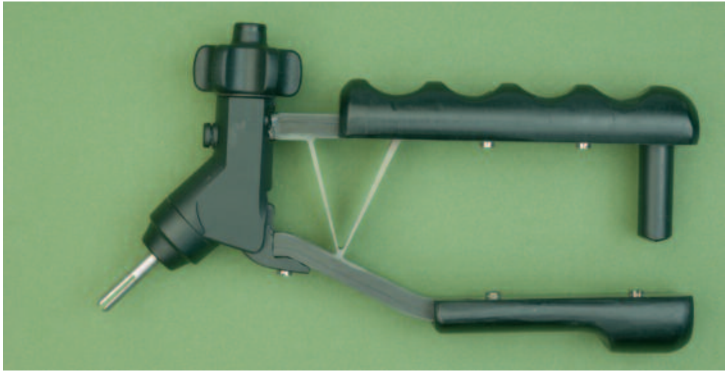
MONOLITIX AG: an example of Empa MedTech activities transferred to the market

Monolitix AG (www.monolitix.com) is an Empa spin-off company focusing on Compliant Systems, an innovative class of mechanisms and devices in which relative motion between rigid, loaded parts is originated in the material instead of being produced outside the material like in conventional, pin-jointed mechanisms. This leads to higher precision, reduced manufacturing costs, high cyclic reproducibility, clean and silent operation, absence of particle release and more effective sterilisation. The applications under development range from subcomponents for laparoscopic instruments and surgery tools to implants for orthopaedic prostheses.



Prototype of a compliant handle for a laparoscopic tool.

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Working with Empa

Thanks to its years of experience in the field, Empa is able to offer its industrial partners solutions tailored to meet their specific needs.

Research Collaborations

Our aim is to help make marketable products from innovative ideas. Research agreements clearly define the tasks allotted to each individual partner and regulate the ownership, exploitation and publication rights to the research results (inventions, know-how etc.). The collaborations come in the form of:

Funded Research – partial cost recovery through Swiss Commission for Technology and Innovation (CTI), EU or other national or international funding organizations;

Joint Research – Empa investment and partial cost coverage through partner in a project of mutual interest;

Contract Research – full cost coverage through business partner

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Technology Exploitation

Through individual agreements partners can obtain the right to commercially exploit research results. Licensing has become the most important form of assignment of a limited rightof-use of intellectual property in modern business life. If Empa has no interest in further research or exploitation in an item of intellectual property then it may, in individual cases, cede the rights to it to a partner.

Consulting and Services

Empa offers professional consultation in all our scientific and technical expert areas, as well as the capability to carry out a range of highest level, challenging investigative studies and measurement tasks.

Hightech User Labs

World-class research requires cutting-edge infrastructure. Empa possesses state-of-the-art facilities and devices to use in projects or services for its partners.

Empa in Brief

EMPA

Materials Science & Technology

Vision. Materials and Technology for a sustainable future

Mission. Bridging research and applications Profile. Interdisciplinary research, development and service institution located in 3 sites (Dübendorf, St. Gallen, Thun) with 28 laboratories organized in 5 departments in the area of materials science and technology, offering use-inspired research, innovative developments, knowledge and technology transfer to industry and society as well as services and consultancy.

Figures. Overall budget 2010: CHF 149 mio, of which CHF 52 mio by third party means. Number of employees 2011: 950 Externally funded R&D projects: >50 EU-funded projects; >90 SNF-funded projects; 80 CTI-funded project

Scientific output. >500 peer-reviewed (SCI/E) publications

As a multidisciplinary R&D institute Empa is a perfect partner to support industry in developing innovative Medtech products.

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