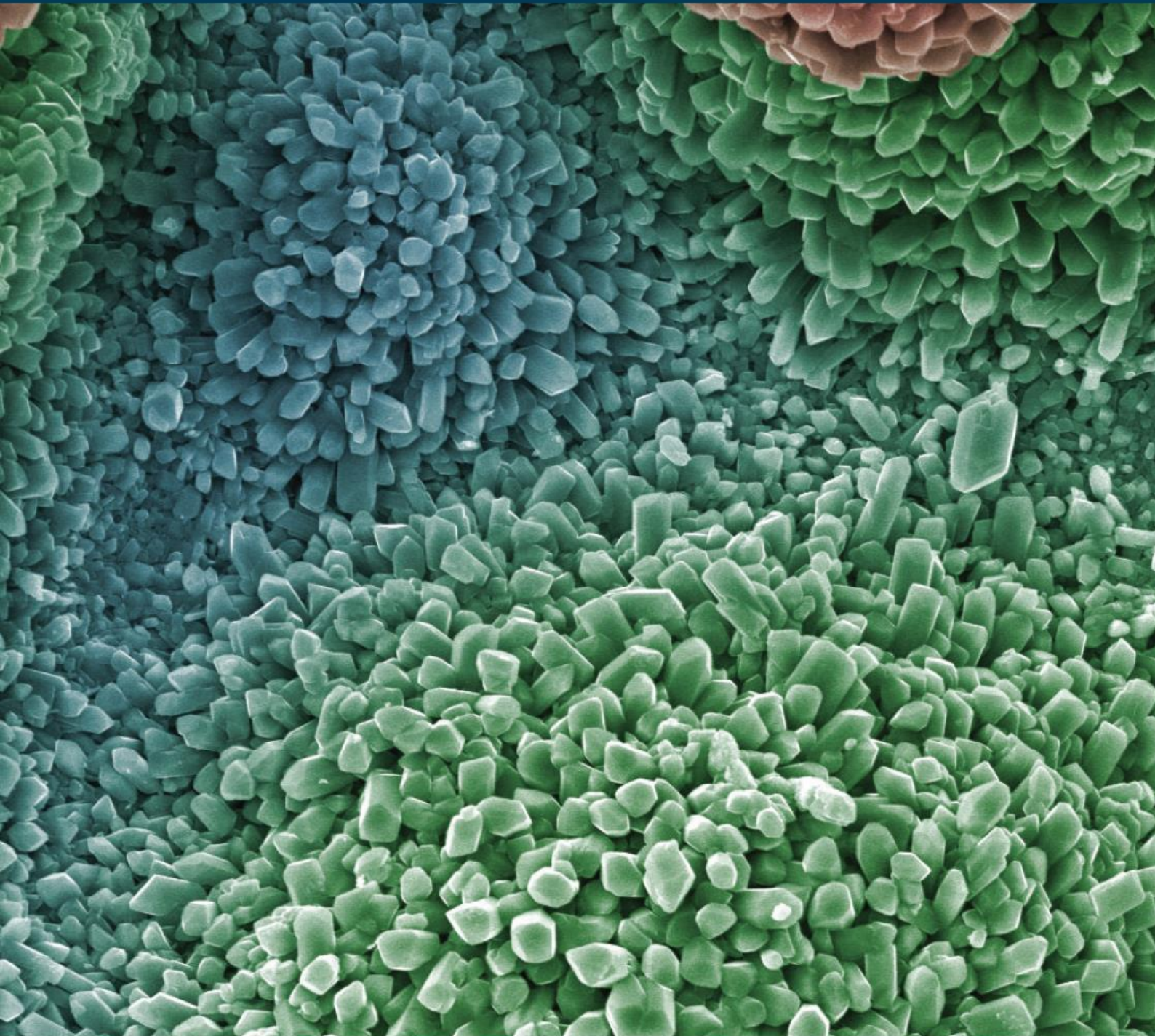


Service catalogue



SERVICE CATALOGUE OF THE RMS FOUNDATION

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GENERAL INFORMATION

The general business conditions (GBC) are the basis of our offers for testing and consulting services to all customers. The former are available under <http://www.rms-foundation.ch/GBC>.

All testing services are provided where possible according to a **standard** or according to internal measurement procedures. Modified tests and specific tests are also possible on request. Since 1995, an accreditation of our services in accordance with **ISO / IEC 17025** by the Swiss Accreditation Service (SAS) exists. Since August 2013 the accreditation includes the **type C accreditation**. This accreditation is based on defined technologies and measurement principles and enables us to include new procedures in the scope of the accreditation without prior assessment as long as technologies and measurement principles already established in the laboratory are used.

We bill the services on a time and material basis per hour or as unit price, partly sorted according to the number of units. Many tests require a preparation of the specimens. This will always be invoiced on a time and material basis, as it can strongly vary depending on the material and shape. This applies as well to the establishment of reports or to test certificates.

In the individual case, we recommend that you demand an **offer**. You will have to provide the specifics regarding the desired tests, the number, the type of specimens, and the desired reports / certificates (language). We will be happy to make you an offer for your specific requirements. In case of discrepancies, we will support you as well in the formulation of the basics for a test plan. Basically, we distinguish three types of offers depending on the complexity of the assignment:

Fixed price offer: We gladly quote you a fixed price for common and clearly defined test assignments. We invoice the described performances precisely according to the offered price (plus the legal VAT). Should the customer require other or additional non-offered performances when placing the order or in course of rendering the service, we shall invoice the additional costs separately.

Target price offer: We offer you a target price for more complex assignments based on an estimate of the expenditure for the described performances. We effectively record the performances during the order processing. Should the expenditure remain below the offered target price, we will only invoice the effective costs. An exceeding of the offered amount by up to 15% is possible without any advance information. We will invoice additional services separately.

Offer with cap on costs: In novel Investigations, we will indicate a cap on costs for the described performances or those defined in the progress meeting. This is advisable as more complex and new task assignments include a risk for the unforeseen. We record and invoice the services during order processing. We will inform you as customer of any possible exceeding of the cap on costs and discuss the further proceeding.

If desired, we will provide you with monthly interim bills in case of longer-lasting, extensive assignments. This will give you a precise cost control. In short assignments, we only issue one final invoice after completion of the assignment.

More extensive **preliminary clarifications** are recorded and charged according to agreement with the customer. If the order is placed later, preliminary clarifications / consultations are free of charge up to an amount depending on the scope of the order.

The relevant employees of the RMS will be happy to provide you with further information. The responsibilities and contact data are available on our Website www.rms-foundation.ch.

PHYSICAL AND CHEMICAL ANALYSES

X-ray photoelectron spectroscopy (XPS)

XPS is a very surface-sensitive technique (top 5 – 10 nm) to determine the chemical composition of solids quantitatively. It is used for the non-destructive detection of all elements (with the exception of hydrogen and helium) and for the determination of the oxidation states of an element. Applications: Analysis of cleanliness / soiling, residues, discolorations, surface modifications, coatings etc.

Device: Kratos Axis NOVA

Determination of C, S, H, N, O and Ar content in metallic materials

This analysis is based on the carrier gas hot extraction (CGHE) principle, which involves melting of the sample material in a graphite crucible at high temperatures. The principle is also commonly termed a melt extraction (ME). It is used to determine the carbon, sulphur, hydrogen, nitrogen, oxygen and argon content of metallic or non-metallic materials.

Device: LECO CS 230 carbon and sulphur determination device / Bruker G8 Galileo and mass spectrometer ESD 100

X-ray fluorescence analyses (XRF) of metallic and non-metallic materials

The qualitative and quantitative energy dispersive and wavelength dispersive X-ray fluorescence analyses (XRF) serve to determine the composition of metallic and non-metallic materials (all elements from sodium to uranium).

Device: X-ray fluorescence spectrometer BRUKER S8 Tiger (WD-XRF)
Handheld X-ray fluorescence spectrometer BRUKER S1 Titan LE (ED-XRF)

Optical spark emission spectrometry (OES) on metallic materials

Quantitative optical spark emission spectrometry (OES) on metallic materials to determine the chemical composition.

Device: Optical spark emission spectrometer (OES) BRUKER Q4 Tasman

Energy dispersive microanalyses (EDX)

In the qualitative and quantitative analysis of the surface of solid or powdery materials, the energy dispersive spectroscopy by X-rays (EDX) on the electron microscope is used to identify the elements from boron to uranium contained in the sample surface. The quantitative analyses allow determining the content of selected elements.

Device: Zeiss Sigma 300 VP with Oxford x-Max 50 detector

Inorganic analysis using inductively coupled plasma - mass spectrometry (ICP-MS)

ICP-MS is a very sensitive technique applicable to a large variety of inorganic analytical tasks. A total of 70 elements can be simultaneously quantified down to trace levels in the ppb (part per billion; ng/mL) or sub-ppb range. For solid samples or organic matrices, chemical digestion methods are applied prior to analysis.

Device: Agilent 7700x ICP-MS

Infrared spectroscopy (FTIR)

Infrared spectroscopy (Fourier transform infrared spectroscopy FTIR) for the identification of organic compounds, polymers, adhesives, greases, oils, etc. A fully automated FTIR microscope with motorized ATR crystal (ATR = attenuated total reflection) is available for measurements on microscopic samples (solids, powders, liquids) in the measurement modes transmission, reflection and ATR.

Device: FTIR microscope Bruker Lumos

Assessment of the degree of crosslinking in cross-linked polyethylene (PE-X) pipes and fittings

Assessment of the degree of crosslinking in cross-linked polyethylene (PE-X) pipes and fittings by determination of the gel content by solvent extraction.

The mass of the sample is determined before and after immersion into the solvent for a defined period of time. The degree of crosslinking is expressed as the mass percentage of insoluble material.

Devices: Analytical balance Mettler Toledo XS205DU / Rotary microtome Leica RM 2165 / Reflux cooler with round-bottomed flask and heating mantle

Calorimetric analyses (DSC)

This differential scanning calorimetry (DSC) is used to measure a specimen's enthalpy variations when heated, cooled or at a constant temperature. This method enables not only to measure the temperatures at which the variations in enthalpy occur, but also the heat of reaction in a quantitative way. The measurements can be realised in different gas atmospheres using various heating or cooling rates.

Device: Mettler STAR system DSC1

Microcalorimetric measurements of solutions and solid materials (non-accredited service)

The measurement of the heat emitted by a chemical and/or physical reaction permits to pinpoint the heat-flow data in the milliwatt range and on isothermal conditions continuously as a function of time. During the measurement, the specially constructed «Admix» injection ampoule enables to mix and inject the liquids on isothermal conditions in order to investigate, for instance, the first phases of a cement reaction.

Device: TAM Air 3115/3238 calorimeter (isothermal) with Admix injection ampoule

Residual moisture content

The residual moisture content is calculated from the weight loss after intense drying according to Ph. Eur. Monography 2.2.32. «Loss on drying» 01/2008:20232.

Devices: Drying furnace Memmert type ULP 500 and UFP 500 / Precision scale Mettler Toledo AX205

Setting time and setting reaction temperature

This test setup determines the setting time and the maximum reaction temperature of exothermic cement reactions according to ASTM F451-99a (reapproved 2007).

Devices: Centre 309 data logger with thermocontrol TKI20/50FIM.K thermo couples

Cohesion of pastes and cements

In a specifically developed test setup we analyse the cohesion of pastes and cements in an aqueous environment. The result reveals how fast a paste dissolves or disintegrates in water. The setup can analyse paste volumes from 0.5 to 10 ml at room temperature.

Equipment: Precision scale Mettler-Toledo PR5002

Corrosion measurements (electrochemical methods)

These measurements are used to determine the local corrosion properties of real surfaces of metallic materials using the EC-pen. Pen tip: A = 1.5 mm².

Devices: EC-pen with Jaisle potentiostat / PGU Touch potentiostat

Titrimetric analyses

This analysis permits to calculate an unknown quantity of a dissolved substance after its reaction to an appropriate reagent solution, to measure the exact volume of reagent used, and to take into account the content of the effective substance. The addition of a reagent with a known chemical efficiency (titre) permits to quantitatively convert the substance to be determined from an exactly defined chemical initial state into an equally defined final state.

Device: Metrohm Titrand 907

Determination of the pH value

Serves to determine the acid and/or the base value (pH value between 0 and 14) of an aqueous solution.

Devices: Metrohm Titrand 907 and Knick Portamess

Determination of the residues on ignition of polymers

The incineration or calcination method is used to determine the residues on ignition or the ash of polymers as well as the textile-glass and mineral-filler content of fibreglass reinforced plastics.

Determination of viscosity

Serves to determine the inherent viscosity and molecular weight of PE and polylactides.

Devices: LAUDA Proline PV 15 viscometer

Density of solids and liquids

Determination of the density following the principle of Archimedes (measurement of the lifting force). The density of a solid is determined using a liquid of known density. The sample is weighed in air and in the liquid separately. The density is calculated from the two measurements.

The density of a liquid is determined using a displacer of known volume. The displacer is weighed in air and in the unknown liquid separately. The density is calculated from the two measurements.

Devices: Precision scale Mettler Toledo XS205DU with density kit

Determination of the specific surface area of powders and porous solids

In the BET method (Brunauer, Emmet and Teller) we use gas adsorption to determine the specific surface of solids. The nitrogen adsorption at a temperature of liquid nitrogen is used as standard method.

Device: Tristar Plus 3030, Micromeritics

Identification and quantification of ceramic degradation products

This test determines the amount of dissolved material from ceramic products according to ISO 10993-14.

Devices: Climate chamber Feutron KPK 200 / Orbital shaker GFL type 3017 / Agilent 7700x ICP MS

Phase purity of β -tricalcium phosphate and hydroxyapatite

The phase purity of β -tricalcium phosphate bone graft substitute material is determined by X-ray diffraction (XRD). Data evaluation by state-of-the-art Rietveld refinement was adapted from ISO 13175-3 and ISO 13779-3 and is compliant with ASTM F1088.

Devices: Bruker D8 Advance diffractometer with CuK α radiation and a LynxEye XE energy dispersive linear detector / current release of the ICDD PDF-4+ structure database / BGMN and Profex Rietveld refinement software

Identification of crystalline main phases (XRD) (non-accredited service)

Crystalline main phases are identified in ceramic and metallic samples by comparing an X-ray diffraction pattern (XRD) with a crystal structure database. Depending on the complexity of the diffraction pattern, phases of less than ten weight percent can be identified.

Devices: Bruker D8 Advance diffractometer with CuK α radiation and a LynxEye XE energy dispersive linear detector / current release of the ICDD PDF-4+ structure database / Match! identification software

Trace element analysis of calcium phosphates (ISO 13175-3, ASTM F1088, F1185 and F1581)

Calcium phosphate bone graft substitute materials are tested for heavy metals and impurity elements using inductively coupled plasma - mass spectrometry (ICP-MS). The analysis includes As, Cd, Hg, Pb, Bi, Sb, Sn, Ag, Cu, Mo, Fe and Cr contents along with a simultaneous screening for 50 additional impurity elements according to the maximum limits defined in ISO 13175-3, ASTM F1088, F1185 and F1581.

Devices: Agilent 7700x ICP-MS

Dissolution testing of calcium phosphates (ISO 13175-3)

The dissolution properties of resorbable calcium phosphate bone graft substitute materials are determined in an *in vitro* dissolution test according to ISO 13175-3, which provides pH changes and Ca release in the incubation solution.

Devices: *Temperature-controlled incubator shaker IKA™ KS 4000i control / Agilent 7700x ICP-MS / Mettler Toledo MA235 pH meter*

Leachables & extractables (ISO 10993)

Inorganic leachables and extractables from medical devices or device components are quantified by inductively coupled plasma – mass spectrometry (ICP-MS) following extraction in a temperature-controlled incubator shaker according to ISO 10993.

Devices: *Temperature-controlled incubator shaker IKA™ KS 4000i control / Agilent 7700x ICP-MS*

Reprocessing validations for medical devices

Reprocessing of reusable medical devices means in particular cleaning, disinfecting, checking functionality, packaging, sterilisation and storage. The efficacy of the manufacturer's reprocessing instruction is tested for the worst-case scenario, using BCA method for residual protein quantification. If necessary, the appropriate number of reprocessing cycles over the lifespan of a medical device can be evaluated.

Devices: *Miele professional washer-disinfector G 7836 CD, Tuttnauer autoclave Elara 10, Biotek ELx808 reader*

MATERIALOGRAPHIC INVESTIGATIONS

Sample preparation for materialographic investigations

The preparation of samples for the materialographic investigation includes working steps such as cutting, embedding, grinding, polishing, and etching.

Devices: *Embedding press Metkon ECOPRESS®200 / Struers CitoPress / grinding and polishing devices Struers TegraPol-21 (+ Tegra Doser 5) and PRESI Meccatech 334*

Determination of the grain size and the volume fraction in multiple-phase structures

Determination of the grain size number and the grain size of metallic and ceramic materials based on standard methods as well as the volume fraction in multiple-phase structures by point count with picture documentation.

Devices: *Light microscope Leica DMI5000 M with camera Jenoptik Gryphax Naos and IMS Image Management Software*

Determination of non-metallic inclusions in metals

Characterization and determination of the non-metallic inclusions of non-etched sections of metallic materials with documentation.

Devices: *Light microscope Leica DMI5000 M with camera Jenoptik Gryphax Naos and IMS Image Management Software*

Determination of precipitated phase contents

Estimation of the contents of precipitated phases such as delta ferrite, sigma phase and iron beta phase using standard series and documentation.

Devices: *Light microscope Leica DMI5000 M with camera Jenoptik Gryphax Naos and IMS Image Management Software*

Intergranular corrosion test ASTM A262 practice A and E

The test is used to detect intergranular attack in austenitic stainless steels. The oxalic acid etch test practice A is used as a method to rapidly screen certain grades of stainless steel. Practice E (Strauss test) is conducted to determine the susceptibility of austenitic stainless steel to intergranular attack associated with the precipitation of chromium-rich carbides.

Devices: *Practice A: electro-polisher/etcher Buehler PoliMat 2
Practice E: glass apparatus with return cooler*

Measurement of coating thickness

Measurement of the local thickness of metallic coatings and oxide layers by investigating the cross-sectional surface by means of a light microscope with documentation.

Devices: *Light microscope Leica DMI5000 M with camera Jenoptik Gryphax Naos plus and IMS Image Management Software*

MICROSCOPIC INVESTIGATIONS

Scanning electron microscopy (SEM)

The scanning electron microscopy (SEM) is used to document the surfaces and fracture surfaces of organic and inorganic test bodies and component samples to determine the topography and the structure of the surface.

Device: *Zeiss Sigma 300 VP with a secondary and backscattered electron detector, Alicona MEX Software (3D images, roughness measurements)*

Light-optical microscopy, stereomicroscopy, macroscopic documentation

Macro- and microscopical documentation of all kinds of samples.

Devices: *Inverse light microscope Leica DMI5000 M / Stereo microscope Leica M205A / Canon EOS 700D*

Test of technical cleanliness VDA 19 part 1 / ISO 16232

Standard component cleanliness analyses regarding particles (residual soiling). Preparation of cleanliness test procedures (decay measurements, blank values, number of measurements, purging parameters, filters). Gravimetric measurements, determination of the total mass of all particles on the component (residual soiling). Light-optical analysis, counting and measurement as well as classification of the particles into metallic and non-metallic particles and fibres. Extensive analyses, material identification of particles and analyses by means of SEM / EDX or FTIR.

Devices: *Stainless steel vacuum filtration unit Sartorius / Contamination test unit Hydac CTU 1040*

Analytic balance Mettler AX 205 / Automatic filter analysis system Jomesa HFD4

Scanning Electron Microscope Zeiss Sigma 300 VP with EDX analysis (AZtecFeature with x-Max 50 detector) / FTIR

Microscope Bruker Lumos

Topography and roughness measurement

Contactless measurement of the topography using interferometry, confocal microscopy or focus variation. From the topography, for example the roughness parameters can be determined based on areas or on extracted profiles.

Device: *S neox Sensofar*

PHYSICAL AND MECHANICAL TESTS

Tensile test, compression test, bend test

Static and quasi-static tensile, compression, and flexural tests of metallic, polymeric and ceramic samples to determine the tensile strength, the yield strength, the elongation at rupture, the reduction of cross sectional area and the modulus of elasticity as well as graphic plotting of the test values.

Devices: *Zwick tensile testing machines 1475 and Z250 and Zwicki-Line Z5.0 with Software testXpert III (force and displacement according to accuracy class 0.5 - 1.0 to DIN EN ISO 7500-1 or DIN EN ISO 9513 respectively)*

Torsional test

The static and quasi-static torsional tests of metallic and polymeric samples as well as of devices and components are used to determine the torsional stiffness, the torsional strengths and the resulting twisting angles, as well as to measure the tightening/loosening moments. Tests are optionally combined with axial tension or compression loads.

Device: *Torsion testing machine Zwick TL500 (Software testXpert III)*

Static testing of devices and components

Static and quasi-static tensile, compression, and bend tests of devices and components to determine the strength, stiffness, and elasticity as well as graphic plotting of the test values.

Devices: *Zwick tensile testing machines 1475 and Z250 and Zwicki-Line Z5.0 with Software testXpert III (force and displacement according to accuracy class 0.5 - 1.0 to DIN EN ISO 7500-1 or DIN EN ISO 9513 respectively)*

Charpy impact test

The notched bar impact test is used to determine the tendency of a material to behave in a brittle manner. This type of test will detect differences between materials which are not observable in a tension test.

Device: *Pendulum impact testing machine Zwick RKP 450 GE with a pendulum head 300 joule (Software testXpert III)*

Dynamic tests with uniaxial testing devices

Serves to determine the fatigue resistance (stress-number curves) of metallic samples and polymers, components, and implants using uniaxial dynamic tests).

Devices: *5 uniaxial hydraulic rams with Schenk hydraulic cylinders and Inova EU3000 digital control*

Rotating beam fatigue tests (non-accredited service)

The rotating bending fatigue test serves to determine the fatigue strength under reversed bending stresses of metallic samples allowing for specific surface structures, and to investigate the adhering strength of coatings on metallic and synthetic samples.

Device: *BIG1 Rotating bending testing device (self-made, corresponds to DIN EN ISO 7500-1)*

Vickers hardness test

Hardness test of metallic and non-metallic materials according to the test procedure of Vickers.

Device: *Vickers hardness testing device UHL VMH-002V (up to HV2)*

Shore hardness test

Hardness test of polymers and rubbers according to the test procedure of Shore A und D.

Devices: *Type A Durometer / Type D Durometer*

Coating thickness measurement (eddy current and magnetic induction method)

Non-destructive coating thickness measurement according to the eddy current method (DIN EN ISO 2316) and the magnetic induction method (DIN EN ISO 2178). Due to automatic substrate material recognition and the integration of both methods, non-magnetic coatings on steel and iron (Fe) and nonconductive layers on non-ferromagnetic metals or nonconductive substrates can be measured. The method permitted a determination of the coating thickness in a range of 0 – 2000 μm (Fe) respectively 0 – 1200 μm (NFe). With a measurement stand a precise and exact measurement even on small samples is possible.

Device: *Fischer Dualscope FMP20*

Electrical conductivity measurement of non-ferrous metals

Fast, non-destructive and precise measurement of the electrical conductivity of non-ferrous metals using various frequencies. Determination of the hardening condition of precipitation hardenable alloys (e.g. Al, Cu).

Device: *Fischer Sigmascope SMP10*

Particle analysis (laser diffraction, optical microscopy)

Particle size analysis is used to determine particle size distributions of granules, powders and suspensions. The size distribution of abrasion particles from wear tests can also be investigated. The following measuring methods are available: Laser diffraction and automated microscopy.

In laser diffraction, the particles pass through a laser beam. The monochromatic laser light is more or less diffracted depending on the particle size. The characteristic, ring-shaped intensity distribution is recorded by numerous detectors and can be converted into a particle size distribution using a suitable model (according to Mie or Fraunhofer). The measuring range is 0.04 - 2000 μm for dry measurement and, using additional polarization detectors, 0.017 - 2000 μm for wet measurement. In automated microscopy, optical or electron beam based microscopes are used after filtration of a suspension to measure the particles remaining on the dried filter. Alternatively, non-spherical granules or powders can be distributed on a suitable surface and measured automatically by light-optical means (dry measurement).

Devices: *Beckman Coulter LS 13320 (laser diffraction) / Jomesa HFD4 (automated light microscopy, dried filters or glass plate) / SEM (X-ray electron beam microscopy, dried filters)*

Climatic chamber tests

The climatic chamber test serves to condition, precipitate and age samples, components and prefabricated parts on defined climatic conditions (temperature, humidity) in order to assess their resistance and/or implement possible subsequent tests.

Device: *Feutron climatic chamber type KPK 200*

Washing, sterilization and cleaning test for medical devices

It serves to verify and validate the application requirements of medical devices regarding washing, sterilization and cleaning, handling and aging. Investigations may include determination of residual contamination, material aging, stress-cracking susceptibility, corrosion or operability according to standards or customers specification.

Devices: *«Tuttnauer 2540E» autoclave / «MIELABOR G7783» automated laboratory washer / «WTB Binder» drying oven / Miele Professional Washer-disinfector G 7836 CD*

Contact angle measurement

A measurement of the contact angle allows a quick characterisation of a surface. Is it hydrophilic or hydrophobic? Are there contaminations? Did a coating work or not? Using two different test liquids, the surface energy can be determined.

Device: *Surftens universal (OEG GmbH)*

Crack detection / penetrant testing

Liquid penetrant examination to detect flaws with openings to the surface (cracks, overlaps, wrinkles and pores) for all materials that are resistant to the penetrant and do not have high porosity.

Device: *red penetrant of fluorescent, solvent based cleaner and developer*

Finite element analyses (FEA)

The Finite Element Method (FEM) or the Finite Element Analysis (FEA) serves to determine the tensions, elongations or temperatures in prefabricated parts, components and products. Based on geometric data and/or CAD models, this analytical,

computer-based calculation method permits structural and/or thermal analyses and optimisations as well as the presentation of the results as individual values or as distribution pictures.

Device: *High-performance PC with ANSYS analytical software V. 18.0*

Failure analyses

This analysis consists in establishing the causes of damage and in proposing the improvement measures by means of investigations and technical expert opinions of the damages of the medical products (particularly orthopaedic and traumatologic implants and instruments), the technical products and the components as well as a concise and comprehensible documentation of the investigation results and conclusions.

Packaging testing

Testing of packaging (blister, peel bags) for seal strength using tensile testing and leak detection by dye penetration and bubble emission.

Devices: *Zwicki Z5.0, Inv. Nr. 761 / Labthink Leak Tester MFY-01, Inv. Nr. 01006 / Vacuum measurement device DVR 2*

TRIBOLOGICAL INVESTIGATIONS

Pin-on-disk friction and wear tests (OrthoPOD)

The OrthoPOD 6-station test setup and weight measurement are used for screening tests to investigate and determine the wear behaviour of two gliding partners in a freely selectable type of burden and motion sequence.

Devices: *2 AMTI OrthoPOD™ pin-on-disk test setups*

Hip Simulator / Spine Simulator

Wear test of implants for intervertebral disc replacement according to ISO 18192 and hip simulation tests according to ISO 14242.

Devices: *Hydraulic 6-station hip and spine simulator, EndoLab GmbH*

CONSULTING / VALIDATION / LITERATURE*

* non-accredited services

Advisory, planning of investigations and validation

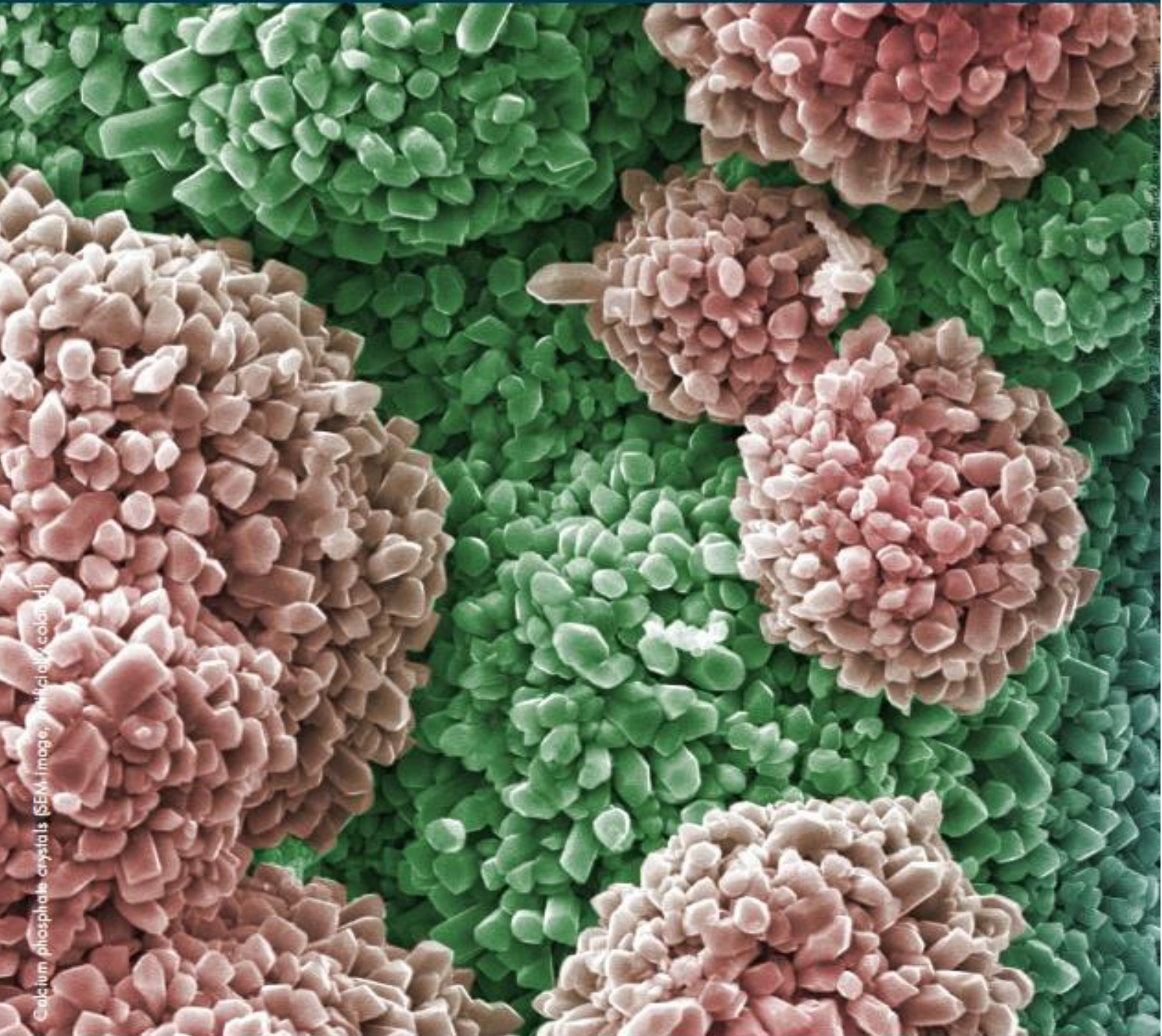
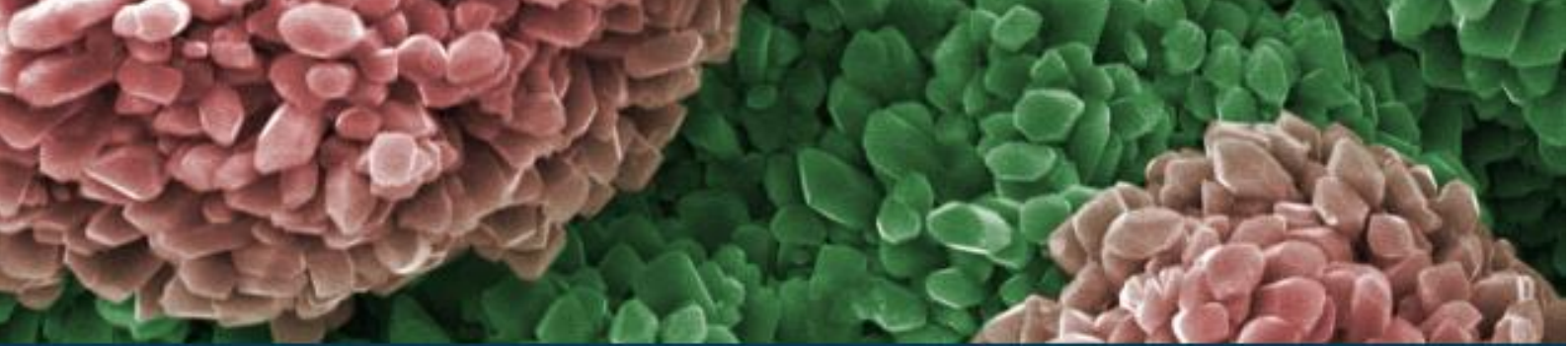
Consulting services and training regarding all technical and scientific expertise and tests, in which the RMS Foundation is involved through its research activities, studies and services themselves. Investigation planning of surgical instruments and implants. Advice on validations.

Cleanliness of implants / cleaning validation

On the subject of «cleanliness of implants» both consulting services and chemical analyses are offered. We advise our clients on cleaning issues and process validations. We support you from the planning of the validation studies to the final report. In addition, we assess or develop risk analyses, evaluate the IQ and OQ documents or conduct performance qualification (PQ) studies, including the preparation of customized test specimens, appropriate staining and chemical analysis.

Systematic literature reviewing (ISO 10993-1)

Search and critical evaluation of relevant literature on medical, material and process related topics based on customer specifications.



Calcium phosphate crystals (SEM image, artificial colour)

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