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## TESTING LABORATORY FOR MEDICAL DEVICES

As an accredited testing laboratory for medical devices we support manufacturers in the area of approval testing and damage analysis.

# ALWAYS ONE STEP AHEAD

## ACCREDITED TEST LABORATORY ACCORDING TO DIN EN ISO/IEC 17025



### APPLUS+ GROUP AND APPLUS+ LABORATORIES

Applus+ is a worldwide leader in the testing, inspection and certification sector. Applus+ Laboratories, a division of the Applus+ Group, provides testing, certification and development engineering services to improve the competitiveness of its clients' products and encourage innovation. We have a network of multidisciplinary laboratories in Europe, Asia and North America.



# ALL IN ONE HAND WITH APPLUS+ IMA DRESDEN

## PART OF APPLUS+ LABORATORIES SINCE MAY 2021

Our mobility forms an essential and integral part of our day to day life. In this instance, assistive medical devices work as auxiliary aids that can restore or improve our mobility after an accident or impediment.

To guarantee that these medical devices are fit for endurance and long-standing support it's key we ensure their quality and efficiency at all times. We test passive implants for fatigue and assess their wear behaviour under multi-axial loading.

The accreditation by DAkkS confirms our competence, reliability as well as independence, enabling us to test materials and products according to different standards.

We are currently accredited for almost 100 testing methods. If you're looking for more information, a comprehensive overview of the scope of our accreditation can be found on our IMA website: [ima-dresden.de](http://ima-dresden.de)

We'll support you in the development of test specifications, based on scientific studies and databases. Our additional DAkkS accreditation for the development of new testing methods in the field of medical devices enables us to do so.

**We've been successfully performing medical device testing services on implant products since 1995, including:**

- + Wear testing
- + Fatigue testing (tension, pressure, torsion, shear, etc.)
- + Corrosion testing
- + Contact area/stress test (surface pressure)
- + Artificial aging
- + Simulation and strength assessment
- + Materialography (microstructure analysis, etc.)
- + Damage analysis
- + Materials and coatings
- + PE particle analysis – all in one hand: filter preparation and SEM analysis
- + Sample preparation
- + Determination of metal ion concentration
- + Mechanical and physical tests on PE (crystallinity, degree of crosslinking, Charpy, etc.)



# RANGE OF MEDICAL DEVICE TESTING



# JOINT IMPLANTS



Joint implants are loaded for up to ten million cycles in the anatomically correct position under physiologic conditions in our laboratories. Thanks to the help of our accredited testing programs, we can simulate the lifetime of an implant.

- Wear testing with up to 5 controllable axes for simultaneous testing of up to 8 implants
- Standard-compliant performance of abrasion tests on knee, ankle and shoulder endoprostheses
- Wear tests under more stringent conditions according to ISO 14243
- Optional: artificial aging of UHMWPE-components according to ASTM F2003 (takes a duration: 2 weeks)

## STANDARD TESTS ON JOINT IMPLANTS

### ISO 7206-1...-2

Classification, definitions, determination, dimensions (hip)

### ISO 7206-4, -6, -10, -12, -13

Static and dynamic tests (hip stems, cups, heads)

### ISO 7207-1...-2

Classification, definitions, determination, dimensions (knee)

### ISO 14879-1, ASTM F3140

Fatigue test on knee tibia tray

### ISO 14242, ISO 14243, ISO 22622

Wear test on hip / knee / ankle joints

### ASTM F1875

Corrosion tests



## HIP JOINT IMPLANTS

The technical documentation of hip joint implants requires proof of a wide variety of product properties using standardized test procedures.

Our laboratory equipment consists of multi-station simulators, strength testing machines and measuring equipment that enables high precision testing.

- Wear simulation: testing with up to four controllable axes
- An axial force combined with rotational movement
- Simulator with 12 test stations



## KNEE JOINT IMPLANTS

The large number and diverse range of knee endoprotheses depending on fitting type, fixation, bearing couple, design and degree of coupling requires a set of defined tests for the approval process.

### STANDARDS WITHIN THE SCOPE OF ACCREDITATION:

- ISO 14879-1, ASTM F3140  
Tibia component
- IMA-PV C/38  
Stem of tibia component
- IMA-PV C/31  
Femur component

*Multi-station simulator: Five controllable axes, that allow to simultaneously test 8 implants – knee, patella, ankle or anatomical shoulder joint*



## ANKLE JOINT IMPLANTS

Since 2019 we perform standardized wear tests on ankle joint implants. These are developed reliably and in accordance with standards in our modern wear simulators.



## SHOULDER JOINT IMPLANTS

We have added in-house test instructions to the standardized test procedures to generate even more meaningful results based on scientific publications and databases.

Thus, we cover anatomical and reverse designs. Edge loading is of particular interest for these endoprotheses.

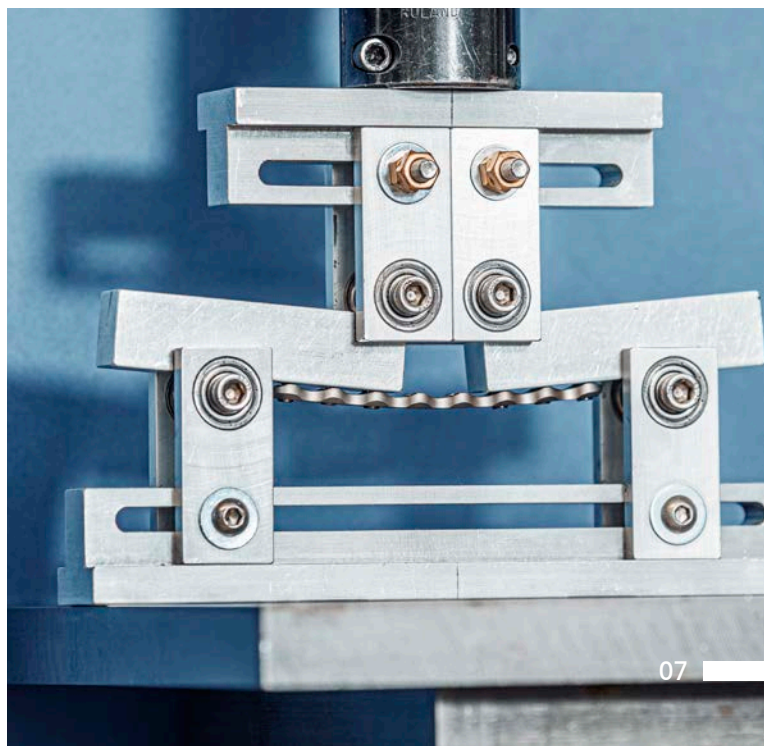


## OSTEOSYNTHESIS IMPLANTS

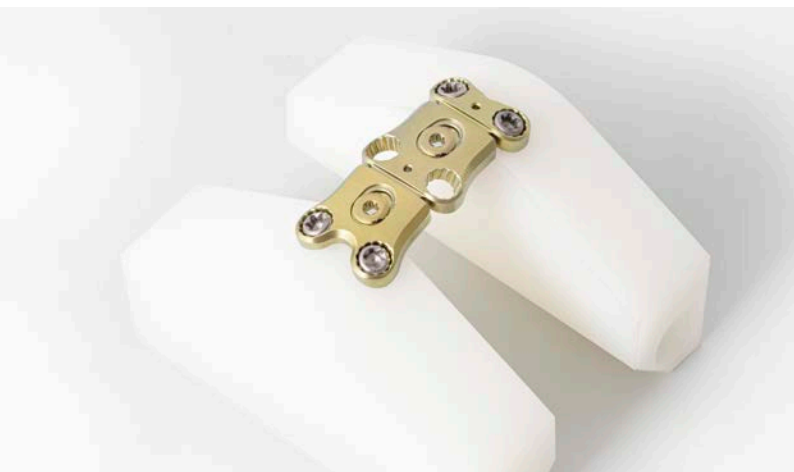
Among other things, bone screws must resist defined torsional stresses. The assessment of the flexural strength is of particular importance for bone plates. In case you fail to meet the testing requirements, you can rely on the expertise in our materialography laboratory.

### WE TEST FOR YOU:

- ASTM F382, F384  
Test methods for metallic bone plates
- ASTM F543  
Test methods for metallic medical bone screws
- ASTM F1264  
Test methods for intramedullary fixation devices







## SPINAL IMPLANTS

In addition to the tension, compression and torsion loading tests, combined loading scenarios on spinal systems can also be carried out. The components can be tested statically as well as dynamically in our laboratories according to current standards.

Target: prevention of failure under tensile, compressive or torsional loads

### TEST RANGES

- Spinal fixators (screw-rod system)
- Fusion implants
- Artificial discs

### STANDARD RANGES

- ASTM F2077, F2267, IMA-PV C/40  
Test methods for cages
- ASTM F1717, F1798, F2193  
Test methods for interior fixators
- ASTM F2346  
Test methods for intervertebral discs



## DENTAL IMPLANTS

Dental implants resemble artificial tooth roots. They must be accepted by the jawbone, grow in and permanently withstand the loads during mastication.

In our laboratory, we perform dynamic testing of single-abutment endosseous dental implants with their prefabricated prosthetic components.

### TESTING IN THE STANDARD RANGE

- ISO 14801  
Dynamic loading test for endosseous dental implants



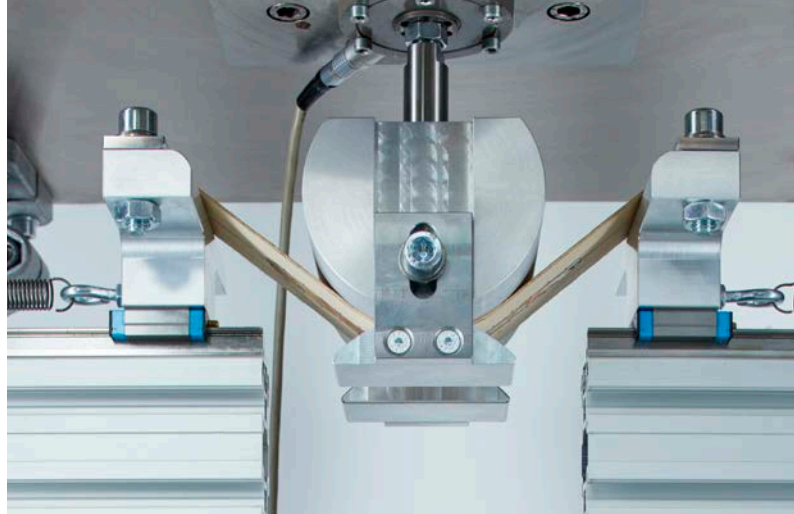


## ADHESIVES FOR SKIN

Wound or tissue adhesives are an alternative to the conventional wound closure through surgical sutures.

To ensure safe use, the adhesive properties must be determined and the wound closure strength demonstrated before clinical use.

**Our laboratory is accredited according to the DIN EN ISO/IEC 17025 regulation.**



## SURGICAL INSTRUMENTS

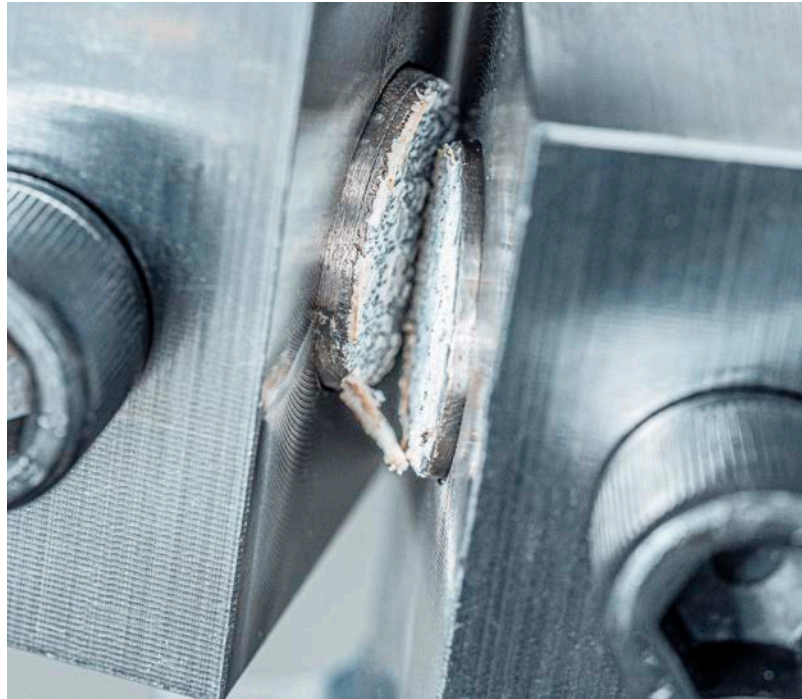
We also test impact-loaded surgical instruments for their durability and check for any functional impairment through the testing process. The conversion is carried out through cyclic impact test procedures on a specially developed test fixture. The produced load profiles are validated through extensive clinical measurement data sets.

Methods of endurance and load tests for instruments of different designs and adaptations are described in an Applus+ IMA Dresden test specification.

### TEST RANGE

- Dynamic testing of orthopedic instruments
- Testing for fatigue strength in endurance and load increase tests
- Including impact and setting instruments of the joint types shoulder, hip and knee
- Testing of up to 40,000 cycles
- Detection of weak points (e.g. weld seams, pins)

# TESTING OF MATERIALS, CALCIUM PHOSPHATE AND METALLIC COATINGS



In addition to design, the use of suitable materials or coatings is crucial as the basis for long-term success after implantation. Materials tests and analyses on material samples as well as on finished implants and surgical instruments ensure an increasingly reliable product for the patient.

## WE CAN TEST:

- Materials: metals, plastics and ceramics
- Coatings

## STANDARD RANGES

### ASTM F1160

Determination of shear fatigue and bending fatigue strength

### ASTM F1044

Determination of static shear strength

### ASTM F1147

Determination of static tensile strength

### ISO 13179-1

Titanium / Ti-6Al-4V

### ISO 13779-4

Hydroxylapatite

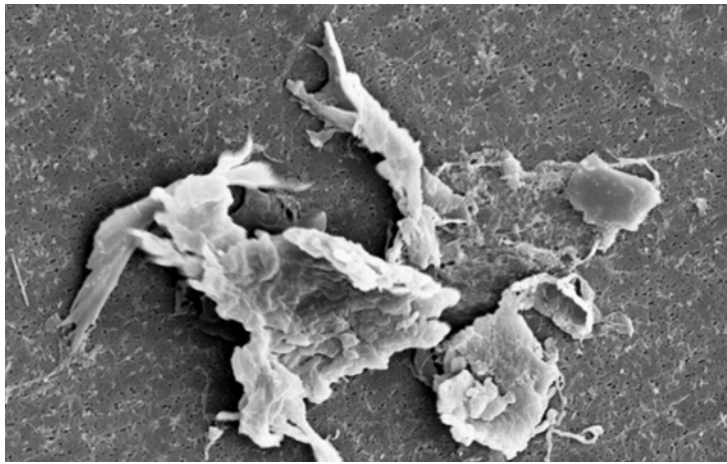


# PARTICLE ANALYSIS & SEM ON ABRASION PARTICLES

We identify causes to ensure fast decision-making.

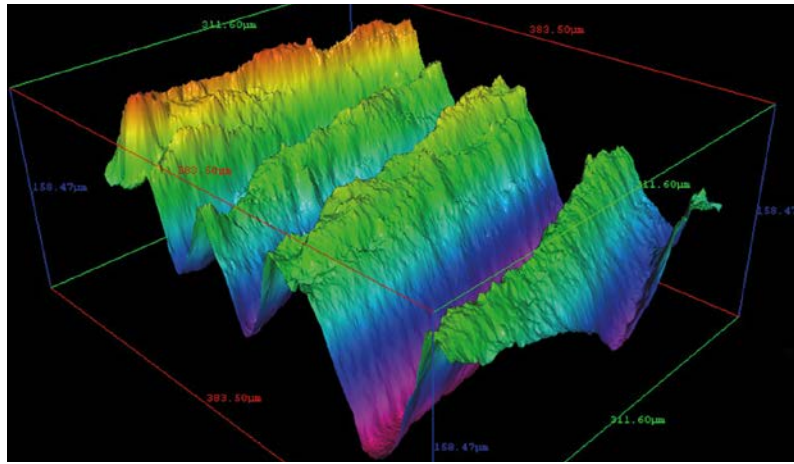
Evaluate the identity, origin, and potential toxicity of each particle type, as well as particle sizes, shapes, and quantities. All of these factors are critical to the development process.

We perform particle analyses according to ISO 17853 and ASTM F1877 as an optional service for you after wear tests.



## OUR SERVICES

- Isolation and filtration of PE particles from fluid test medium
- Imaging of manufactured filters with scanning electron microscope (SEM)
- Characterization of particle size and morphology
- Detailed visualization of scratches, burnishing and pitting on the joint surfaces
- 3D fracture surface analysis

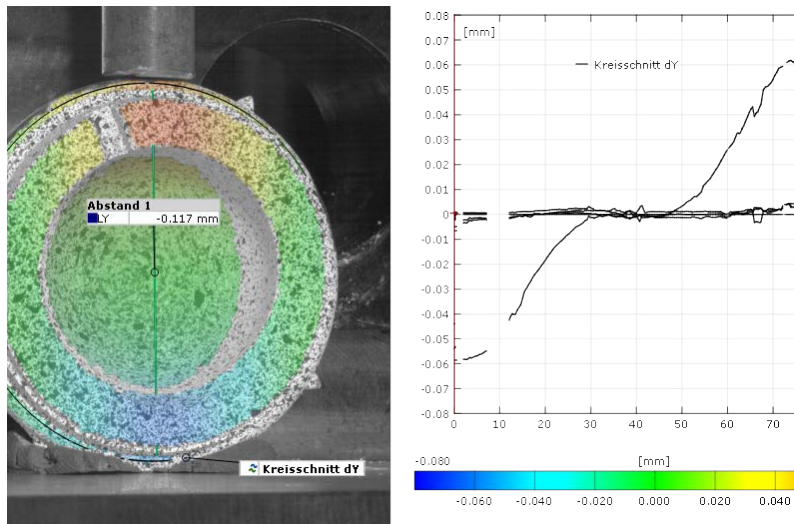


# OPTICAL MEASURING METHODS: ARAMIS

Non-contact measuring and non-destructive testing, utilizing optical measuring methods.

State-of-the-art measurement techniques that turn what's hidden to the human eye into visible and numerically measurable data.

The results, which can be obtained with optical measuring technology, contribute to a significant increase in knowledge through many diverse examinations.



## TEST RANGE

- Deformation measurement during the test procedure (vertical load)
- ISO 7206-12: Deformation testing of acetabular shells
- Measurement of deformation by photogrammetry (accuracy: 4 µm)
- Determination of deformation in x-, y- and z-direction

# MATERIALOGRAPHY AND DAMAGE ANALYSIS

Our accredited materialography laboratories are fit for quality assurance, damage analysis or research and development.

We have also developed the capabilities to examine both metallic and non-metallic materials of different compositions using the appropriate qualitative and quantitative characterisation procedures.

This includes the test preparation process and the use of a wide range of microscopic methods from light to electron microscopy as well as the analysis, evaluation and documentation of research results.

The investigations can be supported and supplemented by further materials analysis, technological and physical procedures upon request.



We document the damage for you and determine the cause of the damage.



## ANALYSIS METHODS

- Light and scanning electron microscopy
- Evaluation of the microstructure
- Evaluation of the welded and soldered seam quality
- Determination of grain size
- Determination of purity level
- Measurement of layer thickness
- Changes in surface layer (decarburisation, alpha case, corrosion, oxidation)
- Determination of cell sizes (PUR), homogeneity and carbon black dispersion (PE)

## SERVICES

- Identification of the type of damage
- Classification of damages
- Condition assessment of the material or the product
- Determination of cause
- Help to prevent future damage of the same cause





## RELY ON OUR EXPERTISE:

We provide our full support, whether for qualified damage analysis or the preparation of legal expertise. This includes:

- Individual creation of test or verification programs for damage investigations
- Interdisciplinary implementation of all necessary verifications
- Professional and independent assessment of the current position and recommendations using the damage documentation, component history, inspection and testing reports, etc.

Together with our cooperating surveyors and experts, we will find the optimal solution for you to eliminate problems and increase operational safety.

Let us advise you. We can draw on extensive experience in the fields of construction, plant engineering, installation technology and mechanical engineering.





## SIMULATION AND STRENGTH ASSESSMENT

We live in a time when economic demands for shortened production development times and for innovative as well as high-quality designs with better material efficiency are more important than ever.

With strength assessment and diverse simulation capabilities, Applus+ IMA Dresden supports you in optimizing your designs to make product developments marketable faster.

From all-encompassing simulation tasks in product development to the virtual test bench.

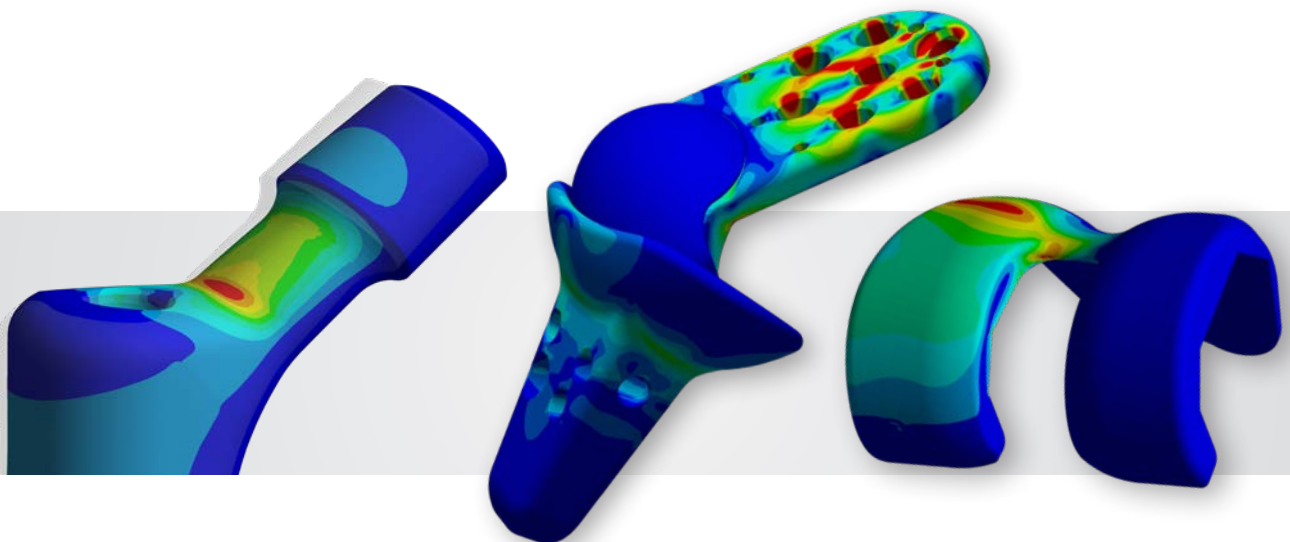
### RANGE OF SERVICES

- Simulation of contact situations
- Simulation of interference fits
- Simulation of hyperelastic materials and plastics
- Lifetime analyses of the structure
- Determination of worst-case geometry variants. (e.g. according to ASTM F2996-20, ASTM F3161-16), which can lead to a shortening of the test times and to a reduction of costs in the experimental proofs.

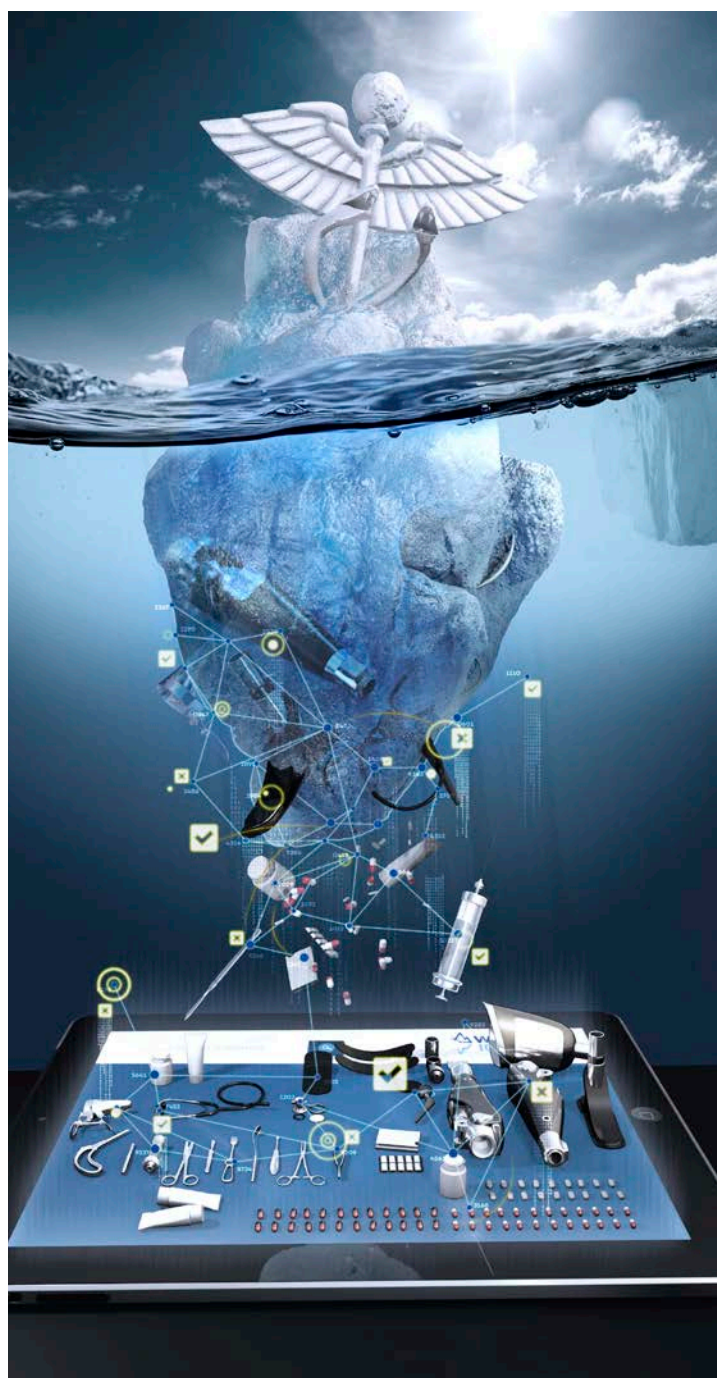
### FINITE ELEMENTE ANALYSES (FEA)

- Dimensioning of the product
- Optimization of mass, shape
- Determination of stresses, deformations
- Investigation stability behavior
- Static, operational and fatigue strength verifications

Our target is the structural and cost optimization of your medical device already in the development stage.







## FIND INFORMATION, MANAGE DATA, NET- WORKING KNOWLEDGE: WIAM® ICE

The structuring, processing and management of information helps ensure expert technological know-how in the long term, streamline processes and thus increase quality and efficiency.

The software product WIAM® ICE promotes the flow of knowledge, simplifies areas of complexity and ensures added value and innovative strength.

Having originated in the field of Material Sciences, the generic WIAM data model can now manage all kinds of knowledge and information.

With WIAM® ICE, you can record, research, link, visualize, compare and evaluate diverse data easily and clearly.

## BENEFIT FROM THE COMPETENCE OF APPLUS+ IMA DRESDEN FOR YOUR TESTS AND CERTIFICATIONS.

IMA Materialforschung und Anwendungstechnik GmbH, in short Applus+ IMA Dresden, is the development and test centre which can speed up the process for your new developments and ensure that they are suitable for the market. As an independent test provider we guarantee reliable results and strict confidentiality.

Whenever it comes down to strength, resistance, validation or material characteristic data, then Applus+ IMA Dresden can combine its efforts in regards to test standards, approval and certification tests as well as experimental investigations. We have over 10,000m<sup>2</sup> of test area in certified and accredited testing laboratories where we can test innovative products and technologies from aerospace, rail vehicle, automotive and medical technologies, shipbuilding, plastic, metal and electrical industries and other industrial branches. You can rely on us: the testing tasks at Applus+ IMA Dresden will be processed according to the current state of the art technology and enjoy worldwide acceptance and trust.

Since May 2021, IMA Dresden is part of Applus Laboratories.



According to accreditation certificate



## CONTACT

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