



Deutsche  
Akkreditierungsstelle  
D-PL-20691-01-00

# INN O PROOF

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## ACCREDITED IMPLANT TESTING

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[www.innoproof.de/en](http://www.innoproof.de/en)

# THE COMPANY

INNOPROOF GmbH is an award-winning testing laboratory for implantable medical devices such as total joint replacements, dental implants, osteosyntheses, spinal and breast implants as well as surgical instruments.

We are accredited by ISO 17025:2018 standards with continuously growing scope including ISO, ASTM and FDA protocols. Our test reports include the ilac MRA symbol and are recognized by implant manufacturers worldwide to obtain the certification for medical devices.

Our testing equipment includes 20 electro-dynamic universal test frames, 3 static testing machines, and 48 stations for mammary implant fatigue testing, amongst others. We are equipped for testing in physiological environment and thorough implant analysis following the tests including digital microscopy.



# THE FOUNDERS

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The founders of INNOPROOF GmbH, Dr. Carmen Zietz and Dr. Daniel Kluess, have a long history of implant technology research which is documented in numerous international publications.

Together with their team of test engineers and technicians, the INNOPROOF crew delivers high quality testing for most implantable devices and surgical instruments.

We also have the competence to develop new test setups if there are no existing standardized tests for the product you wish to bring into the market.

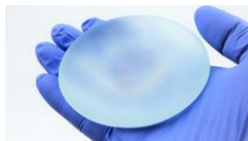
Besides testing, we also provide consulting of current state of science and technology as benchmark for your product, which can be used for assessment of preclinical data for market clearance.



# OUR SERVICES

## Breast implant testing

We offer testing of breast implants (mammary implants) by FDA and ISO standards.



### FDA Docket No. 2004D-0002

### Axial fatigue test

Aim of this test standard is development of an applied force versus number of cycles to failure (AF/N) curve in order to estimate fatigue strength. Unlike the ISO 14607 fatigue tests under shear stress, the fatigue test covered by FDA directive addresses cyclic compressive stress. Sinusoidal load cycles are driven up to a run-out level of 6.5 million cycles. [Pricing available on request](#)

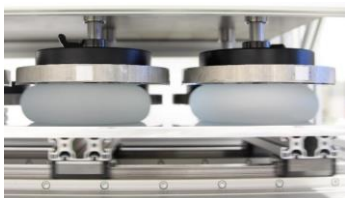
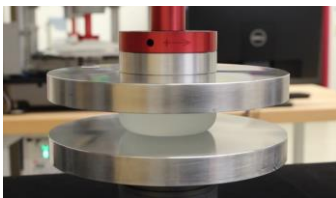
### ISO 14607:2018 Annex C.1

### Shear fatigue test

We offer fatigue testing of breast implants under shear load. Thereby, the implant is placed between two horizontally arranged plates and a static load of 50 N is applied. One of the plates is moved back and forth, whereby a shear load acts on the implant. The test is run for 6.5 million cycles at a frequency of 3.3 Hz. [Pricing available on request](#)

### More breast implant tests we offer:

ISO 14607:2018 Annex B	Test for shell integrity
ISO 14607:2018 Annex C.2	Impact resistance test
ISO 14607:2018 Annex D	Injection site competence
ISO 14607:2018 Annex E	Silicone gel cohesion
ISO 14607:2018 Annex H	Surface characteristics



# OUR SERVICES

## Dental implant testing

We offer testing of dental implants and instruments by ISO and in-house standards.



### ISO 14801

### Fatigue test and static test

Aim of the fatigue test is the development of a load-cycle diagram describing the fatigue behavior of single endosseous dental implants. Thereby, a sinusoidal load is applied for 2 million cycles at 2 Hz at different load levels in saline solution at 37°C. Fractured implants can be analyzed using digital microscopy. [Pricing available on request](#)

### ISO 11953

### Hand torque instruments

Torque wrenches for setting dental implants are tested for the repeat accuracy of the torque display or the triggering of the torque wrench. For the dentist, in practice, the question arises how precise the torques are still maintained after a certain number of applications. With our torque test bench, additional fatigue tests, and instrument processing for reuse, we simulate the applications in an accelerated manner. [Pricing available on request](#)

### More dental implant and instrument tests we offer:

ISO/TS 13498

Endosseous implants torsion test

IP-06-02

Fatigue test bridge constructs

In-house test developed by Nobel Biocare, Switzerland



# OUR SERVICES

## Hip replacement testing

We offer testing of hip replacements by ISO and ASTM standards. See below our list of services:



### ISO 7206-4 and -6

### Fatigue test

These test standards refer to the shaft or neck area of the femoral component of hip endoprostheses. The fatigue strength of the hip stem is determined under a given sinusoidal load and over a defined number of cycles. If the product has taper connection in the shaft or neck area, the tests are performed in a water bath in saline solution at 37 ° C. Pricing available on request

### ASTM F2009

### Femoral head pull-off test

In the femoral head pull-off test, the strength of the taper connection between the hip stem and the femoral head after defined assembly, is determined. The pull-off force is measured in the axial direction of the taper connection. Pricing available on request

### More hip implant tests we offer:

ISO 7206-9

Femoral head torque test

ASTM F1820

Insert push-out test

ASTM F1875

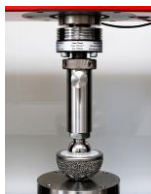
Corrosion test of taper connections

ASTM F2582

Impingement test

ISO 21535

Range of motion analysis



# OUR SERVICES

## Knee replacement testing

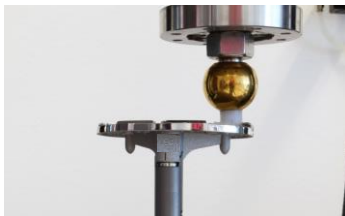
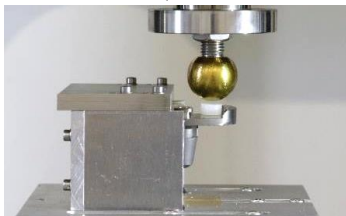
We offer testing of knee replacements by ISO and ASTM standards. See below our list of services:



### ISO 14879-1 / ASTM F1800

### Tibial plateau fatigue test

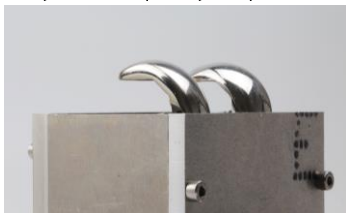
This fatigue test is used in bicondylar knee endoprostheses and especially addresses the metallic tibial plateau (tibial tray). The tibial plateau is fixed on one side (medial or lateral) for the test, with the other side oscillating freely. The fatigue strength of the tibial plateau is determined for a predefined load and number of cycles. Pricing available on request



### ASTM F3210

### Femoral component fatigue test

The femoral component fatigue test was published by ASTM in 2022 and has as its goal the determination of an S/N curve (stress-life). The run-out number of cycles is 10 million. Load is applied to one condyle only. Test frequency is up to 20 Hz. Pricing available on request



# OUR SERVICES

## Trauma implant testing

We offer testing of trauma and osteosynthesis implants by ASTM and in-house standards.



### ASTM F382

### Bone plates bending test

According to this standard the bone plate is tested into a four-point-bending device. In the static test the bone plate is subjected to a single cycle load. Thereby, the bending stiffness and bending strength are determined. In the dynamic test a sinusoidal load is applied at a frequency of 1 to 10 Hz for a defined number of cycles to determine the fatigue strength of the bone plate. [Pricing available on request](#)

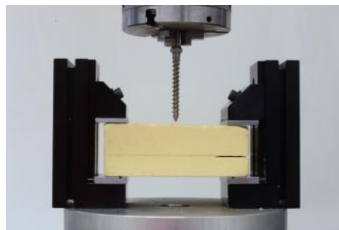
### ASTM F543

### Metallic bone screw tests

We offer you multiple test methods for the mechanical characterization of bone screws such as torsion test, determination of insertion and removal torque, axial pull-out strength or self-tapping performance. [Pricing available on request](#)

### More trauma and osteosynthesis implant tests we offer:

ASTM F383 and F1264	Intramedullary rods
ASTM F564	Bone staples
ASTM F384	Angled fixation devices bending test
IP-0505	Fatigue test of gliding nails





# OUR SERVICES

## Spinal implant testing

We offer testing of spinal implants by ASTM and ISO standards. See below our list of services:



### ASTM F1717

### Corpectomy model

We offer various test methods for the mechanical characterization of spinal implants in a vertebrectomy model in which the bridging of a vertebral body without anterior support is simulated. The standard describes compression and tensile bending as well as axial torsion as static tests and a dynamic compression bending fatigue test.

Pricing available on request

### ASTM F2077

### Intervertebral body fusion devices

This test standard covers the testing of intervertebral body fusion device assemblies. To evaluate the mechanical properties the devices can be tested in static compression, shear compression and in torsion.

Pricing available on request

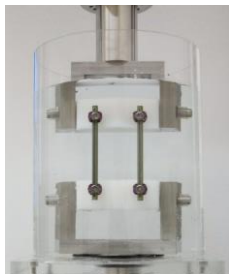
### More spinal implant tests we offer:

ISO 12189

Fatigue test using anterior support

ASTM F1798

Partial constructions for spinal implants



# OUR SERVICES

## Materials testing

We offer testing of materials by ASTM and ISO standards. See below our list of services:



### ASTM F1160 / ISO 13179-1

### Shear fatigue test of coatings

To test the shear strength of implant coatings, the coating is applied on the face of two cylinders, which are glued together before testing. The bonded layers are aligned vertically through the load axis to ensure a shear stress without bending. Constraining forces are prevented by double cardan joints. The ISO standard requires 10 million load cycles for a successful test. [Pricing available on request](#)

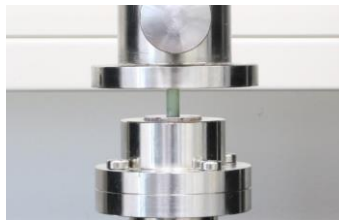
### ISO 5833

### Requirements for bone cements

The mechanical requirements for acrylic resin cements are evaluated in a compression test and a four-point-bending test to calculate compressive strength, bending modulus and bending strength. Beside further test, also the doughing time of liquid-powder mixture of cement is determined. [Pricing available on request](#)

### More material tests we offer:

ISO 16402	Flexural fatigue testing of acrylic resin cements
ASTM F1978	Abrasion resistance of coatings (taber test)
ASTM F1044	Shear testing of coatings
ASTM F1147	Tension testing of coatings



# OUR SERVICES

## Surgical instruments testing

We offer testing of surgical instruments by ASTM, ISO and in-house standards. See below our list of services:



### ISO 3630-1

### Endodontic instruments tests

We test the mechanical properties of root canal instruments according to the requirements of DIN EN ISO 3630-1. We are accredited for testing the resistance to fracture by twisting and angular deflection as well as the bending stiffness. In addition, we offer tests regarding handle and shank security of endodontic instruments and resistance test to reprocessing. Pricing available on request

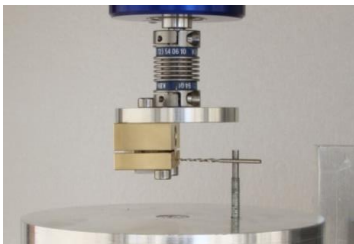
### ASTM F1089

### Corrosion of surgical instruments

The ASTM F1089 describes the procedures of the boil test and the copper sulfate test on surgical instruments. Evaluation criteria are given to assess the corrosion resistance of new and reusable surgical instruments made of stainless steel alloys. Pricing available on request

### More surgical instruments tests we offer:

ISO 11953	Hand torque instruments
In-house standard	Torque load test of screwdrivers
In-house standard	Torque load test of handles



# OUR SERVICES

## Packaging testing

We offer testing of packaging and sterile barrier by ASTM standards, as listed in DIN EN ISO 11607-1.



### ASTM F2096

### Bubble Emission Testing

When performing the bubble emission test according to ASTM F2096, the integrity of the packaging or sterile barrier is tested by means of applied internal pressure. For this purpose, the packaging film is pierced on one side with a cannula and air pressure is applied. The packaging is held under water and checked for emission of bubbles. In our setup, the internal pressure is measured directly with a second cannula and a digital barometer. [Pricing available on request](#)

### ASTM D642

### Compression test for packaging

The compression test is used to simulate the transport or storage of packaging. The sample package is placed between two metal platens and a compressive load is established. The end of the test is defined by a reduction of the maximum load or by reaching a deformation limit. [Pricing available on request](#)

### More packaging tests we offer:

ASTM F88

Seal strength

ASTM F1886

Visual inspection

ASTM F1929

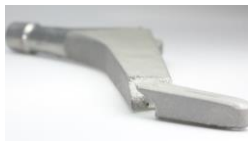
Dye penetration test



# OUR SERVICES

## Failure analysis

We offer damage analysis of implants.  
See below our list of services:



### VDI Guideline 3822

We offer damage analysis of implants as a service. The aim of the investigations is to find the cause of failure, with a structured approach based on VDI Guideline 3822.

Typical investigations in the context of damage analysis on implants are the following:

- Digital microscopy: Analysis for visual defects, contamination, corrosion, abrasion, wear mechanism, notch effect (non-destructive)
- Determination of wear volume: Tactile examination of the wear volume in cubic millimeter (non-destructive)
- REM and EDX investigation of the fracture surface, analysis of the fracture type and crack initiation, and material composition (partially destructive)
- Examination of the implant material (destructive), analysis of the microstructure, investigation of inclusions and voids



# OUR SERVICES

## Consulting

We offer appropriate research on test methods and their results in international literature and advise on corresponding test services in our company.

### EU MDR 2017/745

### Pre-clinical data

In addition to accredited and established test procedures, we also carry out literature reviews on the current state of science and technology based on publications and applicable standards for testing services.

Especially with regard to the new medical device regulation EU MDR 2017/745, pre-clinical data are required for the verification and validation of medical devices (Annex II, paragraph 6.1), which include test results as well as an evaluation of the current scientific literature.

INNPROOF GmbH · Joachim-Jungius-Str. 9 · 18059 Rostock · Germany  
www.innproof.de · info@innproof.de · T +49 381 8011 3000 · F +49 381 8011 3009



INNPROOF

## Research Report

*Title:*

**State of the art in mechanical testing of intramedullary nails as basis for assessment of preclinical data (Medical Device Regulations Annex II, Chapter 6.1)**

# INNOPROOF Academy

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INNOPROOF Academy is a new training program offered by our accredited testing laboratory to interested parties in the field of implant testing:

- Notified Bodies
- Manufacturers
- Users

At the Notified Bodies, test reports within the technical documentation are evaluated on a daily basis. For the assessor it is of great advantage to get to know corresponding test setups in practice at the INNOPROOF Academy and to learn the theoretical background.

Also for manufacturers of medical devices it is important to see how tests are performed in an accredited laboratory according to the standard and how they are realized in detail.

INNOPROOF Academy is also aimed at users of implantable medical devices who would like to broaden their horizons and experience live how implants and instruments are tested.

The training courses are offered as multi-day workshops for groups of up to 15 participants. In addition to the lecture program, implant testing is demonstrated. Hands-on exercises on the testing machines can also be offered upon request.

# IMPRINT

INNOPROOF GmbH  
Joachim-Jungius-Strasse 9  
18059 Rostock  
Germany  
Tel.: +49 381 8011-3002  
Fax: +49 381 8011-3009  
E-Mail: [info@innoproof.de](mailto:info@innoproof.de)  
URL: [www.innoproof.de/en](http://www.innoproof.de/en)  
CEOs: Dr. Carmen Zietz and PD Dr. Daniel Klüß  
HRB 13286 Amtsgericht Rostock  
Tax ID: 079/111/04584  
USt.Id-No.: DE301735203



INNOPROOF GmbH is accredited by the German Accreditation Body DAkkS according to DIN EN ISO/IEC 17025:2018.



The accreditation is valid for all testing services included in the certificate annex D-PL-20691-01-00.



INNOPROOF

