Testing Machines and Testing Systems for

Biomechanics, Orthopedics, Dental and Biomaterial Applications

Zwick / Roell

Testing for biomechanics, orthopedics, dental and biomaterial applications

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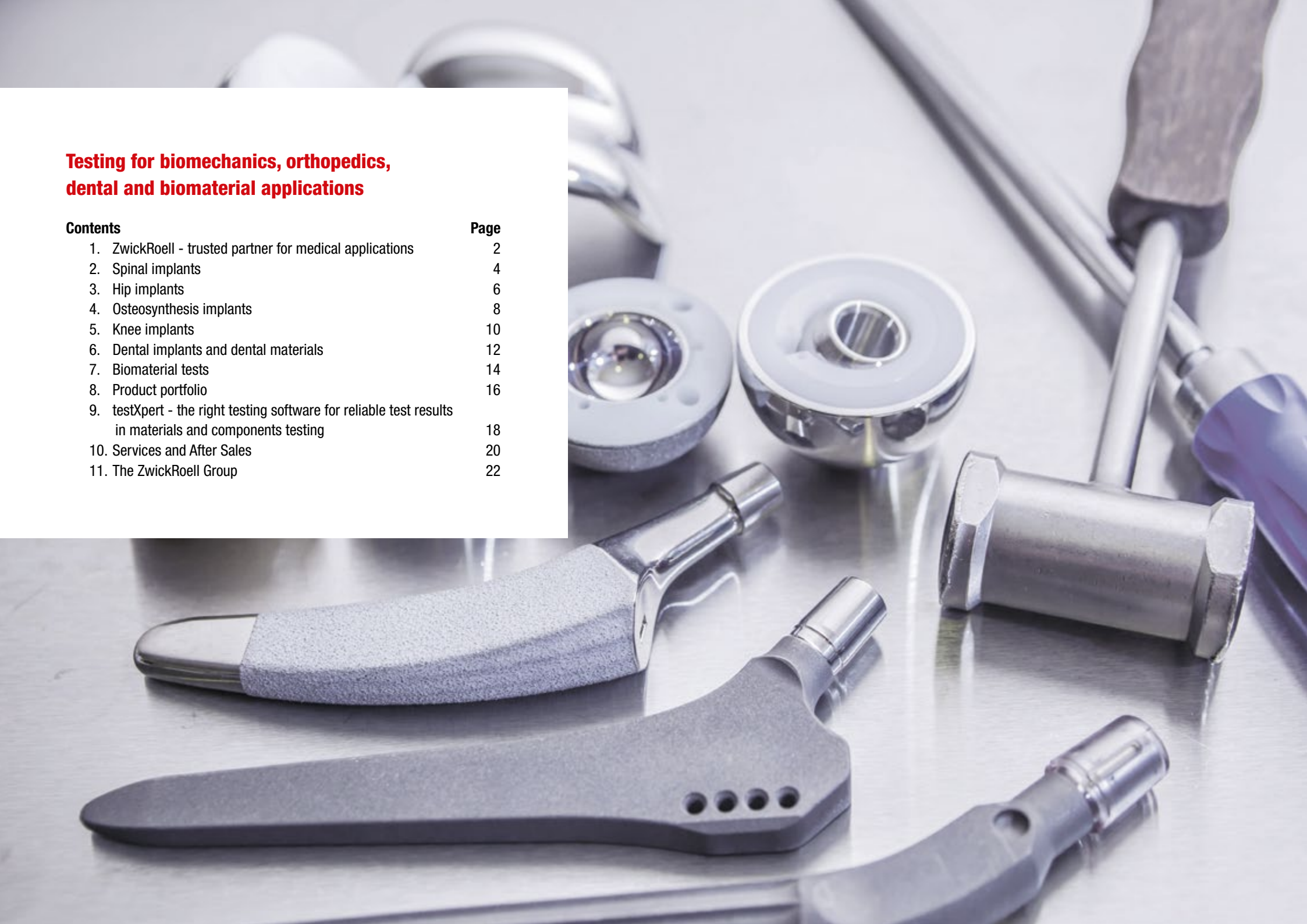
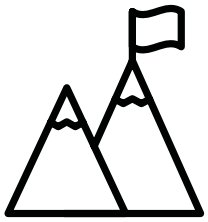


1. ZwickRoell – your trusted partner for medical applications

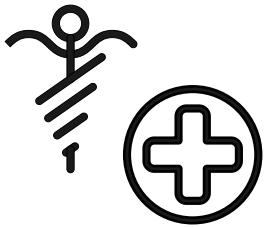


50+ years

of experience in the medical industry

Connectivity and digitalization— let us help lead you into the future.

Smart products and networking are here to stay in the medical and pharmaceutical industries. ZwickRoell offers innovative and flexible testing solutions, the product of close collaboration with research and industry quality management.



Testing solutions for all areas of biomechanics and orthopedics

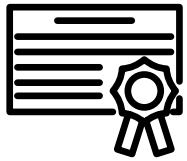
In addition to testing systems for fundamental challenges in the field of materials engineering, we offer comprehensive testing solutions for all relevant areas of biomechanics and orthopedics as well as for R&D and quality management.

FDA

Traceable and tamper-proof test results

Testing in Mediums

Do you want to test not only at ambient temperatures but rather also under physiologically representative conditions at 37 °C ? Our temperature control bath makes this possible. Our test fixtures are also available as stainless steel versions.



Intelligent testing solutions— from standard test methods to customized solutions

We offer the right solution for every one of your test tasks— whether you follow standard test methods or require customized test sequences, for changing test tasks within one testing system to fully automated, complex test sequences.

Statistical evaluation

We support you in the practical statistical evaluations of fatigue tests in the finite life range (high cycle fatigue) and in the transitional range to fatigue strength (long life fatigue).

New manufacturing methods and digitalization

3D printing is increasingly replacing conventional manufacturing processes and enabling completely new possibilities in the production of implants and medical products. This requires the digitalization and networking of processes. In close cooperation with research and industry, we offer innovative and flexible testing solutions.

The implants shown are systems from ulrich medical GmbH & Co KG. www.ulrichmedical.com

2. Testing of spinal implants

In order to ensure patient safety during the entire time the spinal implants are in the body, they are tested continuously and comprehensively. Numerous international standards describe corresponding static test methods and fatigue tests in various load directions.

Testing of screw and rod systems

Screw and rod systems are used to stabilize the spine and are used, for example, for spinal fusion surgery (spondylodesis). By means of rods, screws and/or hooks, individual vertebral bodies or even entire groups are connected to each other.

ASTM F2193 refers to the individual components. ASTM F1798 is relevant for testing subassemblies and connectors. The standards ASTM F1717, ASTM F2706 and ISO 12189 describe different static compression or flexure tests, pure or combined torsion tests and fatigue tests in a corpectomy model. During these tests, the implants are first mounted on a vertebral body replacement test block made of ultra-high-molecular-weight polyethylene (UMMWPE) material and installed in our standard-compliant test fixture. A special compensating bearing enables the required free rotation around the z-axis for tensile, compression and fatigue testing.

Test fixture for subassemblies to ASTM F1798 with temperature-controlled bath

Test fixture for spinal implant constructs to ASTM F1717 and ASTM F2706

Test fixture for spinal implant constructs to ISO 12189

Shear test device to ASTM F2077

Compression test kit to ASTM F2077

Testing of cages/intervertebral disc prostheses

Cages or intervertebral disc prostheses replace the natural disc and are placed between the affected vertebrae as placeholders. They are often made of titanium or polyetheretherketone (PEEK).

ASTM F2267 and ASTM F2077 describe a series of different quasi-static and oscillating tests for a mechanical comparison of vertebral implants. These include shear, compression, and torsion tests, which provide a simplified in-vitro simulation of the loads applied to a vertebral body implant.

The vertebral body implant is loaded in a corresponding ZwickRoell test fixture between two plastic (oscillating test) or metal blocks (quasi-static test). These are adapted to the outer contour of the vertebral body.

Testing of vertebral body replacement implants

Severe fractures or tumors can lead to vertebral body fractures. These are unstable and often require surgery to remove the damaged vertebra and replace it with an implant. In a vertebral body replacement implant, the affected vertebral body is replaced with a small metal cage filled with bone graft, which is then screwed into the adjacent healthy vertebra.

For quasi-static and oscillating torsion tests, the test fixtures for cages/ intervertebral disc prostheses can also be used.

LTM 3 THR electrodynamic testing machine for testing spinal implants

3. Testing of hip implants

Generally, a hip joint implant consists of the femoral stem, femoral head, acetabular shell and a plastic or ceramic inlay. Static and dynamic tests are performed either on the entire hip joint implant or on individual components.

Tests on the acetabular shell and inlay

Both the mechanical stability of the acetabular shell and the anchorage between the acetabular shell and the insert are key factors for the longevity of the hip implant. Using the test methods described in ASTM F1820, disassembly forces can be determined by axial push-out, offset pull-out, or lever-out and unscrewing. In addition, testing the deformation behavior of acetabular shells (ISO 7206-12) under 2-point flexural load plays an important role. The test fixtures required for this purpose can all be found in our portfolio.

Test fixture for lever-out test to ASTM F1820

2-point flexure test kit for testing acetabular shells to ISO 7206-12

Test fixture for testing hip endoprosthesis to ISO 7206-4

Test fixture for testing femoral heads to ISO 7206-13

Tests on the femoral stem

ISO 7206-4 and ISO 7206-6 describe fatigue testing of stemmed femoral components and the neck region of the stemmed femoral components of hip endoprostheses. First, the hip endoprosthesis must be embedded. The mechanical general requirements defined in the standard, including the orientation of the hip endoprosthesis to the test load, the embedding height and the load-application angle, can be defined precisely via a ZwickRoell embedding device.

A special test fixture is required for the test. The compensating bearing ensures a purely axial load on the femoral stem. The vibration load and the number of cycles differ depending on the design and length of the hip endoprosthesis and the part of the standard to be tested.

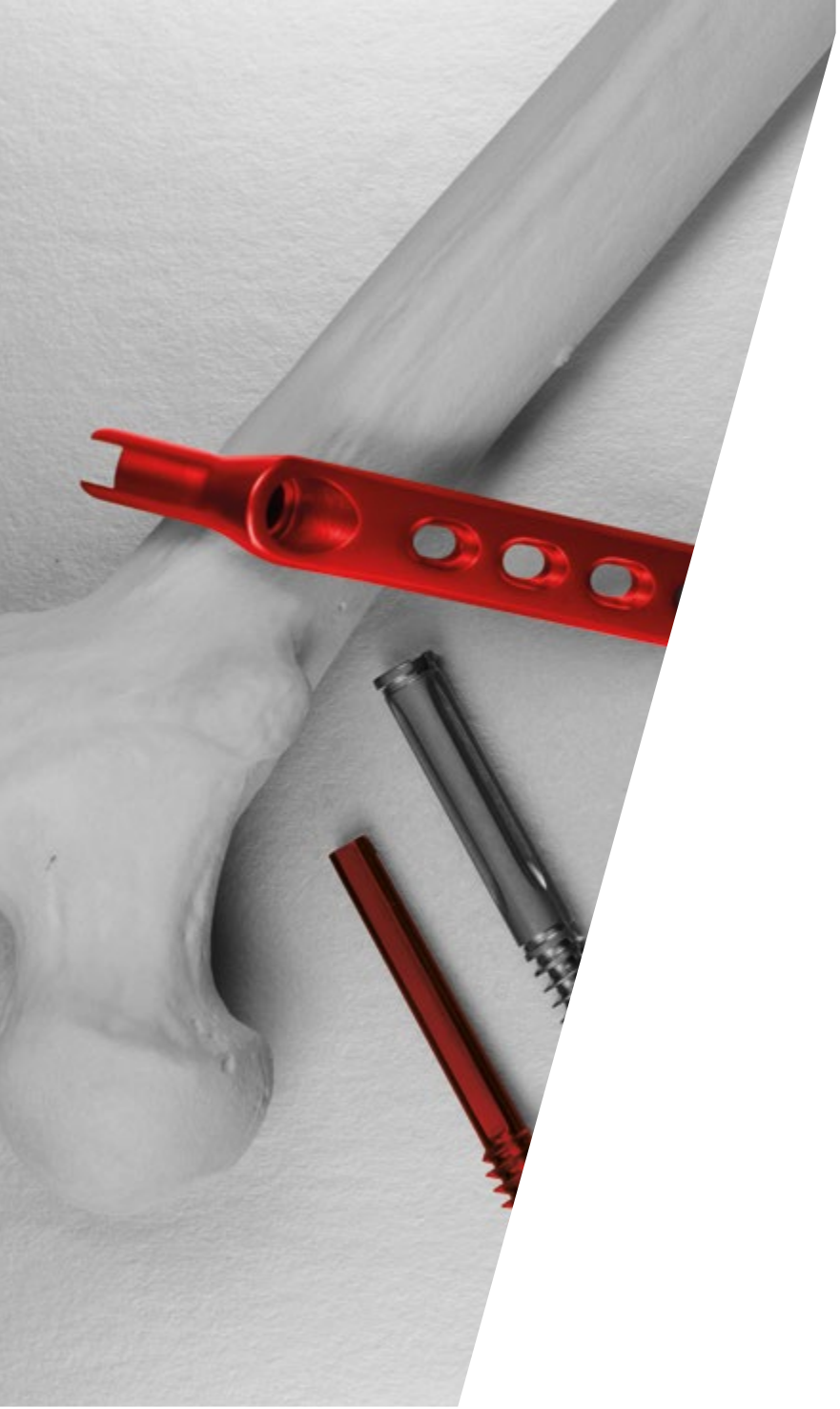
Tests on the femoral head

For testing modular femoral heads, i.e., with a conical connection between femoral head and stem, the components must first be inserted with a defined force. This can be done with the same testing system that will be used for the subsequent tests.

The test methods from ISO 7206-10 are used to determine the tensile force required to pull off the femoral head (also in ASTM F2009) and the compressive or breaking force required until the femoral head bursts. For the burst test, we strongly recommend a safety door to protect the operator. ISO 7206-13 describes a test method for determining the torque required to loosen the femoral head from the femoral stem.

In addition to the purely static load, the cyclic fatigue strength of ceramic femoral heads to ASTM F2345 is determined.

ZwickiLine Torsion testing machine for testing to ISO 7206-13



4. Testing of osteosynthesis/trauma implants

For stabilization of bone fractures, various osteosynthesis methods with plates, screws, intramedullary nails or wire are used.

The most important materials are stainless steel and various types of titanium alloys. In the meantime, absorbable trauma plates that degrade in the body are also being approved at an increasing rate, the requirements of which are described in the ASTM F2502 test standard. The trauma implants used vary widely in size and shape and depend on the bone structure and the anatomical location of the fracture.

Testing of bone plates

For bone plates, the structural bending stiffness or flexural strength is an important parameter. In the standards ASTM F382 and ISO 9585, this is determined by means of a static and dynamic 4-point flexure test. The ZwickRoell flexure test kit is designed for both quasi-static and pulsating compressive loads, and is universally applicable with easy adjustment of the lower and upper anvil diameter.

4-point flexure test kit for testing of bone plates to ASTM F382

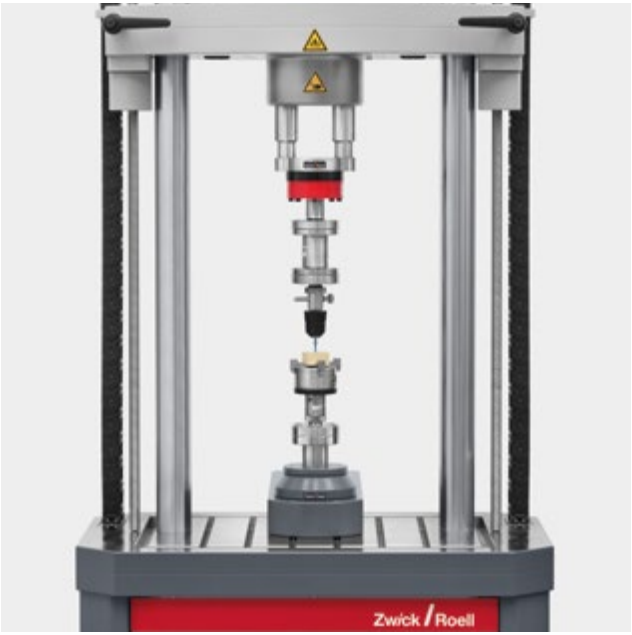
3-point flexure test on bone plates in a temperature-controlled bath

Testing of bone screws

Testing of bone screws to ASTM F543 refers to four mechanical tests in simplified clinical use. The primary properties include torsional strength, insertion and removal behavior, pull-out strength and self-tapping performance. ISO 6475 also describes torsion stiffness. The methods essentially specify a multi-axis movement with the application of a constant preload and introduction of a superimposed torsional motion. In particular, the determination of the "biting points" (Annex A4) for self-tapping screws is very complex in terms of rules. We support you fully with our preconfigured test sequences and the corresponding test fixtures.

Testing of intramedullary systems

ASTM F1264 summarizes the test methods for intramedullary systems. For determination of the static and dynamic strength and the torsion stiffness, the corresponding test fixtures and, if desired, preconfigured test sequences, are available.



Testing of bone screws to ASTM F543 with an LTM electrodynamic testing machine

4-point flexure test kit for testing of bone pins to ASTM F1264

Test fixture for testing external fixation devices to ASTM F1541

Testing of external fixation devices

In the case of open injuries with a high risk of infection, an external fixation device is often used. This temporarily stabilizes the bone parts. ASTM F1541 describes the various test methods for doing so. We have extensive experience in performing static and dynamic tests on individual components, on partial constructs or on the entire construct itself.

Testing of more osteosynthesis/trauma implants

In addition to the implants mentioned above, other implant systems are also used. These include clamps and wires. We are happy to discuss your needs and advise you on the available test standards and corresponding testing fixtures for mechanical characterization.

LTM 5 testing machine system for testing of knee implants to ISO 14879

5. Testing of knee implants

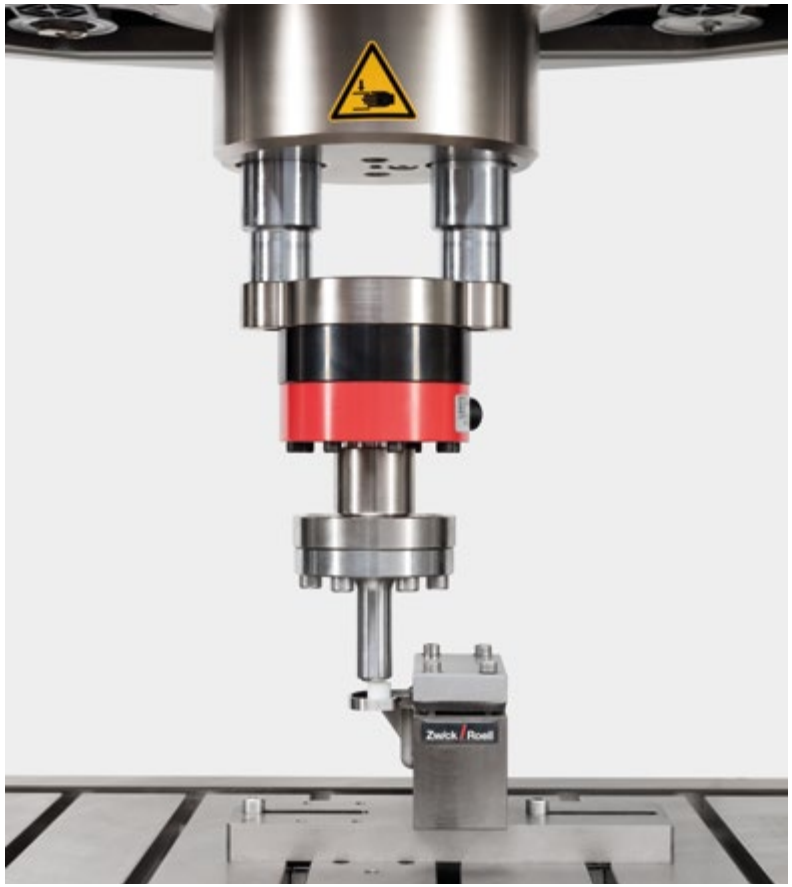
A knee implant is a complete (knee endoprosthesis) or partial (partial knee prosthesis) replacement of the knee joint, which is usually by an artificial joint. Knee endoprosthesis consists of a femoral component, a tibial component and a patellar component. The components of a knee endoprosthesis are constructed in such a way that a metal surface always slides on a plastic surface (sliding pairing). This makes the joint much more durable. The metal components consist of an alloy made of chromium, cobalt and molybdenum. It is stable, elastic and has good sliding properties to withstand a wide range of flexure and compressive loads.

Fatigue testing on the tibial tray of artificial knee joints

Schematic design of a knee endoprosthesis

Fatigue testing on tibial trays involves examining the effects of these large compressive loads as well as the loads generated by movement, with up to 10 million load changes. The fatigue test to ASTM F1800 and ISO 14879 is performed under “worst case” conditions under pulsating compressive loading applied to one end of the tibial tray.

Thanks to our universal test fixture, various tibial tray geometries can be tested. One half of the tibial tray is clamped and additionally and additionally cast with bone cement, for example. The other half is subjected to physiologically representative loads with a defined compression die. ISO 21536 as well as ASTM F2083 specify a test load of 900 N.



Test fixture for testing the tibial tray to ISO 14879

6. Testing of dental implants and dental materials

Testing of dental implants

Dental implants are used to replace teeth and consist of an implant body, an abutment, and an implant crown (suprastructure).

The testing of dental implants and their prefabricated implant abutments is performed by means of an oscillating, pulsating compressive load while maintaining the required degrees of freedom according to ISO 14801. This test enables a comparison of dental implants of different designs or sizes. Our special test fixture allows the implant axis to be adjusted to the test axis at an angle of 0° to 50° and allows for a quick-adjust 30° setting. Thus, dental implant systems with and without angled connection parts can be examined.

Testing of dental implants to ISO 14801 with an LTM1

Test fixture for testing to ISO 14801

DuraScan 20 G5 hardness tester for testing of dental materials

Testing of dental materials

Different types of dental materials are used for dentistry. These range from ceramics to gold to various types of plastics. In addition to health and optical aspects, these materials must also meet requirements in terms of strength, wear and durability.

The strength properties can be demonstrated, for example, via hardness tests. In addition to classic tensile tests, flexure tests play an important role. Therefore, 3- and 4-point tests are performed to determine flexural strength. Furthermore, there are special requirements for flexure tests on ceramics. International standards such as EN 843-1, ISO 6872 or ISO 4049 require special test fixtures to enable the specifications regarding the ideal loading of the specimen. A comprehensive portfolio of testing solutions is available for you to meet your testing requirements as ideally as possible.

We look forward to discussing your needs.

4-point flexure test kit for testing of dental ceramics

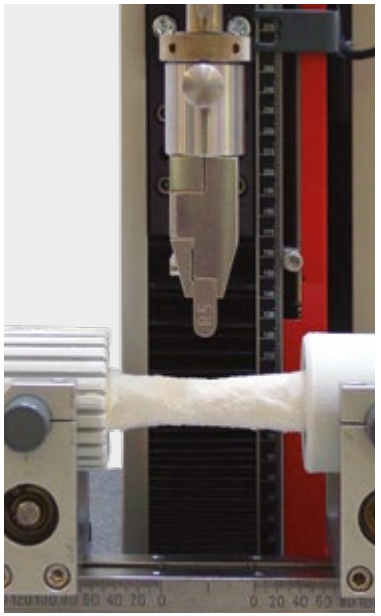
7. Testing of biomaterials

Understanding the human body is essential for the development of novel biomaterials. Research is being conducted into the structure, function and interaction of muscles, ligaments, skin and bones. Extensive testing is performed to determine mechanical properties, including fatigue testing in addition to simple tensile, compression and flexure tests. The investigation of multiaxial loads is possible through special test systems.

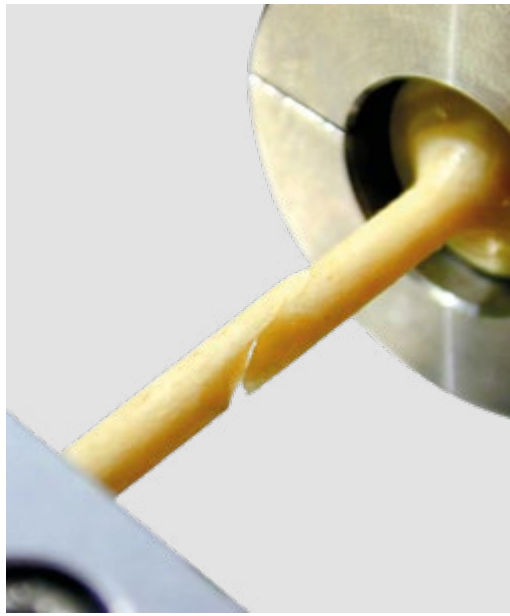
Testing of bones

Our skeleton has to withstand many stresses in daily life: Our bones are very stable and, at the same time, extremely elastic. In addition to compressive, they can also carry tensile and flexural loads. Tensile and compressive strength are determined in tensile and compression tests. Frequently, 3-point bending tests are also performed to determine the bending stiffness. They are performed on both human and animal bones from mice, rats, sheep or dogs and monkeys. Additionally, tests are performed in combination with implanted endoprostheses. The goal is to understand to what extent the implant stiffens the bone and thus creates what is referred to as a stress shielding effect.

Load test on human femur

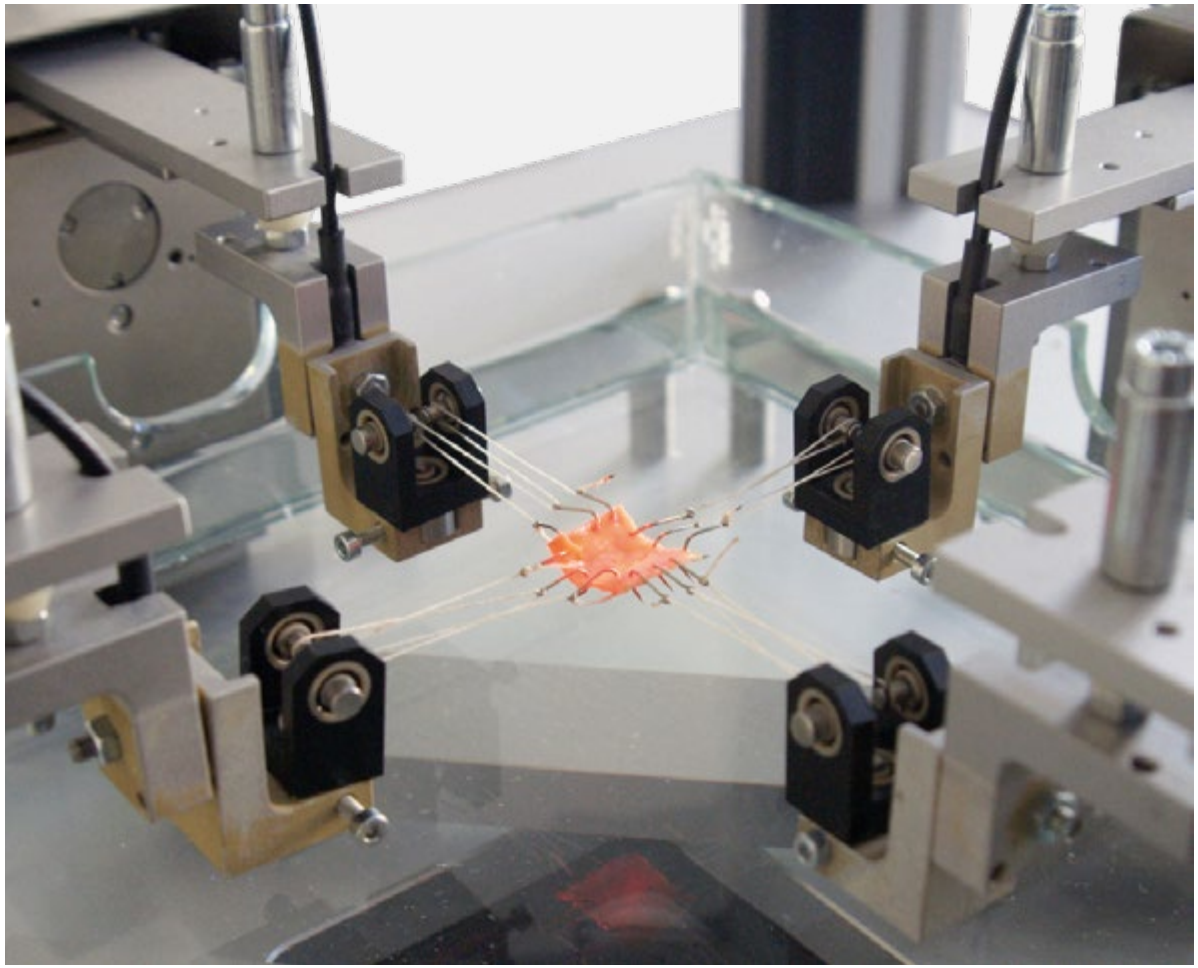


Flexure tests on sheep bones

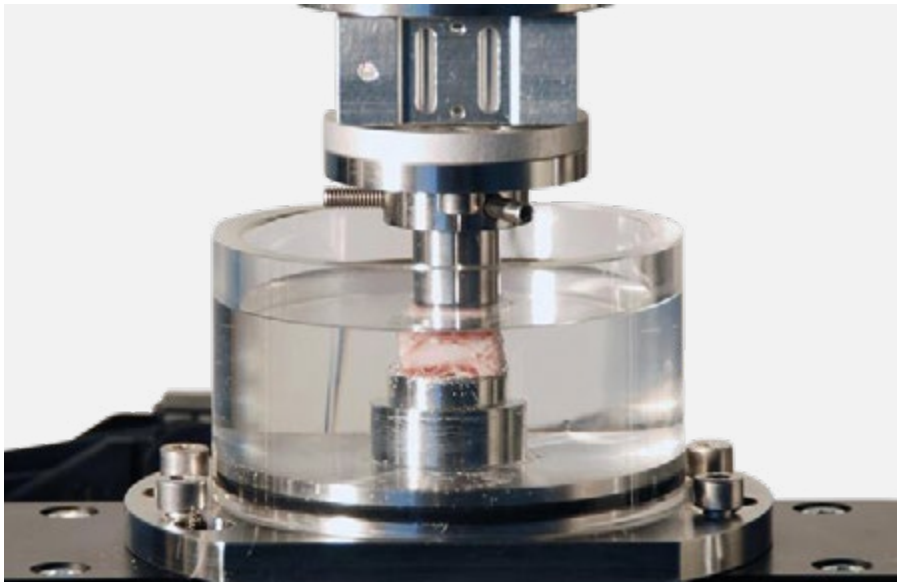


Testing of muscles, ligaments and tendons

Together with bones and muscles, tendons and ligaments form the human musculoskeletal system. The function of the muscles is to set parts of the body in motion. Tendons connect muscles to bone and transmit the force of muscles. Ligaments stabilize joints and connect bones to each other. Various tests are performed to understand the mechanical properties of the individual components or how they interact. ZwickRoell offers comprehensive testing solutions for both static and dynamic testing for this purpose.



Biaxial testing of soft tissue



Determination of the shear properties of soft tissue by means of a special triaxial testing fixture

Testing of soft tissues

Since biological tissues found in the body are continuously subjected to multiaxial loads, we have developed a special testing machine that applies multiaxial loads on the tissue specimen in order to investigate these loads. This allows unrestricted lateral movements and ensures homogeneous specimen deformation.

To determine the shear properties of soft biological (orthotropic) tissues, our test system was also developed for triaxial applications. For the mechanical characterization of vessels, such as cardiovascular tissues, arteries, esophagi and tracheae, is the application of an axial force (strain), a torsional force (rotation) and an internal pressure (inflation) is crucial. The strains are measured optically in this case, so as not to influence the sensitive structures of the specimens to be tested.


Hardness testing machines
Static materials testing machines

Biaxial and triaxial testing machines

Dynamic and fatigue testing machines


Zwick Roell
testXpert® III
Set up testing system
Configure test
Run test
View results
testControl II - The connection to testControl has been established.
User: Administrator Group: Administrator
Differentiation of specimen by color
Stress in MPa
Strain in %
274,000
5,000
434,444
PRÜFSYSTEM EINRICHTEN
PRÜFUNG KONFIGURIEREN
PRÜFUNG DURCHFÜHREN
PRÜFDATEN EXPORTIEREN
SET UP TESTING SYSTEM
CONFIGURE TEST
RUN TEST
EXPORT TEST DATA

8. testXpert - the right software for reliable test results in materials and components testing

Easy operation

Future-proof design

Flexible integration

testXpert allows you to efficiently run standardized tests, individual test sequences, and complex tests, such as those used in research and development."

Robert Strehle
Product Manager testXpert

Reliable and efficient testing

Reliable import and export of data

Ready for touch-operation

The intelligent wizard

>40,000
successful testXpert installations

Traceable and tamperproof test results to FDA 21 CFR Part 11

600+
standard test programs in testXpert


Zwick / Roell

9. Services and After Sales

Your trusted partner for the entire machine life cycle

We support you from every angle: Not only do we meet the widest range of test requirements, we support you throughout the entire life cycle of the testing system with tailored services—anywhere in the world.

- **DQ / IQ / OQ qualification service**
  An essential component of the validation of processes in the medical and pharmaceutical industries is the technical inspection of individual systems and devices. This qualification is also required for ZwickRoell testing systems used in the medical and pharmaceutical industries, as these are subject to various legal requirements or regulations (e.g., in accordance with AMWHV (German Ordinance for the Manufacture of Medicinal Products and Active Pharmaceutical Ingredients), EU GMP guidelines or FDA 21 CFR Part 11).

  ZwickRoell supports you during the qualification in the steps for DQ (design qualification), IQ (installation qualification), and OQ (operational qualification) processes by offering comprehensive and, if requested, individually tailored qualification documentation, as well as in the practical performance of qualification on site.

- **Consulting and application technology**
  Our experts will advise you in detail and according to your specific needs before you purchase a machine. Together, we will find the optimal testing solution for you.

- **Maintenance and inspection**
  Our regular maintenance and inspection services protect your machine from downtime and unnecessary costs associated with repair work.

- **Calibration**
  We operate calibration laboratories around the world. Among other standards, we perform calibrations to DAkkS, COFRAC, UKAS, A2LA, INMETRO, TÜRKAK and NABL.

- **Software services**
  Our experienced software engineers develop custom solutions for every task and every requirement.

- **Online services**
  We work continuously on the development of our digital services—from system monitoring to web demos, we support you digitally.

- **Hotline and customer support**
  Do you have questions or need support? Our service engineers are always happy to help. We will provide you with fast, expert assistance, whether it is regarding your testing machine or your testing software.

- **Modernization**
  Even testing systems from different manufacturers can be transformed into state-of-the-art equipment using modern measurement and control electronics, drive technology, and testXpert testing software.

1,700
employees worldwide

85
million tests performed by our machines annually

You can rely on us for custom-fit solutions and reliable test results.

For over 160 years.
And into the future.

Our more than 1,700 employees make sure of it with competence, openness and passion.

Klaus Cierocki
Chairman of the Board

CO_2 neutral
since 2014

€255
million in sales in 2021

>190
product and industry experts
Worldwide network of experts

We provide support for our customers in every country in which medical and pharmaceutical products are manufactured. Our qualified team of employees participates in continuous training in order to provide our customers around the world with optimal consultation and support.

BB 541 0.0323

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