KNIGHT
TESTING

Quality

Knight Testing is accredited to ISO 17025, the international standard of quality governing all types of laboratories. ISO 17025 includes all of the quality system requirements of ISO 13485 and ISO 9001, in addition to strict technical requirements relating to testing and calibration laboratories.

To ensure the accuracy and repeatability of testing data, Knight uses all MTS load frames, controllers, and software in its laboratory. MTS is a leader in the test equipment industry, supplying servo-hydraulic test frames to the most advanced laboratories in the world.

ANAB
ANSI National Accreditation Board
ACCREDITED
ISO/IEC 17025
TESTING LABORATORY

MTS®

Common Orthopaedic Test Methods:

Hip Prostheses

ISO 7206
- Part 4: Stemmed femoral components
- Part 6: Head and neck region of stemmed femoral components
- Part 10: Determination of resistance to static load of modular femoral heads
- Part 12: Deformation test method for acetabular shells

ASTM F 1820-22: Disassembly of Modular Acetabular Devices
ASTM F 2009-20: Axial Disassembly Force of Taper Connections of Modular Prostheses

Knee Prostheses

ASTM F 1800-22: Cyclic Fatigue Testing of Metal Tibial Tray Components
ASTM F 1223-20: Total Knee Replacement Constraint

Spinal Implants

ASTM F 1717-21: Spinal Implant constructs in a Vertebrectomy Model
ASTM F 2077-22: Intervertebral Body Fusion Devices
ASTM F 1798-21: Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
ASTM F 2706-18: Occipital-Cervical and OCT Spinal Implant Constructs
ASTM F 2193-20: Components Used in the Surgical Fixation of the Spinal Skeletal System

Trauma/Extremities/Dental

ISO 14801:2016 — Endosseous Dental Implants
ASTM F 2028-17: Dynamic Evaluation of Glenoid Loosening
ASTM F 382-17: Metallic Bone Plates
ASTM F 384-17: Metallic Angled Orthopaedic Fracture Fixation Devices
ASTM F 1264-16: Intramediary Fixation Devices
ASTM F 564-17: Metallic Bone Staples

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Knight Testing is an ISO 17025 accredited independent test laboratory focusing on mechanical testing for orthopedic devices. Drawing on decades of mechanical testing experience, Knight offers a wealth of knowledge and world-class laboratory facilities. We are proud to provide testing and engineering services to top-tier orthopedic OEMs and start-up companies alike. Our service offering includes:

Mechanical test services
- ISO 17025 accredited test methods for regulatory submission
- Multi-axis loading (axial and torsion, orthogonal loading)
- Force, displacement, and strain control modes
- High speed video extensometer

Engineering services
- Test protocol development
- Predicate test data
- Failure analysis

Machine shop services
- In-house CNC machining (Mastercam/Haas)
- Fixture design (Solidworks)

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Specializing in Mechanical Testing for Orthopaedic Devices

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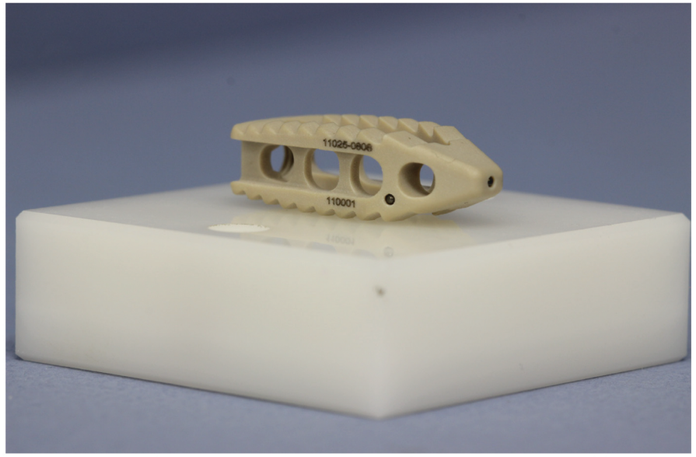
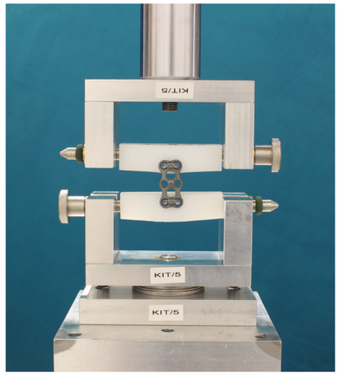
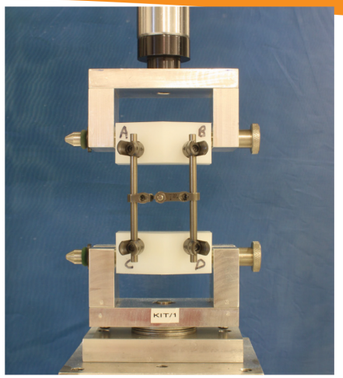
Spine



Spinal implant test standards can't keep up with the rapid pace of device development. You need a laboratory that can. In addition to routine spinal system tests, such as ASTM F1717 and ASTM F2077, Knight Testing can advise you on the most cost-effective test strategies for meeting FDA, ANVISA, MLHW, CE, or other international regulatory requirements, even in the absence of industry-standard test methods. We understand the importance of time to market. Knight has the capacity to get tests done quickly, but more importantly, the knowledge, experience, and customer focus to get tests done right.





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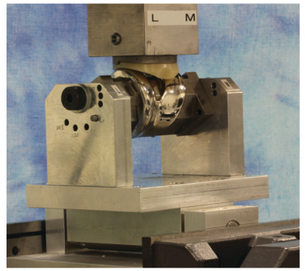
Hip

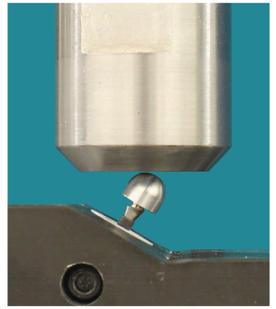
Simple hip test programs consist of proximal and distal stem fatigue (ISO 7206), taper disassembly strength (ASTM F2009), and liner disassembly (ASTM F1820). Consult Knight Testing for more complex situations, such as ceramic heads and liners, modular necks, or systems with additively manufactured components.

Knee

TKR systems undergo tibial tray fatigue (ASTM F1800), liner lock strength, tibiofemoral constraint, and contact area and stress evaluation. Additional testing may be required for posterior stabilized, high flexion, unicondylar, or systems with additive manufactured components.

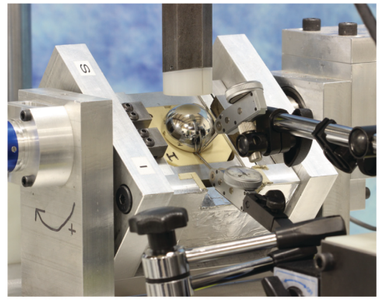


Dental

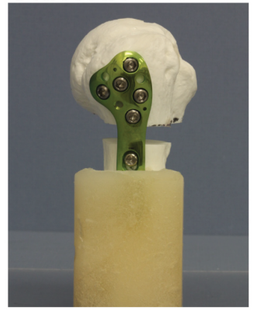


From head to toe, if it is used to repair or replace bone, Knight has tested it. We are well versed in plating and screw systems used for cranial and maxillofacial repair. Dental implants (ISO 14801) are commonly tested, including blade or root form and single-piece "mini" systems. Shoulder systems are tested for loosening in both reverse and anatomic configurations (ASTM F2028). Trauma plating systems for long bone fractures and extremity repair are tested for static and fatigue strength (ASTM F382), as well as bone screw integrity (ASTM F543).

Shoulder



Trauma



Foot and Ankle