SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

EMPIRICAL TESTING CORP.
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MECHANICAL

Valid To: January 31, 2020 Certificate Number: 2142.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on finished medical device products following ASTM, ISO, and/or FDA guidelines comprised of metals, alloys, and polymers:

The testing below is completed within these parameters:

Load	(0 to ± 25) kN
Torsion	(0 to ± 100) Nm
Stroke	(0 to 100) mm
Angular Displacement	(0 to 260) deg

Test	Test Methods
DENTAL	
Dentistry – Implants – Dynamic Fatigue Test for Endosseous Dental Implants	ISO 14801
EXTREMITIES	
Standard Specification and Test Method for Metallic Bone Plates	ASTM F382[2]
Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices	ASTM F384[2]
Standard Specification and Test Methods for Metallic Medical Bone Screws	ASTM F543
Standard Specification and Test Methods for Metallic Bone Staples	ASTM F564[2]
Standard Specification and Test Methods for Intramedullary Fixation Devices	ASTM F1264[2]

Test	Test Methods
Standard Specification and Test Methods for External Skeletal Fixation Devices	ASTM F1541[2]
Standard Test Method for Small Punch Testing of Ultra-High Molecular Weight Polyethylene Used in Surgical Implants	ASTM F2183 *(Withdrawn 2017)*
Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants	ASTM F2502
JOINT REPLACEMENT IMPLANTS	
Standard Test Method for Determination of Total Knee Replacement Constraint	ASTM F1223
Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials	ASTM F2118
Standard Specification for Articulating Total Wrist Implants Range of Motion of the Device Before Implantation	ASTM F1357, Section 6.3
Standard Specification for Shoulder Prostheses	ASTM F1378
Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices Method for Cleaning and Weighing of Specimens Only	ASTM F1714, Annex 4
Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants Range of Motion of the Device Before Implantation	ASTM F1781, Section 6.2
Standard Test Method for Cyclic Fatigue Testing of Tibial Tray Components of Total Knee Joint Replacements	ASTM F1800[2]
Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device	ASTM F1820
Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses	ASTM F2009
Standard Practice for Gravimetric Measurements of Polymeric Components for Wear Assessment Method for Cleaning and Weighing of Specimens Only	ASTM F2025, Annex 1
Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation	ASTM F2028
Implants for Surgery – Partial and Total Hip Joint Prostheses – Determination of Endurance Properties and Performance of Stemmed Femoral Components	ISO 7206-4
Implants for Surgery – Partial and Total Hip Joint Prostheses – Determination of Endurance Properties of Head and Neck Region of Stemmed Femoral Components	ISO 7206-6

Test	Test Method
Implants for Surgery - Partial and Total Hip Joint Prostheses - Endurance Performance of Stemmed Femoral Components with Application of Torsion	ISO 7206-8[1] *(Withdrawn 2011)*
SPINE	
Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	ASTM F1717
Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	ASTM F1798
Test Methods for Intervertebral Body Fusion Devices	ASTM F2077
Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System	ASTM F2193[2]
Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression	ASTM F2267
Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs	ASTM F2346
Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses	ASTM F2423
Standard Test Method for Static, Dynamic and Wear Assessment of Extra-Discal Spinal Motion Preserving Implants	ASTM F2624
Standard Practice for Functional and Wear Evaluation of Motion-Preserving Lumbar Total Facet Prostheses	ASTM F2694
Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model	ASTM F2706
Standard Guide for Mechanical and Functional Characterization of Nucleus Devices (Except Viscoelastic Testing)	ASTM F2789
Standard Practice for Static and Dynamic Characterization of Motion Preserving Lumbar Total Facet Prostheses	ASTM F2790
Implants for Surgery - Mechanical Testing of Implantable Spinal Devices – Fatigue Test Method for Spinal Implant Assemblies Using an Anterior Support	ISO 12189
Implants for Surgery - Wear of Total Intervertebral Spinal Disc Prostheses	ISO 18192

[1] This laboratory's scope contains withdrawn or superseded methods. As a clarifier, this indicates that the applicable method itself has been withdrawn or is now considered "historical" and not that the laboratory's accreditation for the method has been withdrawn.

[2] Equipment for this test is calibrated to ASTM E4 but the dynamic verification of the equipment per ASTM E467 is not performed.

Accredited Laboratory

A2LA has accredited

EMPIRICAL TESTING CORP.

Colorado Springs, CO

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated April 2017*).

Presented this 8th day of February 2018.

President and CEO
For the Accreditation Council
Certificate Number 2142.01
Valid to January 31, 2020
Revised 04/17/2018

For the types of tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.