



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

EMPIRICAL TESTING CORP.  
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MECHANICAL

Valid To: January 31, 2022

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 $\pm$ 100) kN
Torsion	(0 to $\pm$ 100) Nm
Stroke	(0 to 100) mm
Angular Displacement	(0 to 280) deg

**Test**

**Test Methods**

**GENERAL**

Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials	ASTM F2118
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Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems <sup>3</sup>	ASTM F2554
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Prosthetics- Structural testing of lower-limb prosthesis Requirements and test Methods	ISO 10328
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**Test**

**Test Methods**

**DENTAL**

Dentistry – Implants – Dynamic Fatigue Test for Endosseous Dental Implants

ISO 14801<sup>2</sup>

**EXTREMITIES**

Standard Specification and Test Method for Metallic Bone Plates

ASTM F382<sup>2</sup>

Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices

ASTM F384<sup>2</sup>

Standard Specification and Test Methods for Metallic Medical Bone Screws

ASTM F543

Standard Specification and Test Methods for Metallic Bone Staples

ASTM F564<sup>2</sup>

Standard Specification and Test Methods for Intramedullary Fixation Devices

ASTM F1264<sup>2</sup>

Standard Specification and Test Methods for External Skeletal Fixation Devices

ASTM F1541<sup>2</sup>

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(withdrawn  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 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 Specification for Resurfacing Patellar Prosthesis

ASTM F1672  
(section 6.3.1)

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

**Test****Test Methods**

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 <sup>2</sup>
Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device	ASTM F1820
Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear	ASTM F1829
Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface	ASTM F1875 (except 9.1.8 & 10.0)
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 <sup>2</sup>
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 <sup>2</sup>
Implants for Surgery - Partial and Total Hip Joint Prostheses - Endurance Performance of Stemmed Femoral Components with Application of Torsion	ISO 7206-8 <sup>1</sup> (Withdrawn 2011) <sup>2</sup>

**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



<u>Test</u>	<u>Test Methods</u>
Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System	ASTM F2193
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 <sup>2</sup>
Implants for Surgery - Wear of Total Intervertebral Spinal Disc Prostheses - Loading and Displacement Parameters for Wear Testing and Corresponding Environmental Conditions for Test	ISO 18192-1 <sup>2</sup>

**COATINGS, FRETTING, CORROSION**

Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	ASTM F1044
Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings	ASTM F1147
Standard Test Method for Shear and Bending Fatigue Testing Of Calcium Phosphate and Metallic and Composite Calcium Phosphate/Metallic Coatings	ASTM F1160



**Test**

**Test Methods**

Standard Test Method for Measuring Abrasion Resistance of  
Metallic Thermal Spray Coatings by Using the Taber Abraser

ASTM F1978

Standard Test Method for Conducting Cyclic Potentiodynamic  
Polarization Measurements to Determine the Corrosion Susceptibility of Small  
Implant Devices

ASTM F2129

Prosthetics- Structural testing of lower-limb prosthesis  
Requirements and test Methods

ISO 10328

<sup>1</sup> 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.

<sup>2</sup> Equipment for this test is calibrated to ASTM E4 but the dynamic verification of the equipment per ASTM E467 and/or ISO 4965 is not performed.

<sup>3</sup> This laboratory meets A2LA R104 – General Requirements: Accreditation of Field Testing and Field Calibration Laboratories for these tests or calibrations.





# 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 17025:2017 *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 21<sup>st</sup> day of February 2020.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 2142.01  
Valid to January 31, 2022

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