



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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MECHANICAL

Valid To: January 31, 2026

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 types of tests on finished medical device products following ASTM, ISO, and/or FDA guidelines comprised of metals, alloys, and polymers:

Test	Test Methods
<b><u>The testing below is completed within these parameters:</u></b>	
Load (0 to ± 100) kN Torsion (0 to ± 100) Nm Stroke (0 to 140) mm Angular Displacement (0 to 280) deg Screw Testing Machine Multiple Revolutions	<b>Fatigue Testing Procedure*</b>  <b>Static Testing Procedure*</b>
<b>GENERAL</b>	
Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials	ASTM F2118 <sup>2</sup>
Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems	ASTM F25541 <sup>1</sup>
Prosthetics- Structural Testing of Lower-Limb Prostheses Requirements and Test Methods	ISO 10328
<b>DENTAL</b>	
Dentistry - Torsion Test of Implant Body / Connecting Part Joints of Endosseous Dental Implant Systems	ISO/TS 13498
Dentistry - Implants – Dynamic Loading Test for Endosseous Dental Implants	ISO 14801

<b>DENTAL continued</b>	<b>Test Methods</b>
Dentistry – Screw Loosening Test Using Cyclic Torsional Loading for Implant Body / Implant Abutment Connection of Endosseous Dental Implants	ISO/TR 18130
<b>EXTREMITIES</b>	
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Test Method for Small Punch Testing of Ultra-High Molecular Weight Polyethylene Used in Surgical Implants	ASTM F2183 (withdrawn 2017)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
Implants for Surgery - Metal Bone Screws with Asymmetrical Thread and Spherical Under-Surface - Mechanical Requirements and Test Methods	ISO 6475
Implants for Surgery - Determination of Bending Strength and Stiffness of Bone Plates	ISO 9585
<b>JOINT REPLACEMENT IMPLANTS</b>	
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 – Contact Area and Contact Pressure Distribution	ASTM F1672 (section 6.3.1) (withdrawn 2023)
Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices-Method for Cleaning of Specimens	ASTM F1714, Annex 4

<b>JOINT REPLACEMENT IMPLANTS continued</b>	<b>Test Methods</b>
Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants Range of Motion of the Device Before Implantation	ASTM F1781, Section 6.3
Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	ASTM F1800 <sup>2</sup>
Standard Test Method for Determining the Forces for Disassembly of 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 of Specimens	ASTM F2025, Annex 1
Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation	ASTM F2028
Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis	ASTM F2580 <sup>2</sup>
Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops	ASTM F2722
Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate / Bearing Resistance to Dynamic Disassociation	ASTM F2723
Standard Test Method for Evaluating Mobile Bearing Knee Dislocation	ASTM F2724
Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion	ASTM F2777
Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement	ASTM F3090
Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements	ASTM F3140 <sup>2</sup>
Standard Test Method for Fatigue Testing of Total Knee Femoral Components Under Closing Conditions	ASTM F3210 <sup>2</sup>
Implants for Surgery – Partial and Total Hip Joint Prostheses – Part 4: 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 – Part 6: Endurance Properties Testing and Performance Requirements of Neck Region of Stemmed Femoral Components	ISO 7206-6 <sup>2</sup>
Implants for Surgery - Partial and Total Hip Joint Prostheses – Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion	ISO 7206-8 (withdrawn 2011)

<b>JOINT REPLACEMENT IMPLANTS continued</b>	<b>Test Methods</b>
Implants for Surgery — Partial and Total Hip-Joint Prostheses — Part 10: Determination of Resistance to Static Load of Modular Femoral Heads	ISO 7206-10
Implants for Surgery — Partial and Total Hip Joint Prostheses — Part 12: Deformation Test Method for Acetabular Shells	ISO 7206-12
Implants for Surgery — Partial and Total Hip Joint Prostheses — Part 13: Determination of Resistance to Torque of Head Fixation of Stemmed Femoral Components	ISO 7206-13
Implants for Surgery – Determination of Impact Resistance of Ceramic Femoral Heads for Hip Joint Prostheses	ISO 11491 (2017-07)
Implants for surgery - Total Knee-Joint Prostheses - Part 1: Determination of Endurance Properties of Knee Tibial Trays	ISO 14879-1
<b>SPINE</b>	
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 <sup>2</sup>
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 <sup>2</sup>
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 Single Level Spinal Constructs	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

<b>SPINE continued</b>	<b>Test Methods</b>
Standard Test Methods for Sacroiliac Joint Fusion Devices	ASTM F3574
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 <sup>2</sup>
<b>COATINGS, FRETTING, CORROSION</b>	
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 Medical and Composite Calcium Phosphate/Metallic Coatings	ASTM F1160 <sup>2</sup>
Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abrader	ASTM F1978
Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	ASTM F2129
<b>PACKAGING</b>	
Determining Integrity of Seals for Flexible Packaging by Visual Inspection	ASTM F1886
Method for Seal Strength of Flexible Barrier Materials	ASTM F88
Methods for Internal Pressurization Failure Resistance of Unrestrained Package	ASTM F1140
Standard Test method for Detecting Leaks in Nonporous Packaging or Flexible Materials by Dye Penetration	ASTM F3039
Method for Detecting Seal Leaks in Medical Packaging by Dye Penetration,	ASTM F1929
Accelerated Aging of Sterile Barrier Systems and devices	ASTM F1980
Method for Detecting Gross Leaks in Packaging (Bubble Test)	ASTM F2096

PACKAGING continued	Test Methods
Method for Burst Testing of Flexible Package Seals,	ASTM F2054
Standard Test Methods for Vibration Testing of Shipping Containers	ASTM D999
Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	ASTM D3078
Determining the Effects of High Altitude on Packaging Systems by Vacuum Method	ASTM D6653
Standard test Method for Seal Strength testing for Round Cups and Containers with Flexible Peelable Lids	ASTM F2824
Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	ASTM D4332
Strength and protective ability of packaged products from sudden shock/free-fall	ASTM D5276
Packaging Products less than 150 lbs	ISTA 2A
Method for Determining Compressive Resistance	ASTM D642

<sup>1</sup>This Laboratory performs field testing activities for these tests.

<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.

\*In-House Procedure



# Accredited Laboratory

A2LA has accredited

## Empirical Testing LLC. DBA Empirical Technologies

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 24<sup>th</sup> day of April 2024.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 2142.01  
Valid to January 31, 2026

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