Empirical Services & Capabilities

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Agenda

1. Empirical's Mission, Vision, and History
2. Service offerings: Machining, Testing, Consulting
3. Additional Services

EMPIRICAL TECHNOLOGIES

Empirical's Mission:

We provide solutions to your problems. Partnering with our clients to find the right testing solution for their needs across a wide range of testing solutions. By providing guidance, perspective, and our experience, we hope to help you make the best products that improve people's lives.

Empirical's Vision:

To be **THE** standard for mechanical testing.

Integrity · Innovation · Industry Experience

Empirical's History

EMPIRICAL
A FAMILY OF COMPANIES

- Empirical Testing Corp. – Dec. 1998
- Empirical Machine, LLC – May 2007
- Empirical Consulting, LLC – Feb. 2013

EMPIRICAL
TECHNOLOGIES CORP.

EMPIRICAL
TECHNOLOGIES
An ATS Company

- Empirical Technologies Corp - Feb. 2020
- Joined ATS Family – March 2022

EMPIRICAL
EUROPE

- Empirical Europe – Oct. 2022

EMPIRICAL TECHNOLOGIES

Our 3 Uniques:

1. **Trusted reputation**
2. **Comprehensive, proven solution**
3. **Extension of your team providing expert guidance & timely execution.**

Our Core Focus:

The **RIGHT** solution **EVERY** time.

The Empirical Guarantee:

Unbiased Expertise To Mitigate Your Testing Risk

EMPIRICAL TECHNOLOGIES

WE SOLVE YOUR PROBLEMS!

1. Industry Partnerships
2. Unbiased 3rd Party Testing
3. Cut Through the Red Tape
4. Get to Market Faster

CAN WE HELP?

Yes we can!

Empirical's Background

- Actively involved with ASTM and ISO – Lead development of several standards; Active in ILS activities
- Conducted FDA Educational Seminars (July 2019, Sep 2015, Aug 2014, Mar 2010, and June 2006)

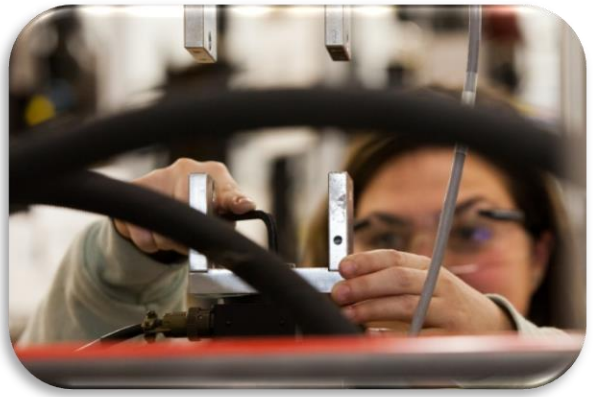
In-House Machining Capabilities

Specialists in:

- Over 25+ years specialized experience
- Works with our Engineering team for best test blocks & fixtures
- 3-4-5 axis CNC equipment

Empirical's Testing Scope of Accreditation

- **ISO/IEC 17025:2017** Accredited test facility (Certification #2142.01)
- Scope of Accreditation covers HEAD TO TOE (Minus Cardiovascular)
- Custom protocol development & testing
- Extensive experience with Class I, Class II, and Class III devices



Empirical's Testing Capabilities

- 30+ Test frames (axial & axial/torsion)
- Spinal and small implant wear testers
- Instrument & life cycle testing
- Screw testing
- Knee/Hip wear simulators (partnership)
- Wear debris analysis (partnership)
- Additive manufacturing IQ/OQ, lot release testing and validations

Empirical's Consulting Services & Experience

- FEA worse case analysis with validation (partnership)
- Custom protocol development
- Acceptance criteria & worse case analysis
- Regulatory support includes assisting with deficiencies, reviewing, or compiling submissions (2-5 submissions/month)
- Design History Files (DHF), review/clarify labelling needs/IFU/Surgical Technique to support submission
- Quality support includes auditing system for ISO 13485 gap analysis
- Validation services – sterilization, cleaning, dry time, cytotoxicity, etc.
- Team includes Former Director of multiple FDA divisions

RAC trained & certified | Over 250+ clearances since 2013

New Capabilities (With ATS Family of Companies)

- Additive Manufacturing – lot release testing (Chemical and Metallurgical)
- CT Micro Scan
- Failure Analysis
- Packaging Testing
- ISO 10993 -1, -13, -14, -15, -17, -18 (E&L Chemical Testing)

Why Choose Empirical Technologies?

Partnership & Experience

- A unique partnership to meet your customized needs
- Over 25+ years of experience with an industry-leading track record for success
- **Dependable**, **transparent**, and **useful** test reports made simple

Expert Comprehensive Services

- Combined industry expertise ensures that only the applicable tests are performed, providing confidence in our quoting accuracy for efficient testing.
- RAC trained & certified
- Over 250+ clearances since 2013
- 20%-30% faster to market, than industry average
- High ratio of submissions accepted without RTA

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Test	Test Methods
DENTAL	
Dentistry - Torsion test of implant body / connecting part joints of endosseous dental implant systems	ISO/TS 13498: 2011
Dentistry – Implants – Dynamic Fatigue Test for Endosseous Dental Implants	ISO 14801[2]
Dentistry - Screw loosening test using cyclic torsional loading for implant body / implant abutment connection of endosseous dental implants	ISO / TR 18130: 2016

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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]
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
Implants for surgery - Metal bone screws with asymmetrical thread and spherical under-surface - Mechanical requirements and test methods	ISO 6475: 1989
Implants for surgery - Determination of bending strength and stiffness of bone plates	ISO 9585: 1990

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

JOINT REPLACEMENT IMPLANTS	
Standard Test Method for Determination of Total Knee Replacement Constraint	ASTM F1781, Section 6.2
Standard Specification for Articulating Total Wrist Implants Range of Motion of the Device Before Implantation	ASTM F1800[1]
Standard Specification for Shoulder Prostheses	ASTM F1820
Standard Specification for Resurfacing Patellar Prosthesis	ASTM F1829
Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices Method for Cleaning and Weighing of Specimens Only	ASTM F1875 (except 9.1.8 & 10.0)
Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants Range of Motion of the Device Before Implantation	ASTM F2009

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

JOINT REPLACEMENT IMPLANTS	
Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	ASTM F2025, Annex 1
Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Device	ASTM F2028
Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear	ASTM F2580 (2013)
Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface	ASTM F2722-15
Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses	ASTM F2723 - 13a
Standard Practice for Gravimetric Measurements of Polymeric Components for Wear Assessment Method for Cleaning and Weighing of Specimens Only	ASTM F2025, Annex 1

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

JOINT REPLACEMENT IMPLANTS	
Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation	ASTM F2028
Standard Test Method for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis	ASTM F2580 (2013)
Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops	ASTM F2722-15
Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate / Bearing Resistance to Dynamic Disassociation	ASTM F2723 - 13a
Standard Test Method for Evaluating Mobile Bearing Knee Dislocation	ASTM F2724-08 (2014)
Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion	ASTM F2777 – 16
Implants for Surgery – Partial and Total Hip Joint Prostheses – Determination of Endurance Properties and Performance of Stemmed Femoral Components	ISO 7206-4[2]
Implants for Surgery – Partial and Total Hip Joint Prostheses – Endurance Properties Testing and Performance Requirements of Neck Region of Stemmed Femoral Components	ISO 7206-6[1]

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

JOINT REPLACEMENT IMPLANTS	
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: 2020
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 Protheses – Endurance Performance of Stemmed Femoral Components with Application of Torsion	ISO 7206-82

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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
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

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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

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

SPINE	
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
Implants for Surgery - Mechanical Testing of Implantable Spinal Devices – Fatigue Test Method for Spinal Implant Assemblies Using an Anterior Support	ISO 12189[1]
Implants for Surgery - Wear of Total Intervertebral Spinal Disc Prostheses	ISO 18192[1]

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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
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

What Else Does Empirical Offer?

Educational Courses

- One-day course product development engineers, "Applicable Test Methods for Spinal Implants"
- Two-day course for test engineers, "Concise, Repeatable, Traceable Test Program"
- "Learn it Today, Live it Tomorrow"

Where to find Empirical

- **Website:** www.EmpiricalTech.com
- **Social Media:** LinkedIn Facebook
- Dawn Lissy, **Contributing E-Writer** for MPO/ODT Magazines
- **Clients Site Visits**

Visit us in beautiful Colorado Springs, CO

EMPIRICAL
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Thank you for your time.

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Learn more at **www.EmpiricalTech.com** and connect with our team on **LinkedIn**