



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

EXPONENT, INC.¹
25 N 38th Street Suite 700
Philadelphia, PA 19104
Ryan Siskey Phone: 215 594 8896
Email: rsiskey@exponent.com

MECHANICAL

Valid To: June 30, 2025

Certificate Number: 2561.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory at the location listed above, *as well as the two satellite laboratory locations listed below*, to perform the following types of tests on the following materials: medical grade plastics, metals and biomaterials, medical consumables, tissue and medical devices in conformance with the U.S. FDA Good Laboratory Practice (GLP) Regulations per 21 CFR 58²:

Testing is completed for the following parameters within the ranges specified below:

<u>Parameter</u>	<u>Range [Units]</u>
Load:	0 to ± 30 [kN]
Displacement:	0 to ± 100 [mm]
Torque:	0 to ± 100 [Nm]
Angle:	0 to 360 [$^{\circ}$]
Pressure:	0 to 500 [psi]
Flow:	0 to 22 [L/min]

<u>Test</u>	<u>Test Method(s)</u>
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Electrochemical Tests:

Corrosion Susceptibility	ASTM F2129
Evaluation of Galvanic Corrosion	ASTM F3044
Potentiostatic and Potentiodynamic Anodic Polarization Measurements	ASTM G5 ⁸
Fretting Corrosion of Modular Orthopedic Components	ASTM F1875

Biotribology:

Spinal Implant Wear Rate	ASTM F2423, F3295; ISO 18192-1
Knee Implant Wear Rate	ISO 14243-1, -2, -3
Material Wear Rate	ASTM F732

Test**Test Method(s)*****Biotribology (continued):***

Particle Analysis

ASTM F1877

Tissue Characterization:Mechanical Characterization of
Cadaveric and Animal TissueSOP.160³, 053³, 116³

MicroCT Imaging and Analysis

SOP.286³

Tissue Ball Burst Testing

SOP.287³***Device Specific Tests:***

Bone Screw Testing

ASTM F543

Static and Dynamic Characterization
of Spinal Constructs

ASTM F1717

Mechanical Methods for Intervertebral
Body Fusion Devices

ASTM F2077

Subsidence Testing

ASTM F2267

Mechanical Characterization of Total
Disc Replacements

ASTM F2346

Push-out Testing

ASTM Draft Guide Dated Aug 29, 2000;
SOP.357³

Hip Rim Impingement

ASTM F2582

Total Hip Disassembly

ASTM F1820

Axial Disassembly Force of Taper
Connections and Modular Prostheses

ASTM F2009

Breast Implant Fatigue

ISO 14607 Annex C

Sample Preparation and Conditioning:

Accelerated Shelf Aging

ASTM F1980

Accelerated Aging

ASTM F2003

Implant Characterization:

Characterization of Retrieved Implants

SOP.200³; ASTM F561; ISO 12891

SEM and EDS

ASTM E1508, E766; SOP.213³Surface Characterization Using a Zygo
White Light InterferometerSOP.011^{3,5}

Test**Test Method(s)*****Implant Characterization (continued):***

Photomicrographs	ASTM E883; SOP.264 ³
Taper Measurement Using a Talyrond	ASTM F3129; SOP.309 ³
MicroCT Imaging and Analysis	SOP.286 ³

Cardiovascular Device Characterization:

Peripheral Stent Testing (MAPS)	ASTM F2942, F2477; SOP.342 ³
Heart Valve Pulse Duplication	ISO 5840-1, -2, -3
Heart Valve Durability	ISO 5840-1, -2, -3

Spectroscopy/Chemical Tests:

FTIR	ASTM E1252, E334; SOP.081 ³
Hydroperoxide Index	SOP.064 ^{3, 4} , SOP.347 ³
Oxidation Index	ASTM F2102; SOP.347 ³
Trans-Vinylene Index	ASTM F2381; SOP.347 ³
UHMWPE Crystallinity Index	ASTM F2102; SOP.347 ³
PEEK Crystallinity Index	ASTM F2778; SOP.256 ³

Biomaterials Testing:

Tensile	ASTM D638, E8
Compression Modulus	ASTM D695, F451
IZOD Impact	ASTM F648 (Annex A1), D256
Poisson's Ratio Testing	SOP.006 ³
Small Punch	ASTM F2183, F2977
Fatigue Crack Propagation	ASTM E647
Nitinol Tensile Testing	ASTM F2516
Bending of Bone Cement	ISO 5833
Fatigue Life of Bone Cement	ASTM F2118
Coefficient of Friction	ASTM D1894

<u>Test</u>	<u>Test Method(s)</u>
<i>Biomaterials Testing (continued):</i>	
Density using Helium Pycnometer	SOP.244
Preparation of Metallographic Specimens	ASTM E3
Standard Practice for Microetching Metals and Alloys	ASTM E407
Standard Test Method for Tension Testing of Calcium Phosphate and Metallic	ASTM F1147
Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	ASTM F1044
Standard Test Method for Shear and Bending Fatigue of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	ASTM F1160
<i>Hydroxyapatite Testing:</i>	
Dissolution Testing	SOP.348 ^{3, 6} ; ASTM F1926
Solubility	SOP.348 ^{3, 6}
<i>Textiles:</i>	
Ball Burst Testing	ASTM D6797
<i>Syringes, Needles and Related Equipment-Conical Fittings/Lock Fittings⁹:</i>	
Gauging	ISO 594/1, 4.1, 5.1
Liquid Leakage	ISO 80369-7; ISO 594/1, 4.2, 5.2; ISO 594/2, 4.2, 5.2, 5.3
Air Leakage	ISO 80369-7; ISO 594/1, 4.3, 5.3
Separation Force	ISO 80369-7; ISO 594/1, 4.4, 5.4; ISO 594/2, 4.3, 5.4
Stress Cracking	ISO 80369-7; ISO 594/1, 4.5, 5.5; ISO 594/2, 4.7, 5.8
Unscrewing Torque	ISO 80369-7; ISO 594/2, 4.4, 5.5
Ease of Assembly	ISO 594/2, 4.5, 5.6
Resistance to Overriding	ISO 80369-7; ISO 594/2, 4.6, 5.7

Test

Test Method(s)

Catheters:

Tensile Testing

ISO 10555-1 Annex B

Leak Testing

ISO 10555-1 Annex C

Gravity Flow

ISO 10555-1 Annex E

Burst Testing

ISO 10555-1 Annex F

Consumer Product Testing:

Football Glove Testing

SFIA Specification FBG - V.001 - 2015

Condom Testing

ASTM D3492

EXPONENT¹
MRI
University of Pennsylvania
3600 Civic Center Blvd Philadelphia, PA 19104

<u>Test</u>	<u>Test Method(s)</u>
<i>Passive Device MRI Testing:</i>	
Artifacts	ASTM F2119
Induced Force and Displacement	ASTM F2052
Induced RF Heating ⁷	ASTM F2182
Induced Torque	ASTM F2213
<i>Active Device MRI Testing:</i>	
RF Heating ⁷	ISO 10974: Clause 8
Gradient Heating ⁷	ISO 10974: Clause 9
Vibration	ISO 10974: Clause 10
Induced Force	ISO 10974: Clause 11
Induced Torque	ISO 10974: Clause 12
RF Unintended Stimulation ⁷	ISO 10974: Clause 15
Gradient Unintended Stimulation ⁷	ISO 10974: Clause 13
Static Field Malfunction	ISO 10974: Clause 14
RF Malfunction ⁷	ISO 10974: Clause 15
Gradient Malfunction ⁷	ISO 10974: Clause 16
Combined Fields Malfunction	ISO 10974: Clause 17
<i>General MRI:</i>	
MRI Safety Labeling	ASTM F2503
MRI Modeling	SOP.398

EXPONENT¹
Liz Smith
Thomas Jefferson Department of Radiology
111 S. 11th St. Suite 300, Philadelphia, PA 19107

Test

Test Method(s)

Device Imaging

Radiopacity

ASTM F640

¹This accreditation covers testing performed at all laboratories listed above.

²The materials testing standards listed on this scope of accreditation may be used for both medical and non-medical plastics and metals.

³In-House method

Literature References:

⁴D. C. Mazzucco, J. Dumbleton, and S. M. Kurtz, "Can accelerate aqueous aging simulate in vivo oxidation of gamma-sterilized UHMWPE?," J. Biomed Water Res B Appl Biomater, vol. 79, pp 79-85, 2006.

⁵S. M. Kurtz, J. Pelaza, R. Siskey, and M. L. Villarraga, "Analysis of a retrieved polyethylene total disc replacement component," Spine J, vol. 5, pp 344-50, 2005

⁶FDA Guidance: 510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants (February 27, 1997)

⁷Method utilizes RF and/or gradient coils found in the main laboratory.

⁸This method is used as a quality control method for the CAB, not used for reporting.

⁹ISO 591-1 and ISO 594-2 are withdrawn and still used in CAB operating procedures



Accredited Laboratory

A2LA has accredited

EXPONENT, INC.

Philadelphia, PA

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 22nd day of September 2023.

A blue ink signature of Mr. Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2561.01
Valid to June 30, 2025

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