



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

EXPONENT, INC.¹
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MECHANICAL

Valid To: June 30, 2023

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 three satellite laboratory locations listed below*, to perform the following 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:	<u>0 to ± 30 [kN]</u>
Displacement:	<u>0 to ±100 [mm]</u>
Torque:	<u>0 to ±100 [Nm]</u>
Angle:	<u>0 to 360 [°]</u>
Pressure:	<u>0 to 500 psi</u>
Flow:	<u>0 to 22 L/min</u>

Test

Test Method(s)

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



<u>Test</u>	<u>Test Method(s)</u>
<i>Biotribology (continued):</i>	
Particle Analysis	ASTM F1877
Dynamic Light Scattering (DLS)	ASTM E2865, ASTM E2490
<i>Tissue Characterization:</i>	
Mechanical Characterization of Cadaveric and Animal Tissue	SOP.160 ³ , 053 ³ , 116 ³
MicroCT Imaging and Analysis	SOP.286 ³
Tissue Ball Burst Testing	SOP.287 ³
<i>Device Specific Tests:</i>	
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.357 ³
Hip Rim Impingement	ASTM F2582
Total Hip Disassembly	ASTM F1820
Breast Implant Fatigue	ISO 14607 Annex C
<i>Sample Preparation and Conditioning:</i>	
Accelerated Shelf Aging	ASTM F1980
Accelerated Aging	ASTM F2003
<i>Implant Characterization:</i>	
Characterization of Retrieved Implants	SOP.200 ³ ; ASTM F561; ISO 12891
SEM and EDS	ASTM E1508, E766 SOP.213 ³
Surface Characterization Using a Zygo White Light Interferometer	SOP.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, ASTM 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; ASTM 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
<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
<i>Catheters:</i>	
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
<i>Consumer Product Testing:</i>	
Football Glove Testing	SFIA Specification FBG - V.001 - 2015

¹This accreditation covers testing performed at the main laboratory listed above, and the satellite laboratories listed below.

EXPONENT
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>	
<u>RF Heating</u> ⁷	<u>ISO 10974: Clause 8</u>
Gradient Heating ⁷	<u>ISO 10974: Clause 9</u>
Vibration	<u>ISO 10974: Clause 10</u>
Induced Force	<u>ISO 10974: Clause 11</u>
Induced Torque	<u>ISO 10974: Clause 12</u>
RF Unintended Stimulation ⁷	<u>ISO 10974: Clause 15</u>
Gradient Unintended Stimulation ⁷	<u>ISO 10974: Clause 13</u>
Static Field Malfunction	<u>ISO 10974: Clause 14</u>
RF Malfunction ⁷	<u>ISO 10974: Clause 15</u>
Gradient Malfunction ⁷	<u>ISO 10974: Clause 16</u>
Combined Fields Malfunction	<u>ISO 10974: Clause 17</u>
<i>General MRI:</i>	
MRI Safety Labeling	ASTM F2503
MRI Modeling	SOP.398

EXPONENT
Liz Smith
Department of Radiology
111 S. 11th St., Philadelphia, PA 19107

<u>Test</u>	<u>Test Method(s)</u>
<i>Device Imaging</i>	
Radiopacity	ASTM F640

EXPONENT
Steve Kurtz
Drexel University
3141 Chestnut Street, Philadelphia, PA 19104

<u>Test</u>	<u>Test Method(s)</u>
<i>Spectroscopy/Chemical Tests:</i>	
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

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. Pelozo, 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.

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

⁹ ISO 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 11th day of August 2021.

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

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2561.01
Valid to June 30, 2023

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