



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ORTHOKINETIC TESTING TECHNOLOGIES, LLC
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MECHANICAL

Valid To: April 30, 2023

Certificate Number: 3140.01

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 devices comprised of titanium, stainless steel, PEEK, PEEK with carbon fibers and ceramics and/or allograft materials.

<u>Test</u>	<u>Test Method¹</u>
Metallic Bone Plates	ASTM F382
Metallic Angled Orthopedic Fracture Fixation Devices	ASTM F384
Metallic Medical Bone Screws	ASTM F543
Metallic Bone Staples	ASTM F564 ²
Intramedullary Fixation Devices	ASTM F1264 ²
Spinal Implant Constructs in a Vertebrectomy Model	ASTM F1717
Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	ASTM F1798
External Skeletal Fixation Devices	ASTM F1541
Cranial Traction Tongs and Halo External Spinal Immobilization Devices (excluding section 13 Test Method for Magnetic Resonance Imaging (MRI))	ASTM F1831
Intervertebral Body Fusion Devices	ASTM F2077
Components Used in the Surgical Fixation of the Spinal Skeletal System	ASTM F2193 ²

Test**Test Method¹**

Load Induced Subsidence of Intervertebral Body Fusion
Device Under Static Axial Compression

ASTM F2267

Static and Dynamic Characterization of Spinal Artificial Discs

ASTM F2346

Occipital-Cervical and Occipital-Cervical-Thoracic Spinal
Implant Constructs in a Vertebrectomy Model

ASTM F2706

Dentistry – Implants – Dynamic Fatigue Testing for Endosseous
Dental Implants

ISO 14801

¹ When the date, edition, version, etc. is not identified in the scope of accreditation, laboratories may use the version that immediately precedes the current version for a period of one year from the date of publication of the standard measurement method, per part C., Section 1 of A2LA *R101 - General Requirements- Accreditation of ISO-IEC 17025 Laboratories*.

² Equipment for this test is calibrated to ASTM E4 but the dynamic verification of the equipment per ASTM E467 is not performed.





Accredited Laboratory

A2LA has accredited

ORTHOKINETIC TESTING TECHNOLOGIES, LLC

Southport, NC

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 21st day of July 2021.

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

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3140.01
Valid to April 30, 2023

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