SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

EXCELEN CENTER FOR BONE AND JOINT RESESEARCH AND EDUCATION
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MECHANICAL TESTING

Valid to: June 30, 2021 Certificate Number: 3786.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following in vitro biomechanical tests on medical devices:

TEST TYPE[1]:	RANGE(s):	METHOD(s):
Uni-axial tension	Axial force: 0 - 15 kN Axial displacement: 0 - 100 mm	ASTM D882
Uni-axial compression	Axial force: 0 - 15 kN Axial displacement: 0 - 100 mm	ASTM D695
Intramedullary fixation devices testing (4-point bending, torsion)	Axial force: 0 – 15 kN Axial displacement: 0 - 100 mm Torque: 0 - 56 Nm	ASTM F1264; ASTM F2183
Spinal implant constructs in a vertebrectomy model testing (compression bending, torsion)	Axial force: 0 – 15 kN Axial displacement: 0 - 100 mm Angular displacement: 140° Torque: 0 - 56 Nm Cyclic frequency: up to 100 Hz	ASTM F1717
Metallic medical bone screws testing (torsion, pull-out)	Axial force: 0 – 15 kN Axial displacement: 0 - 100 mm Angular displacement: 140° Torque: 0 - 56 Nm	ASTM F543
Subsidence of spinal devices	Axial force: 0 - 15 kN Axial displacement: 0 - 100 mm	ASTM F2267
Six-degree-of-freedom spine flexibility testing	Axial displacement: 0 -100 mm Axial rotation: 140° Flexion/Extension rotation: 50° Lateral Bending rotation: 50° Axial force: 0 - 4500 N Torques: 0 - 20 Nm Cyclic frequency: up to 2 Hz	Wilke HJ, Wenger K, Claes L. Testing criteria for spinal implants: recommendations for the standardization of in vitro stability testing of spinal implants. European Spine Journal 1998 (7), pp 148-154.

[1] This laboratory also uses customer supplied specifications and/or methods directly related to the testing technologies and parameters listed above.

WITHDRAWN

Accredited Laboratory

A2LA has accredited

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Minneapolis, MN

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*).

WITHDRAWN

Presented this 19th day of June 2019.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3786.01
Valid to June 30, 2021

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