



THE AMERICAN ASSOCIATION FOR
LABORATORY ACCREDITATION

ACCREDITED LABORATORY

A2LA has accredited

MED INSTITUTE

West Lafayette, IN

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *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 18 June 2005*).



Presented this 8th day of July 2008.

A handwritten signature in black ink, appearing to read "Peter Abney".

President
For the Accreditation Council
Certificate Number 2194.01
Valid to June 30, 2010

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

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

MED INSTITUTE
1 Geddes Way
West Lafayette, IN 47906
Colleen Tennyson Phone: 765 463 7537

MECHANICAL

Valid To: June 30, 2010

Certificate Number: 2194.01

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

<u>Test</u>	<u>Test Method</u>
Immersion Corrosion Testing	Internal document ACOR-716, ACOR-100; ISO 25539-1-Ammendment 1
Electrochemical Corrosion Testing	Internal document ECOR-001; ASTM F2129; ISO 25539-1-Ammendment 1
*Pulsatile Fatigue Testing	Internal document FATG-300, 320; ASTM 2477; ISO 25539-1-Ammendment 1
Tensile Testing (up to 5000N) Stress/Strain Maximum Force	Internal document PULT- 202,204,205,210,211; ISO 10555; ASTM E8; ISO 25539-1-Ammendment 1;
Torque Testing	Internal document TORQ-553; ISO 25539-1-Ammendment 1
Particulate Matter Generation	Internal document PART-01, 02, 03, 04;USP Monograph (788)
*Bone Cement Testing	Internal document BC-100, 200, 300, 700, 710, 900; ISO 5833 (annex C, D and F); ASTM D638
*Bench Deployment Testing	Internal document DPLY-01, 02,03; ASTM F2081, ASTM F2079; ISO 25539-1-Ammendment-1

Test

Test Method

Electrosurgical Accessory Electrical Testing

Internal document ECT-491;
ANSI/AAMI HF18 EN /IED;
60601-2-2,60601-2-18

*Physical Bench Examination and Mechanical Bench Measurements

Internal document EXAM-100; MEAS-825, 829, 830, 832; ABRD-100; ISO 7198, 5084;
ISO 25539-1-Ammendment 1

Fatigue testing (Flat Plate, Low and High Cycle Longitudinal, Bending, Axial, Torsional)

Internal document
FATG-401, 500,
600,610,700,710,800,900

Flow Testing

Internal document
FLOW-100, 302,307;ISO 7198,
ISO 25539-1-Ammendment-1

Pressure Testing

Internal document PRES-191, 195,197;
ISO 7198,25539-1-Ammendment 1

Securement Testing

Internal document
MEAS-100; ASTM 2394

Radial Force Testing

Internal document
RF-300

Compression Testing

Internal document COMP-220;
ISO 7198; 25539-1-Ammendment 1

*Radiographic activity, when performed as part of these tests, is performed at:

Perdue University
Lynn Hall
625 Harrison St.
West Lafayette, IN 47906