



THE AMERICAN ASSOCIATION FOR  
LABORATORY ACCREDITATION

## ACCREDITED LABORATORY

A2LA has accredited

### **MEDICAL DEVICE TESTING SERVICES**

**Minnetonka, MN**

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 8 January 2009*).



Presented this 13<sup>th</sup> day of May 2009.

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

President

For the Accreditation Council

Certificate Number 2783.01

Valid to May 31, 2011

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

MEDICAL DEVICE TESTING SERVICES  
6121 Baker Road, Suite 101  
Minnetonka, MN 55345  
Marcie Wiese Phone: 952-933-1152 x10

MECHANICAL

Valid To: May 31, 2011

Certificate Number: 2783.01

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:

<b><u>Test</u></b>	<b><u>Test Method</u></b>
In-Vitro Pulsatile Durability Testing of Vascular Stents	ASTM F2477-07* ISO 25539-1-Amendment 1 ISO 7198:1998 99128
In-Vitro Curved Pulsatile Durability Testing of Vascular Stents	ASTM F2477-07* ISO 25539-1-Amendment 1 ISO 7198:1998 99128
In-Vitro Simulated Gait Motion for Intravascular Devices	99134
In-Vitro Simulated Tension/Compression for Intravascular Devices	99134
In-Vitro Simulated Torsion/Rotation for Intravascular Devices	99134
In-Vitro Simulated Bending for Intravascular Devices	99134
<i>Medical Device Mechanical Testing:</i>	
Determination of Circumferential Tensile Strength	ISO 7198:1998; 8.3.1 ISO 25539-1-Amendment 1; E.5.3.9
Determination of Longitudinal Strength	ISO 7198:1998; 8.3.2 ISO 25539-1-Amendment 1; E.5.3.12
Determination of Kink Diameter/Radius	ISO 7198:1998; 8.9
Determination of Dynamic Compliance	ISO 7198:1998; 8.10
Crush Resistance	ISO 25539- Amendment 1; E.5.3.10
Migration Resistance	ISO 25539- Amendment 1; E.5.3.13
Pull Test for Modular Components	ISO 25539- Amendment 1; E.5.3.14
Strength of Stent Attachment to System to Graft Compression	ISO 25539- Amendment 1; E.5.3.17 ISO 25539- Amendment 1; E.5.3.11

\* Other Methods Used Per Customer Specifications