SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

COOK RESEARCH INCORPORATED (CRI)
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MECHANICAL

Valid To: June 30, 2020 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:

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Abrasion	Abrasion Testing	ASTM D4966 Lab Developed Method MART-100
Bend and Free Recovery	Bend and Free Recovery	ASTM F2082 Lab Developed Method BFR-100
Corrosion	Immersion Corrosion Testing	ASTM G31 BS EN 1618 BS EN ISO 9626 BS ISO 16428 ISO 11070 ISO 10555-1 ISO 20696 ISO 20697 ISO 25539-1 Amd.1 ISO 25539-2 JIS T 3214 JIS T 3215 JIS T 3216 JIS T 3260 Lab Developed Method ACOR-716
	Electrochemical Corrosion Testing	ASTM F2129 ASTM F3044 ASTM G5 ASTM G59 ASTM G71 BS ISO 16428 ISO 25539-1 Amd.1 ISO 25539-2 Lab Developed Method ECOR-001

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GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Deployment[1]	Bench Deployment Testing of Balloon Expandable Stents	ASTM F2079 ISO 7198 ISO 10555-4 ISO 25539-1 Amd.1 ISO 25539-2 Lab Developed Method DPLY-01
	Bench Deployment Testing of Vascular Graft Components	ANSI/AAMI VP20 ASTM F2081 ISO 7198 ISO 25539-1 Amd.1 Lab Developed Method DPLY-02
	Bench Deployment Testing of Self-Expanding Implants	ASTM F2081 ISO 7198 ISO 25539-1 ISO 25539-2 ISO 25539-3 Lab Developed Method DPLY-03
Electrosurgical	Electrosurgical Accessory Electrical Testing	IEC 60601-2-2 (Section 201.8.7.3.101 - 201.8.8.3.104, 201.8.10.4.2) IEC 60601-2-18 (Section 201.11.101.2) Lab Developed Method ECT-491
Examination	Examination	ISO 7198 ISO 25539-3 Lab Developed Method EXAM-100
Fatigue	Pulsatile Fatigue Testing	ASTM F3211 ASTM F2477 ISO 7198 ISO 25539-1 ISO 25539-1 Amd.1 ISO 25539-2 Lab Developed Method FATG-320
	Flat Plate Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-2 ISO 25539-3 Lab Developed Method FATG-401
	Sling Radial Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 Lab Developed Method FATG-500

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Fatigue (continued)	Low Cycle Longitudinal Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 Lab Developed Method FATG-600
	Low Cycle Longitudinal Fatigue Testing of External Sutures	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 Lab Developed Method FATG-610
	Bending Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 Lab Developed Method FATG-700
	Longitudinal Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 Lab Developed Method FATG-800
	Torsional Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 Lab Developed Method FATG-900
Flow	Simulated Ureteral Flow Model Testing	ASTM F1828 ISO 10555-1 ISO 10555-2 ISO 20696 ISO 20697 Lab Developed Method FLOW-100
	Flow Testing	BS EN ISO 10555-1 BS EN 1616 BS EN 1618 BS EN 13868 ISO 20696 ISO 20697 Lab Developed Method FLOW-225

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Flow (continued)	Pressurized Leak and Water Permeability	ANSI/AAMI VP20 BS EN 1618 ISO 10555-1 ISO 10555-2 ISO 20696 ISO 20697 ISO 7198 ISO 25539-1 Lab Developed Method FLOW-302
Force	Compression Testing	ASTM F2606 ISO 7198 ISO 25539-1 ISO 25539-2 Lab Developed Method COMP-220
	Stent Securement	ASTM F2394 ISO 25539-2 Lab Developed Method MEAS-100
	Force Measurement	ISO 25539-1 Amd.1 ISO 25539-2 ISO 25539-3 Lab Developed Method MEAS-900
Particulate Counting	Particulate Counts of Endovascular Devices Using the Hiac Royco Liquid Particle Counter	USP 788 AAMI TIR42 Lab Developed Method PART-02
	Acute Simulated Use Particulate Counts of Endovascular Devices with Continuous Flow	Lab Developed Method PART-03
	Particulate Counts of Endovascular Devices during Pulsatile Fatigue	Lab Developed Method PART-04
	Particulate Counts of Endovascular Devices during Axial Fatigue	Lab Developed Method PART-05

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Pressure	Burst Pressure Testing	ANSI/AAMI VP20 ISO 7198 ISO 10555-1 ISO 10555-2 ISO 10555-4 ISO 20696 ISO 20697 ISO 25539-1 Amd.1 ISO 25539-2 ISO 25539-3 Lab Developed Method PRES-191
	Pressurized Dimensional Measurement	ANSI/AAMI VP20 ISO 7198 ISO 10555-2 ISO 10555-4 ISO 20696 ISO 20697 ISO 25539-1 Amd.1 ISO 25539-2 Lab Developed Method PRES-195
	Balloon Inflation/Deflation Time and Fatigue Testing	ANSI/AAMI VP20 ISO 7198 ISO 20696 ISO 20697 ISO 10555-2 ISO 10555-4 ISO 25539-1 Amd.1 ISO 25539-2 Lab Developed Method PRES-197
Tensile	Suture Retention Strength	ASTM E8 / E8M ISO 7198 Lab Developed Method PULT-202
	Circumferential Tensile Strength Testing	ISO 7198 Lab Developed Method PULT-204
	Longitudinal Tensile Strength Test of Tubular Graft Materials	ISO 7198 ISO 25539-1 Lab Developed Method PULT-205

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Tensile (*continued*)	Tensile Testing Maximum Force	ASTM E8 / E8M ASTM F1828 BS EN 1617 BS EN 1618 ISO 7198 ISO 11070 ISO 20696 ISO 20697 ISO 10555-1 ISO 25539-1 ISO 25539-2 ISO 25539-3 JIS T 3215 JIS T 3216 JIS T 3229 JIS T 3242 JIS T 3243 JIS T 3244 JIS T 3245 JIS T 3246 JIS T 3247 JIS T 3260 JIS T 3270 Lab Developed Method PULT-210
	Tensile Stress and Tensile Strain Testing	ASTM F2516 ASTM E8 / E8M Lab Developed Method PULT-211
Radiopacity[1]	Radiopacity Testing	ASTM F640 ISO 25539-1 ISO 25539-2 ISO 25539-3 Lab Developed Method RAD-01
Radial Force	Automated Radial Force	ASTM F3067 ISO 25539-1 ISO 25539-2 ISO 25539-3 Lab Developed Method RF-300
Torque	Acute Automated Torque Testing	ASTM A938 ISO 25539-1 ISO 25539-2 ISO 25539-3 Lab Developed Method TORQ-553

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
ISO 7198 Cardiovascular Implants and Extracorporeal Systems – Vascular Prostheses – Tubular Vascular Grafts and Vascular Patches	Visual Inspection	Section 8.7
	Porosity	Section 8.7.2.1.3
	Water Permeability	Section 8.7.2.1.4
	Integral Water Permeability/Leakage	Section 8.7.2.1.2
	Water Entry Pressure	Section 8.7.2.1.3
	Circumferential Tensile Strength	Section 8.7.2.2.2
	Longitudinal Tensile Strength	Section 8.7.2.2.4
	Pressurized Burst Strength	Section 8.7.2.2.5
	Length	Section 8.7.2.3
	Relaxed Internal Diameter	Section 8.7.2.4
	Pressurized Internal Diameter	Section 8.7.2.5
	Wall Thickness	Section 8.7.2.6
	Suture Retention Strength	Section 8.7.2.7
	Kink Diameter/Radius	Section 8.7.2.8
	Dynamic Radial Compliance	Section 8.7.2.9
ISO 10555-1 Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements	Test Method for Corrosion Resistance	Annex A
	Method for Determining Peak Tensile Force	Annex B
	Test Method for Liquid Leakage Under Pressure	Annex C
	Test Method for Air Leakage into Hub Assembly During Aspiration	Annex D
	Determination of Flowrate Through Catheter	Annex E
	Test for Burst Pressure under Static Conditions	Annex F
	Power Injection Test for Flowrate and Device Pressure	Annex G
ISO 10555-2 Intravascular Catheters – Sterile and Single-Use Catheters – Part 2: Angiographic Catheters	Test for Freedom from Leakage and Damage under High Static Pressure Conditions	Annex A
ISO 10555-4 Intravascular Catheters – Sterile and Single-Use Catheters – Part 4: Balloon Dilation Catheters	Test for Balloon Rated Burst Pressure	Annex A
	Balloon Fatigue Test for Freedom from Leakage and Damage on Inflation	Annex B
	Test for Balloon Deflation Time	Annex C
	Test for Balloon Diameter to Inflation Pressure	Annex D

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
ISO 25539-1 Cardiovascular Implants – Endovascular Devices – Part 1: Endovascular Prostheses Amendment 1: Test Methods Annex D	Dimension Verification of the Endovascular System	Section D.5.1.2
	Sizing-Related Testing	Section D.5.1.7
	Hemostasis	Section D.5.1.8
	Simulated Use	Section D.5.1.5
	Visibility	Section D.5.1.9
	Force to Deploy for Self-Expanding Endovascular Prostheses	Section D.5.1.4
	Balloon Deflation Time	Section D.5.1.1.2
	Balloon Rated Burst Pressure for Non-Compliant Balloons	Section D.5.1.1.1
	Balloon Volume to Burst	Section D.5.2.3
	Balloon Rated Fatigue	Section D.5.1.1.3
	Tensile Bond Strength	Section D.5.1.6
	Torsional Bond Strength	Section D.5.1.7
	Dimensional Verification of Implant	Section D.5.2.7.1
	Implant Diameter to Balloon Inflation Pressure (Balloon-Expandable Endovascular Prostheses)	Section D.5.2.7.2
	Implant Length to Diameter Relationship (Endovascular Prostheses that have Clinically Relevant Length Changes with Diameter Changes)	Section D.5.2.7.3
	Recoil (Balloon-Expandable Endovascular Prostheses)	Section D.5.2.7.4
	Integral Water Leakage	Section D.5.2.6.1
	Water Entry Pressure (Non-Textile Materials)	Section D.5.2.6.3
	Water Permeability (Textile Materials)	Section D.5.2.6.4
	Burst	Section D.5.2.8.1
	Crush Resistance to Perpendicularly Applied Load (Self-Expanding, Non-Aortic Endovascular Prostheses)	Section D.5.2.5.1
	Resistance to Kinking (Flexibility)	Section D.5.2.5.5
	Crush Resistance with Perpendicularly Applied Load (Balloon-Expandable Non-Aortic Endovascular Prostheses)	Section D.5.2.5.2
	Longitudinal Tensile Strength	Section D.5.2.8.3
	Migration Resistance	Section D.5.2.4.2
	Separation Force for Overlapping Endovascular Prostheses	Section D.5.2.4.3
	Radial Force (Self-Expanding Endovascular Prostheses)	Section D.5.2.5.4
	Strength After Repeated Puncture (Endovascular Prostheses for Vascular Access)	Section D.5.2.8.4

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
ISO 25539-1 Cardiovascular Implants – Endovascular Devices – Part 1: Endovascular Prostheses Amendment 1: Test Methods Annex D (continued)	Strength After Repeated Puncture (Endovascular Prostheses for Vascular Access)	Section D.5.2.8.4
	Strength of the Connection(s) Between the Graft Material and a Discrete Fixation System(s)	Section D.5.2.8.5
	Corrosion Assessment	Section D.5.2.1
	Fatigue and Durability Test – in Vitro Testing	Section D.5.2.3
ISO 25539-2 Cardiovascular Implants – Endovascular Devices – Part 2: Vascular Stents Annex D	Dimension Verification and Component Dimension Compatibility	Section D.5.1.1
	Profile/Diameter Test	Section D.5.1.2
	Simulative Use	Section D.5.1.3
	Visibility	Section D.5.1.4
	Force to Deploy	Section D.5.1.5
	Balloon Inflation and Deflation Time	Section D.5.1.6
	Balloon Rated Burst Pressure	Section D.5.1.7
	Balloon Rated Fatigue	Section D.5.1.8
	Bond Strength	Section D.5.2.1
	Torsional Bond Strength	Section D.5.2.2
	Stent Diameter to Balloon Inflation Pressure	Section D.5.3.1
	Dimensional Verification and Stent Length to Diameter Relationship	Section D.5.3.2
	Recoil	Section D.5.3.3
	Crush Resistance with Radially Applied Load	Section D.5.3.4
	Crush Resistance with Parallel Plates	Section D.5.3.5
	Flex/Kink	Section D.5.3.6
	Local Compression	Section D.5.3.7
	Radial Force	Section D.5.3.8
	Corrosion Assessment	Section D.5.3.9
	Fatigue Durability Test	Section D.5.3.10
	Dislodgment Force	Section D.5.3.12
	Dogboning	Section D.5.3.13
	Profile Effect/Flaring	Section D.5.3.14
	Acute Coating Integrity	Section D.5.3.16

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
ISO 25539-3 Cardiovascular Implants – Endovascular Devices – Part 3: Vena Cava Filters	Dimension Verification and Component Dimension Compatibility	D.5.1.1
	Simulated Use	D.5.1.2
	Force to Deploy	D.5.1.3
	Visibility	D.5.1.4
	Fatigue Durability Test	D.5.2.2
	Filter Dimensional Verification	D.5.2.3
	Filter Tensile Strength	D.5.2.4
	Migration Resistance	D.5.2.5
	Radial Force	D.5.2.6
	Visual Inspection	D.5.2.8
	Tensile Strength	D.5.3.1
	Torsional Bond Strength	D.5.3.2
	Catheter Burst	D.5.4.1
	Power Injection	D.5.4.2
	Tensile Strength	D.5.4.3
	Torsional Bond Strength	D.5.4.4
	Dimension Verification and Component Dimension Compatibility	D.5.5.1
	Simulated Use	D.5.5.2
	Force to Retrieve/Convert	D.5.5.3
	Visibility	D.5.5.4
	Tensile Strength	D.5.6.1
	Torsional Bond Strength	D.5.6.2
	Catheter Burst	D.5.7.1
	Power Injection	D.5.7.2
	Tensile Strength	D.5.7.3
	Torsional Bond Strength	D.5.7.4

[1] Radiographic activity, when performed as part of these tests, is performed at:

Purdue University
Lynn Hall
625 Harrison St.
West Lafayette, IN 47907

Purdue University
Martin Jischke Hall
206 S Martin Jischke Dr.
West Lafayette, IN 47907

I. Dimensional Testing[2]

Parameter	Range	Technique / Method
Thickness Measurement[3]	Up to 12.7 mm	Digimatic Indicator (Thickness Gauge) ISO 5084 ISO 7198 ISO 25539-1 Amd.1 Lab Developed Method MEAS-825
Kink Radius Testing[3]	(4.0 to 79.0) mm	Kink Radius Template BS EN 13868 ISO 20696 ISO 20697 ISO 7198 ISO 25539-1 Amd.1 ISO 25539-2 Lab Developed Method MEAS-829
Automated Dimensional Measurement[3]	Up to 50.8 mm	Laser Micrometer ISO 25539-1 Amd.1 ISO 25539-2 Lab Developed Method MEAS-832

[2] This laboratory does not offer commercial dimensional testing.

[3] This test is not equivalent to that of a calibration.

Accredited Laboratory

A2LA has accredited

COOK RESEARCH INCORPORATED (CRI)

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 17025:2017 *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 25th day of July 2018.

President and CEO
For the Accreditation Council
Certificate Number 2194.01
Valid to June 30, 2020

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