



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

COOK RESEARCH INCORPORATED (CRI)

1 Geddes Way

West Lafayette, IN 47906

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MECHANICAL

Valid To: June 30, 2026

Certificate Number: 2194.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the organization's compliance with Good Laboratory Practice (GLP) regulations per 21 CFR 58 requirements), 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

Bend and Free Recovery

Bend and Free Recovery

ASTM F2082
BFR-100 Lab Developed Method

Corrosion

Immersion Corrosion Testing

ASTM G31
ISO 9626
ISO 16428
ISO 11070
ISO 10555-1
ISO 20695
ISO 20696
ISO 20697
ISO 25539-1
ISO 25539-2
JIS T 3214
JIS T 3215
JIS T 3216
JIS T 3260
ACOR-716 Lab Developed Method
ASTM F2129
ASTM F3044
ASTM G5
ASTM G59
ASTM G71
ISO 16428
ISO 25539-1
ISO 25539-2
ECOR-001 Lab Developed Method

Electrochemical Corrosion Testing

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Deployment ¹	Bench Simulated Use and Deployment Testing	ISO 25539-1
		ISO 25539-2
Differential Scanning Calorimetry	Differential Scanning Calorimetry	ISO 25539-3
		DPLY-04 Lab Developed Method
		ASTM E1356
		ASTM F2004
Echogenicity Examination and Measurement	Ultrasound Visibility Testing Examination	DSC-438 Lab Developed Method
		ECHO-01 Lab Developed Method
		ISO 7198
		ISO 25539-1
		ISO 25539-2
		ISO 25539-3
		EXAM-100 Lab Developed Method
		ISO 5084
		ISO 7198
		ISO 25539-1
Fatigue	Thickness Measurement	MEAS-825 Lab Developed Method
		BS EN 13868
		ISO 7198
		ISO 20697
		ISO 25539-1
		ISO 25539-2
		ASTM F3505
		MEAS-829 Lab Developed Method
		ISO 25539-1
		ISO 25539-2
Fatigue	Kink Radius Measurement	ISO 25539-3
		MEAS-900 Lab Developed Method
		ASTM F3211
		ASTM F2477
		ISO 7198
		ISO 25539-1
		ISO 25539-2
		FATG-320 Lab Developed Method
		ASTM F3211
		ASTM F2942
Fatigue	Force Measurement	ISO 25539-2
		ISO 25539-3
		MEAS-900 Lab Developed Method
		ASTM F3211
		ASTM F2477
		ISO 7198
		ISO 25539-1
		ISO 25539-2
		FATG-320 Lab Developed Method
		ASTM F3211
Fatigue	Pulsatile Fatigue Testing	ASTM F2942
		ISO 25539-2
		ISO 25539-3
		FATG-401 Lab Developed Method
		ASTM F3211
		ASTM F2942
		ISO 25539-1
		ISO 25539-2
		ISO 25539-3
		ASTM F3211
Fatigue	Flat Plate Fatigue Testing	ASTM F2942
		ISO 25539-1
		ISO 25539-2
		ISO 25539-3
		FATG-401 Lab Developed Method
		ASTM F3211
		ASTM F2942
		ISO 25539-1
		ISO 25539-2
		ISO 25539-3
Fatigue	Axial Fatigue Testing	ASTM F3211
		ASTM F2942
		ISO 25539-1
		ISO 25539-2
		ISO 25539-3



GENERAL TESTS OR PROPERTIES MEASURED

SPECIFIC TESTS OR PROPERTIES MEASURED

SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED

Fatigue (*continued*)

Axial Fatigue Testing (*continued*):
-Sling Radial
-Low Cycle
-External Sutures
-Standard
Bending Fatigue Testing

FATG-500 Lab Developed Method
FATG-600 Lab Developed Method
FATG-610 Lab Developed Method

FATG-800 Lab Developed Method

Torsional Fatigue Testing

ASTM F3211
ASTM F2942 (Excluding A3)
ISO 25539-1
ISO 25539-2
ISO 25539-3
FATG-700 Lab Developed Method

Flow

Flow Testing

ASTM F3211
ASTM F2942
ISO 25539-1
ISO 25539-2
ISO 25539-3
FATG-900 Lab Developed Method
ISO 10555-1
BS EN 13868
ISO 7198
ISO 25539-1
ISO 25539-2
ISO 20695
ISO 20696
ISO 20697

Pressurized Flow and Water Permeability

FLOW-225 Lab Developed Method
ANSI/AAMI VP20
ISO 10555-1
ISO 20695
ISO 20696
ISO 20697
ISO 7198
ISO 25539-1

MRI Safety Evaluations²

Magnetically Induced Displacement Force; Magnetically Induced Torque; MR Image Artifacts; Radio Frequency Induced Heating

ASTM F1828
FLOW-302 Lab Developed Method
ASTM F2052
ASTM F2213
ASTM F2182
ASTM F2119
MRI-400 Lab Developed Method

Nonclinical Safety Evaluations³

Quantitative Computed Angiography
Histomorphometry

QCA-01 Lab Developed Method
HISTO-01 Lab Developed Method

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Particulate Counting	Particulate Counts of Endovascular Devices Using the Hiac Royco Liquid Particle Counter	USP 788
		AAMI TIR42 ISO 10555-1 ISO 25539-2 PART-02 Lab Developed Method
	Simulated Use Particulate Testing	USP 788 AAMI TIR42 ASTM F2743 ISO 10555-1 ISO 25539-2 PART-03 Lab Developed Method
		PART-04 Lab Developed Method
Power Injection	Particulate Counts of Endovascular Devices during Pulsatile Fatigue Power Injection Testing	ISO 10555-1 JIS T 3268 ISO 25539-3 POWR-864 Lab Developed Method
Pressure	Pressure Testing: Burst and Leakage	ANSI/AAMI VP20 ISO 7198 ISO 10555-1 ISO 10555-4 ISO 20697 ISO 25539-1 ISO 25539-2 ISO 25539-3 JIS T 3268 JIS T 3247 ISO 11070 PRES-191 Lab Developed Method
		ISO 7198
		ISO 10555-4
		ISO 20697
		ISO 25539-1
		ISO 25539-2
Pressurized Dimensional Measurement		ISO 7198 ISO 10555-4 ISO 25539-1 ISO 25539-2 ASTM F2081 PRES-195 Lab Developed Method
		ISO 7198
		ISO 10555-4
Tension and Compression	Balloon Inflation/Deflation Time and Fatigue Testing	ISO 10555-4 ISO 25539-1 ISO 25539-2 PRES-197 Lab Developed Method
		ISO 10555-4
		ISO 25539-1
		ISO 25539-2
Automated Axial Force and Strain Measurement		ASTM E8 / E8M ASTM F1828 ISO 20695 ISO 20696
		ASTM E8 / E8M
		ASTM F1828
		ISO 20695



**GENERAL TESTS OR
PROPERTIES MEASURED**

**SPECIFIC TESTS OR
PROPERTIES MEASURED**

**SPECIFICATION, STANDARD
METHOD, OR TECHNIQUE
USED**

Tension and Compression
(*continued*)

Automated Axial Force and
Strain Measurement (*continued*)

ISO 20697
ASTM F2516
ASTM F2606
ISO 7198
ISO 11070
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 3245
JIS T 3246
JIS T 3247
JIS T 3260
JIS T 3268
JIS T 3270

Radiopacity¹

Radiopacity Testing

PULT-210 Lab Developed Method
ASTM F640
ISO 25539-1
ISO 25539-2
ISO 25539-3

Radial Force

Automated Radial Force

RAD-01 Lab Developed Method
ASTM F3067
ISO 25539-1
ISO 25539-2
ISO 25539-3

Torque

Automated Torque Testing

RF-300 Lab Developed Method
ASTM A938
ISO 25539-1
ISO 25539-2
ISO 25539-3
TORQ-553 Lab Developed Method

¹ Radiopacity activity, when performed as part of these tests, is performed at Cook Research Inc. (CRI) or the following field location:

Purdue University, Martin Jischke Hall

² MRI activity, when performed as part of these tests, is performed at the following field locations:

Purdue Engineering MRI Facility
IU Health Arnett West Side Urgent Care

³ The *in vivo* phases of biological safety activity, when performed as part of these tests, are typically performed at the following locations:

Purdue University, Martin Jischke Hall
Synchrony Labs LLC



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 10th day of June 2024.

A blue ink signature of Mr. Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2194.01
Valid to June 30, 2026

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