

# Testing

& EVALUATION SERVICES



TEST EQUIPMENT




SILICONE VESSELS



SIMULATION SOLUTIONS

**BDC**  
LABORATORIES



*“Using a mix of their tried-and-true systems and new electromechanical components, BDC produced test equipment that precisely met our needs. In addition to being on scope and schedule, I was impressed by the thought that Ben McCloskey put into the GUI and overall usability of the system. He and Craig were a pleasure to work with.”*

— Test Equipment

*Working with the BDC Laboratories team is always a great experience. BDC’s level of expertise and knowledge in the areas of stent graft testing and hemodynamics are truly invaluable. Their range of capabilities from mock vessels, testing services and equipment design makes them a full service vendor that makes for seamless execution. BDC Laboratories capabilities and expertise has allowed me to accelerate my project and gain a greater understanding of our product.”*

— Testing Services

*“We recently purchased the LDT-1500 linear fatigue test machine from BDC Labs. Both the machine and the level of technical support were excellent. With a shorter lead time and a price that was a fraction of the cost of competitive machines from other vendors, we remain very pleased with our purchase.”*

— Test Equipment



## MISSION

The mission of BDC Laboratories is to offer products and services to the medical device industry that aid in functional evaluation of technologies as related to clinical outcomes.

## HISTORY

Biomedical Device Consultants was founded in 1977 by Steven Weinberg, Ph.D. as a consulting company to provide general R&D support services to the medical device community. In 1985, a GLP engineering testing laboratory was established to meet the growing needs of domestic and international clients. Craig Weinberg, Ph.D. joined the company in 2006 and under his leadership, BDC Laboratories embarked on a new chapter with expansion into numerous new services and products tailored to the evaluation of cardiac, endovascular, and vascular medical device technologies. As an industry leader today, BDC Laboratories provides support through our services and products for all aspects of development and evaluation in R&D activities, as well as regulatory submissions. With the support of BDC's services and products, our numerous clients have successfully navigated their device development and regulatory approvals from Early Feasibility Studies (EFS) to Investigational Device Exemption (IDE) to Premarket Approval (PMA).

## CUSTOMER SERVICE

Since inception, BDC Laboratories has held customer service in the highest regard. The BDC team routinely seeks opportunities to exceed our customer's expectations through various avenues such as: being attentive to our customer's needs; proactively engaging to ensure a complete understanding of a project's requirements; actively communicating throughout a project to ensure alignment; offering solutions to encountered technical challenges; and ensuring technical accuracy with every project and product delivered.

## CAPABILITIES

BDC Laboratories' portfolio is comprised of testing services, testing equipment, silicone mock vessels & anatomical models and simulated use solutions, facilitating a comprehensive experience for our clients.

To learn more about BDC, visit [BDCLabs.com](https://www.BDCLabs.com) or call **303.456.4665**



# The Ultimate Device Evaluation Partner

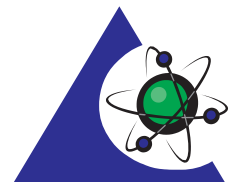
The BDC Laboratories' team has over 40 years of experience in medical device research, development, and design verification testing. Our focus is on functional, engineering based assessment of medical devices, including Class 2 and Class 3 implants.

BDC personnel actively participate in The American Association of Medical Instrumentation (AAMI), the International Standards Organization (ISO) and ASTM standard committees. As participants on these committees for structural heart, cardiac and endovascular technologies, the BDC team have a unique understanding of developing medical device testing and verification plans, along with the associated protocols and methods to support FDA, Notified Body and regulatory submissions worldwide. From this unique expertise, and leveraging the multiple divisions of BDC (testing services, test equipment, silicone vessels & anatomical models and simulation solutions), our team can truly become your comprehensive device evaluation and testing partner, at both the R&D and design verification stages of device development. BDC can provide support and services in:

- Risk assessment and device evaluation strategies
- Novel test method development and validation
- Tracking pathway design and manufacturing
- Test fixture design and manufacturing
- Device testing and evaluation, both acute bench testing and durability/fatigue studies
- Silicone vessel and anatomical model design and manufacturing
- Custom test system design and manufacturing

## ISO/IEC 17025:2017 Accredited

Recognizing our responsibility as a service provider to the medical device industry, BDC Laboratories is committed to providing the highest level of quality and technical accuracy for all our test services and product offerings. In alignment with this philosophy, BDC is an ISO/IEC 17025:2017 Accredited testing laboratory. ISO 17025 is an internationally recognized standard that outlines the general requirements for the competence of testing laboratories. By working with BDC as an Accredited laboratory, the regulatory authorities immediately appreciate the superior quality management system associated with your testing program and test data.



**PJLA  
Testing**

Accreditation #87132

# Technologies Routinely Evaluated

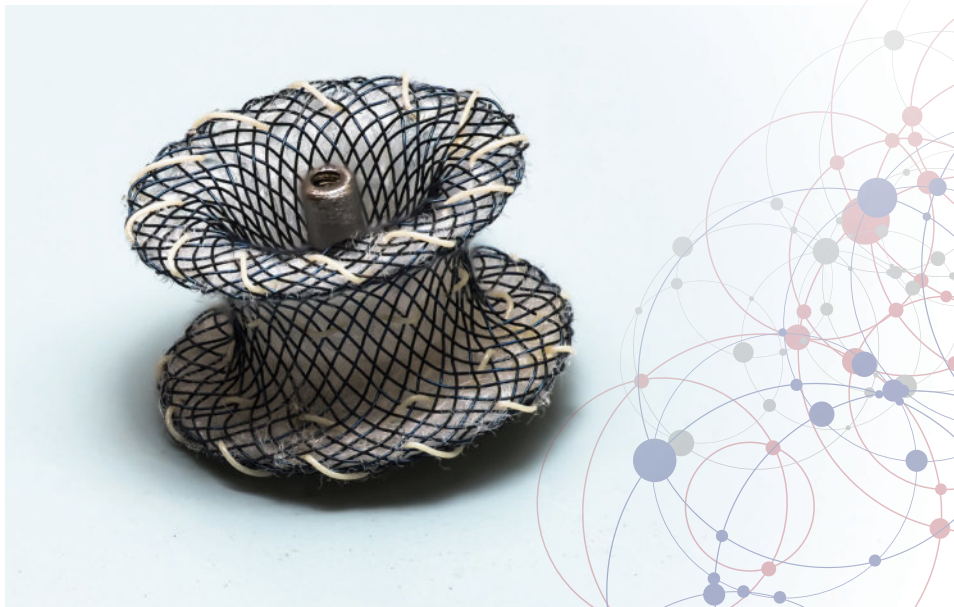
- Heart Valves
- Vascular Grafts
- Heart Valve Repair Devices
- Catheters
- Stent Grafts
- Vena Cava Filters
- Stents
- Guidewires
- Cardiac Occluders
- Dilators

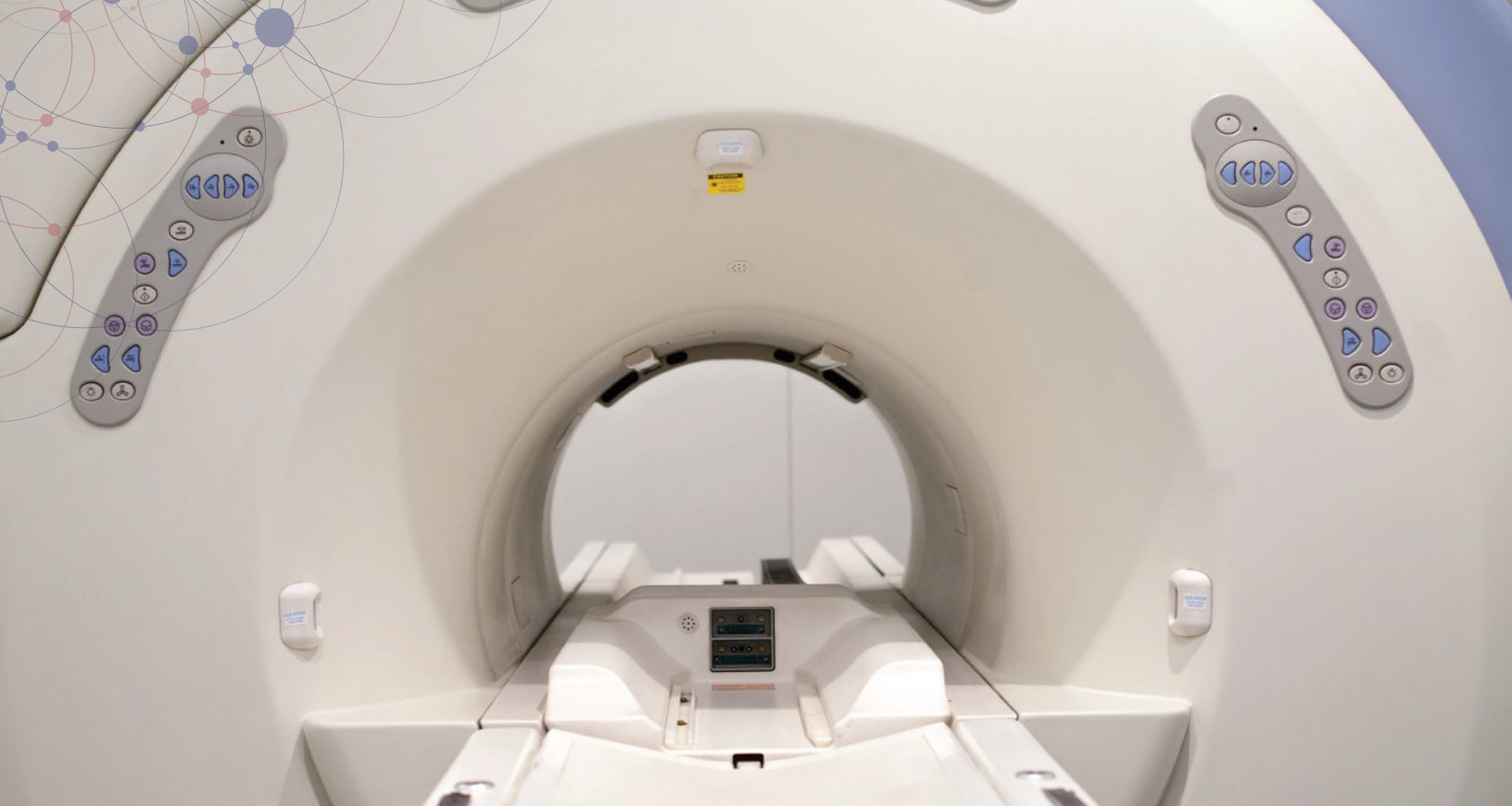
# All-Inclusive Regulatory Programs

BDC Laboratories can evaluate all aspects of your medical device, providing comprehensive test programs as outlined in ISO standards and FDA guidance documents. This rare capability streamlines your device's testing and evaluation program and yields a quicker time to regulatory submission and regulatory approval.

- ISO 25539 (all parts)
- ISO 5840 (all parts)
- ISO 5910
- ISO 7198
- ISO 10555 (all parts)
- ISO 11070
- FDA Guidance for MRI Labeling
- FDA Stent Guidance
- FDA Guidewire Guidance
- FDA PTCA Catheter Guidance
- FDA Hemodialysis Catheter Guidance
- FDA Guidance for Intervascular Catheters

Visit [BDCLabs.com](http://BDCLabs.com) or contact us at **303.456.4665** to fully appreciate all the ISO, ASTM, and FDA standards we can execute





# Beyond Cardiovascular

As an ever-expanding organization focused on the evaluation of Class II and Class III medical devices, BDC Laboratories offers our testing services for technologies beyond structural heart, cardiovascular and endovascular devices.

## SELECTED UNIVERSAL DEVICE TEST METHODS

- MRI Compatibility Evaluation, including Numerical Simulation
- Electrochemical Corrosion
- Material Fatigue (S-N) Characterization
- Coating Integrity & Acute Particulate Characterization

*“We have used BDC testing services, purchased their test equipment and their silicone mock vessels, all of which have met or exceeded our expectations, been cost effective and delivered in a very timely manner. BDC’s knowledgebase surrounding the medical device development and regulatory environment is excellent. The BDC team has been responsive and very supportive of our needs allowing us to develop a very productive relationship with the team and we plan to continue to use their well-tuned services and products.”*

**— Testing Services, Test Equipment, Silicone Vessels**



## TESTING SERVICES

Comprehensive ISO/IEC 17025:2017  
Accredited testing services for regulatory  
submissions or R&D on a vast array of  
medical device technologies



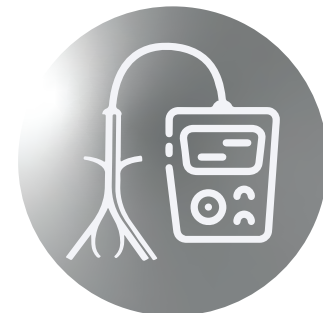
## TESTING EQUIPMENT

Cardiovascular, structural heart and  
endovascular test systems with superior  
control and adaptability for durability,  
fatigue and bench testing applications



## SILICONE VESSELS

Certified silicone mock vessels for  
durability testing and silicone models  
for simulation and R&D activities in all  
geometries, as well as  
patient-based datasets



## SIMULATION SOLUTIONS

Standard or custom turnkey simulation  
systems that include clinically relevant  
vascular pathways and hemodynamics for  
device development and  
physician training

To learn more about BDC's full range of capabilities and equipment,  
visit [BDC Labs.com](http://BDC Labs.com) or call **303.456.4665**

## Questions?

To learn more about BDC, visit [BDCLabs.com](https://www.bdclabs.com) or call **303.456.4665**

[www.bdclabs.com](https://www.bdclabs.com)

[info@bdclabs.com](mailto:info@bdclabs.com)

303.456.4665

4060 Youngfield St.  
Wheat Ridge, CO 80033

© 2021 BDC Laboratories

