



Simulation Solutions

& MOCK CIRCULATORY LOOPS



TESTING SERVICES



TEST EQUIPMENT



SILICONE VESSELS





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 or call **303.456.4665**

Simulation Solutions

Over 40 years of experience supporting the world's most advanced heart valve, endovascular, vascular and catheter device companies has given BDC Laboratories a unique understanding for designing and manufacturing clinically-based simulated use test systems.

Simulation success starts here. Starting with your design requirements for a simulated use system, BDC Laboratories melds a fundamental understanding of cardiovascular fluid dynamics, arterial wall mechanics and cardiac and endovascular device technologies to deliver turn-key solutions that provide the highest level of clinical representation, operator experience and technical sophistication.

DEVICE & DELIVERY SYSTEM DEVELOPMENT

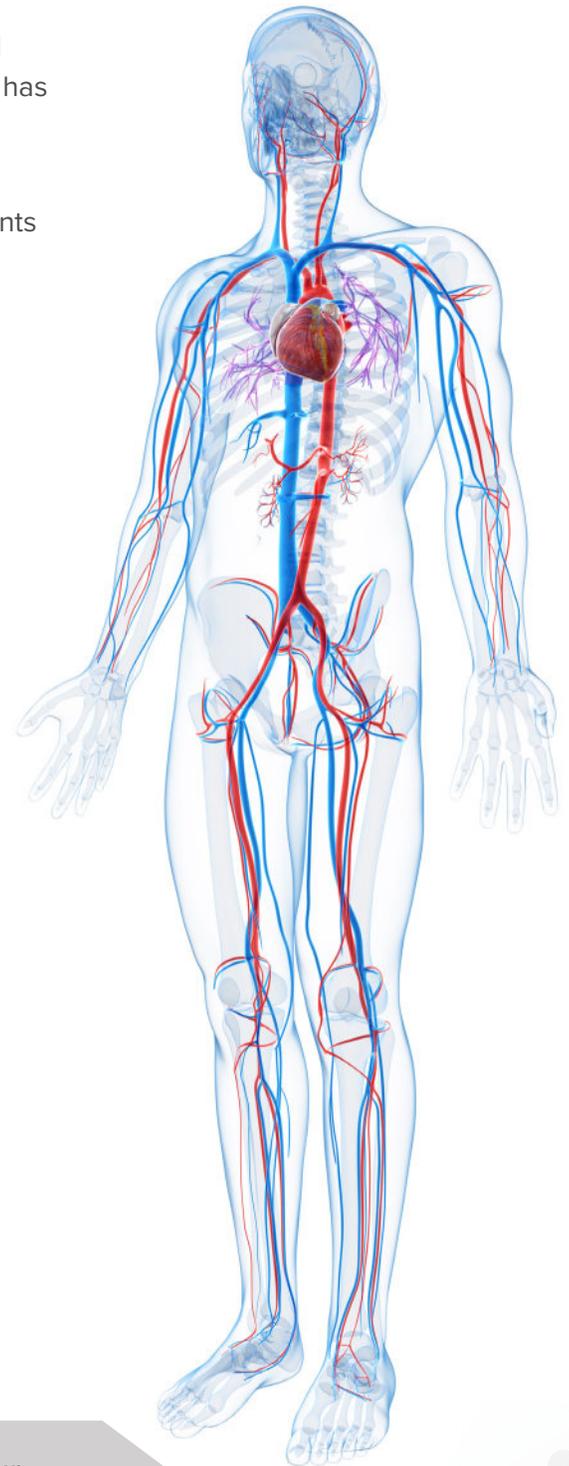
BDC Laboratories offers advanced simulated use bench test systems with high fidelity, leveraging the most advanced technology, allowing you to investigate the implications of the various device design considerations. Our simulation solutions help address challenges encountered during proof of concept, design verification testing, ergonomic engineering and regulatory studies.

MARKETING & SALES

Leverage BDC's 'true-to-life' simulation systems to address audience-specific interests and concerns, differentiate your device from competitive offerings, and generate meaningful discussions with end-users.

PHYSICIAN TRAINING & EDUCATION

With BDC's customized simulation solutions, you can deliver tailor-made training programs on new devices and procedures to educate and build confidence in clinicians through hands-on training in a realistic setting.



"BDC's expertise with hemodynamics is a great asset to our catheter development efforts. Furthermore, their desire and ability to help troubleshoot issues ensures they are not just another contract lab that performs testing and returns reports; instead, BDC is a true partner with our R&D team."

— Testing Services

Coronary Artery Simulation Solutions

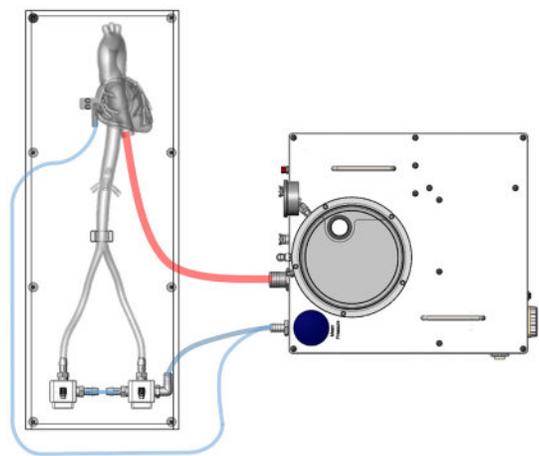
The Coronary Artery Simulated Use Solutions from BDC Laboratories provide a complete, turnkey platform to evaluate coronary intervention procedures and interventions.

This coronary artery simulation solution consists of a heart model, coronary arteries with multiple branches, aortic arch, descending aorta and femoral arteries. The model has access ports with integrated hemostatic valves at the femoral arteries to facilitate insertion, advancement and delivery of coronary intervention implants. Additional custom access approaches through the radial artery can be further integrated into the simulation systems, along with calcified coronary arteries.



BENEFITS & FEATURES

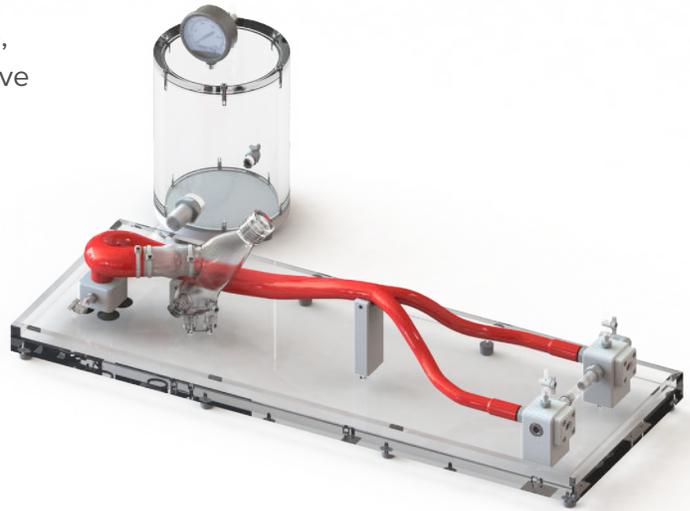
- Clinically relevant bench model for development activities, education and physician training
- Calcified coronary arteries to be integrated within the system available
- Flow through all coronary branch vessels provides a real clinical experience
- Clear, compliant silicone vasculature allow visibility of the delivery system and device
- Integrated hemostatic valves accommodate delivery system entry via femoral access
- Drip tray catches any fluid spills during testing and simulation
- Vessel supports ensures the anatomical model retains its 3D configuration during procedures
- Portable, with optional hard-sided travel case for air-travel or shipment
- Optional PD-0500 Portable Pulse Duplicator offers temperature-controlled, clinically relevant pulsatile flow environment
- SLIC™ friction reduction coating available



Aortic Valve Simulation Solutions

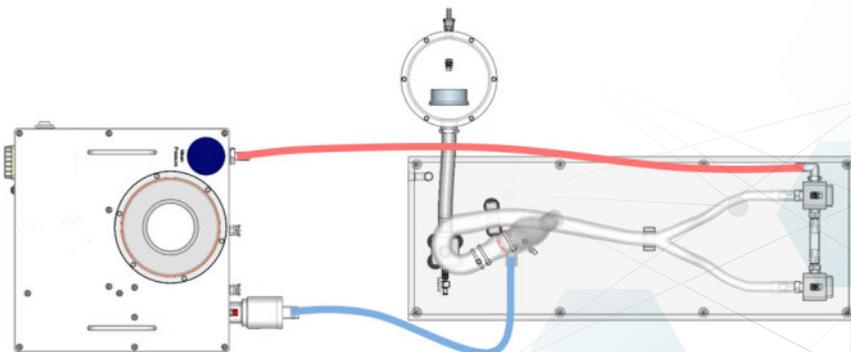
The Transcatheter Aortic Heart Valve Simulated Use Solutions from BDC Laboratories provide a complete, turnkey platform to evaluate Transcatheter Aortic Valve Replacement (TAVR/TAVI) devices and procedures for the treatment of aortic valve stenosis.

This aortic valve simulation solution consists of a left ventricle, functioning silicone aortic valve, aortic arch, descending aorta and femoral arteries. The model has access ports with integrated hemostatic valves at the femoral arteries and transapically to facilitate advancement and delivery of TAVR implants. Additional, custom access approaches through direct aortic or femoral vein can also be integrated into the simulated use system.



BENEFITS & FEATURES

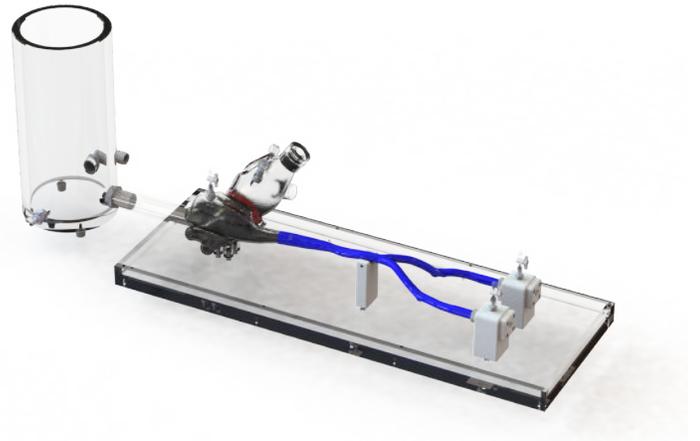
- Clinically relevant bench model for development activities, education and physician training
- Clear heart model and aortic valve allows visibility of the aortic valve and implant and clear, compliant silicone anatomical model allows direct visibility of the delivery system
- Functional silicone aortic valve is easily installed and removed
- Integrated hemostatic valves accommodate delivery system entry via femoral and transapical access
- Drip tray catches fluid spills during testing and physician training exercise
- Vessel supports ensures the anatomical model retains its 3D configuration during procedures
- Portable, with optional hard-sided travel case for air-travel or shipment
- Optional PD-0750-A Portable Pulse Duplicator offers a temperature-controlled, clinically relevant pulsatile flow environment
- SLIC™ friction reduction coating available



Mitral Valve Simulation Solutions

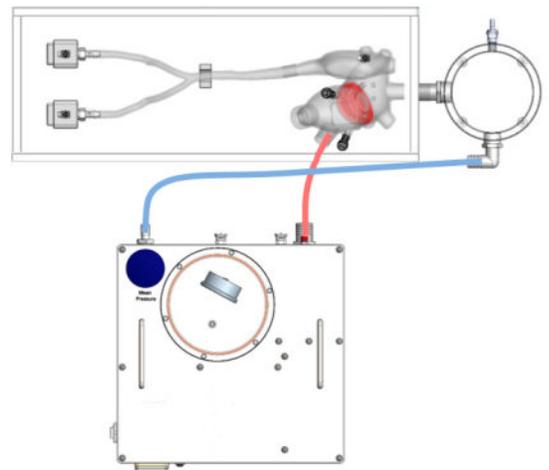
The Transcatheter Mitral Heart Valve Simulated Use Solutions from BDC Laboratories provide a turnkey platform to evaluate both Mitral Valve Replacement (TMVR) and Mitral Valve Repair technologies.

The mitral valve simulation solution consists of the right atrium, left atrium, left ventricle, functioning silicone mitral valve with chordae, inferior vena cava and the femoral veins. Either a pre-defined septal hole or replaceable, puncturable septum is present between the left atrium and the right atrium. The model facilitates transcatheter delivery system access with integrated hemostatic valves at the femoral veins and transapically. Additional, custom access approaches such as direct aortic and subclavian routes can also be integrated into the simulated use system.



BENEFITS & FEATURES

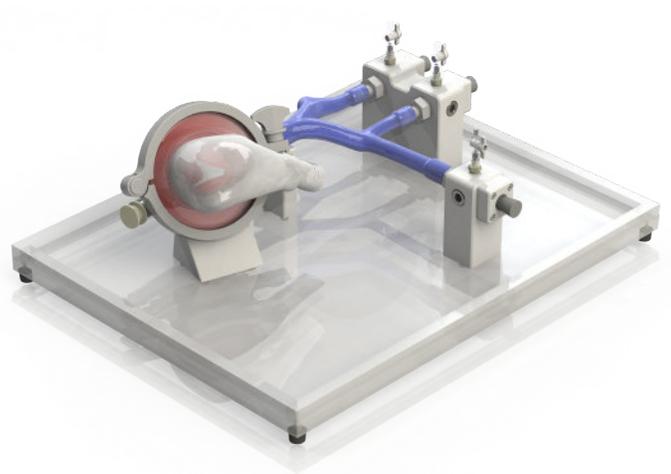
- Clinically relevant bench model for development activities, education and physician training
- Clear heart model allows visibility of the mitral valve and the replacement/repair implant and clear, compliant silicone vasculature allows visibility of the delivery system
- Functional silicone mitral valve with chordae is easily installed/removed
- Mitral valve chordae can be adjusted and tensioned to affect valve performance
- Integrated hemostatic valves accommodate delivery system entry via femoral and transapically access
- Drip tray catches any fluid spills during testing and simulation
- Vessel supports ensures the anatomical model retains its 3D configuration during procedures
- Portable, with optional hard-sided travel case for air-travel and shipment
- Optional PD-0750-M Portable Pulse Duplicator offers temperature-controlled, clinically relevant pulsatile environment
- SLIC™ friction reduction coating available



Tricuspid Valve Simulation Solutions

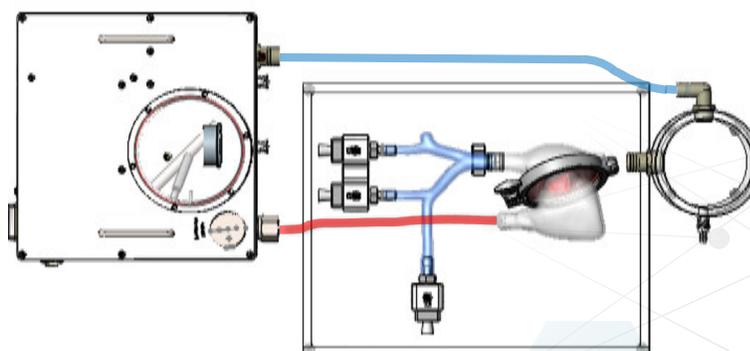
The Transcatheter Tricuspid Heart Valve Simulated Use Solutions from BDC Laboratories provide a turnkey platform to evaluate both Tricuspid Valve Replacement (TTVR) and Tricuspid Valve Repair technologies.

The tricuspid valve simulation solution consists of the right atrium, right ventricle, functioning silicone tricuspid valve with chordae, superior vena cava, jugular veins and the left subclavian vein. The model facilitates transcatheter delivery system access with integrated hemostatic valves at the jugular and subclavian veins. Additional custom access approaches, such as femoral, can also be integrated into the simulated use system.



BENEFITS & FEATURES

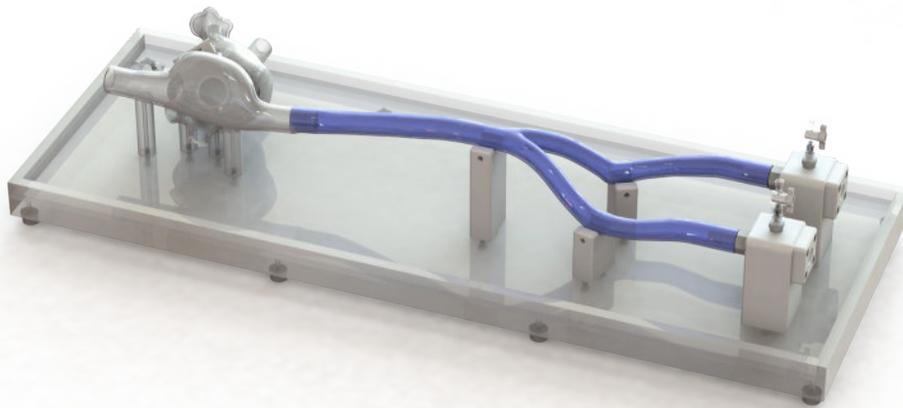
- Clinically relevant bench model for development activities, education and physician training
- Clear heart model allows visibility of the tricuspid valve and the replacement/repair implant and clear, compliant silicone vasculature allows visibility of the delivery system
- Functional silicone tricuspid valve with chordae is easily installed/removed
- Tricuspid valve chordae can be adjusted and tensioned to affect valve performance
- Integrated hemostatic valves accommodate delivery system entry via jugular and subclavian access
- Drip tray catches any fluid spills during testing and simulation
- Vessel supports ensures the anatomical model retains its 3D configuration during procedures
- Portable, with optional hard-sided travel case for air-travel and shipment
- Optional PD-0750-T Portable Pulse Duplicator offers temperature-controlled, clinically relevant pulsatile environment
- SLIC™ friction reduction coating available



Left Atrial Appendage & Septal Crossing Simulation Solutions

The Transcatheter Left Atrial Appendage (LAA) and Septal Crossing Simulated Use Solutions from BDC Laboratories provide a turn-key platform to evaluate both LAA devices, as well as technologies design for septal crossing from the right to left atria.

The LAA & septal crossing simulation solution consists of the right atrium, left atrium with replaceable atrial appendage, replaceable & puncturable atria septum, inferior vena cava and the femoral veins. The model facilitates transcatheter delivery system access at the femoral veins. Additional custom access approaches such as jugular or subclavian routes can also be integrated into the simulated use system.



BENEFITS & FEATURES

- Clinically relevant bench model for development activities, education and physician training
- Clear heart model & clear, compliant silicone vasculature allows visibility of the delivery system and implant
- Replaceable left atrial appendage facilitates evaluation of implant's under various shaped and sized appendages
- Replaceable & puncturable septal wall presents a repeatable in situ experience with every septal crossing
- System can be utilized either dry or immersed into a temperature controlled fluid bath
- Vessel supports ensures the mock vessels retain their 3D configuration during procedures
- Portable, with optional hard-sided travel case for air-travel and shipment
- SLIC™ friction reduction coating available

Simulation Suites

BDC Laboratories' simulation suites are custom designed to each client's specific requirements and evaluation needs. These highly sophisticated simulated use solutions provide the ultimate in physician training, as well as a development platform, yielding a superior result for all objectives at-hand.

The development of a custom simulation suite begins with a submitted requirements document to BDC Laboratories; whereby, all performance, usability and operator experience objectives are presented. The BDC team then works to augment the requirements document by further integrating considerations from our extensive experience in designing and building these high fidelity systems that are aligned with the end-use objects. Therefore, the final delivered, turnkey system fully aligns with each client's needs while exceeding their expectations in nearly every way.



BDC Laboratories has designed simulation suites for...

- Structural heart implants
- Coronary endovascular implants
- Venous implants
- Thermodilution catheter technologies
- Cardiac bypass technologies
- And more...

BENEFITS & FEATURES

- Clinically relevant, high fidelity bench model for development activities, education and physician training
- Designed, developed and manufactured to your unique specifications assures a perfect fit for use upon delivery
- Imagination is the only limitation with fully integrated features available such as pulsatile flow, dynamic force measurements, high-speed imaging, fully autonomous system operation, pressure and flow temporal measurement and fully integrated software for operation and measurements
- Clear, compliant and clinically relevant silicone vasculature allows for visibility of the delivery system and implant throughout use
- Vessel supports ensures the anatomical model retains its 3D configuration during procedures
- SLIC™ friction reduction coating available

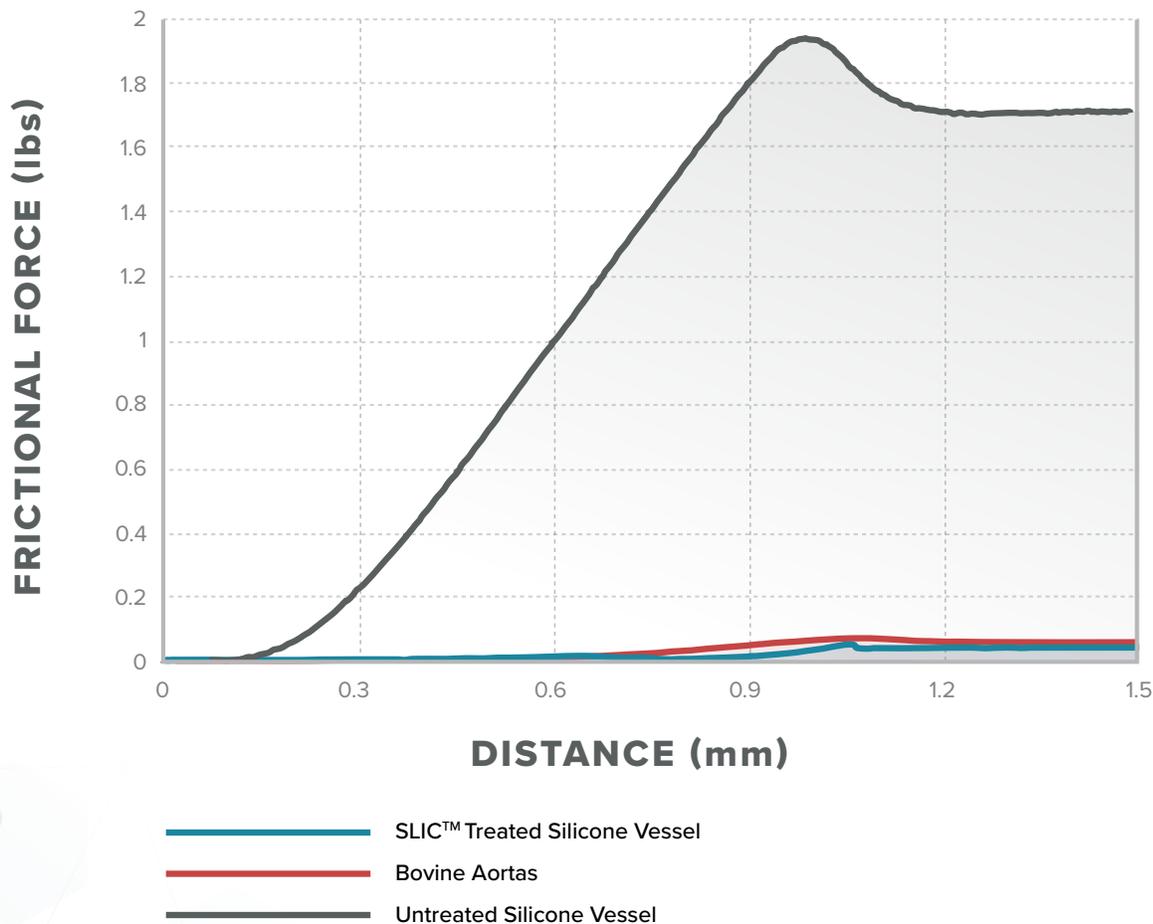
SLIC™ Friction Reduction Coating

The use of silicone for manufacturing complex anatomical models and simple arterial/venous vessels is common and advantageous for its transparency, stability and durability. However, the inherent tackiness of the final product causes challenges in the models' use when tracking catheters, delivery systems and similar technologies.

The SLIC™ lubricious coating from BDC Laboratories is a proprietary surface treatment that serves to achieve a clinically relevant surface friction, specifically on silicone anatomical models. Our coating offers a unique combination of friction reduction coupled with excellent bonding to native silicone and superior resistance to abrasion and erosion. BDC's proprietary process for applying the SLIC™ coating produces an ultra-thin, gap-free, conformal coating of all exposed luminal silicone surfaces, providing a uniform, ultra-low-friction surface. The process also ensures that the compliance of mock silicone vessels is unaffected.

We can coat any of our simulation solutions' silicone anatomical models with SLIC on request!

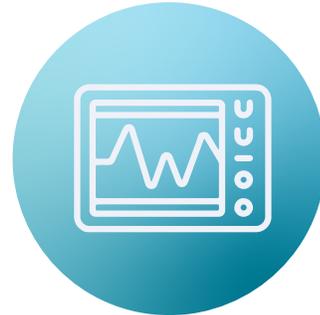
SLIC™ Coating Friction Reduction





TESTING SERVICES

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



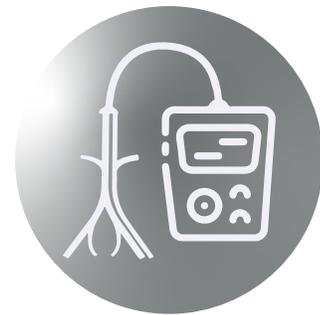
TESTING EQUIPMENT

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 or call **303.456.4665**

Questions?

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

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