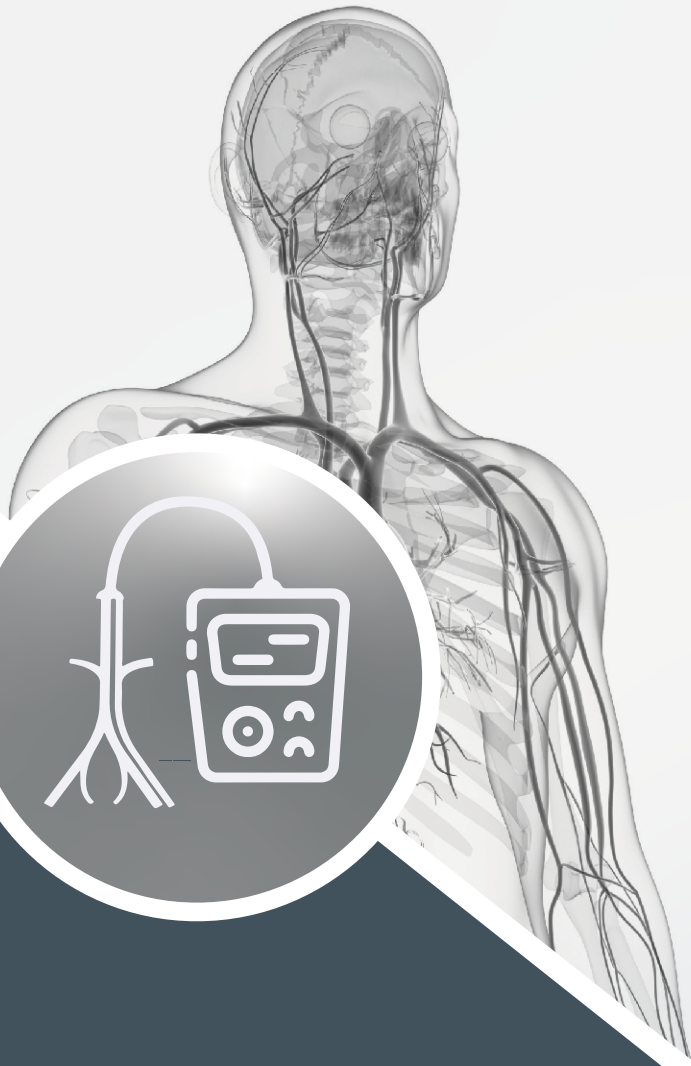


Simulation Solutions

& MOCK CIRCULATORY LOOPS

- TESTING SERVICES
- TEST EQUIPMENT
- SILICONE VESSELS
- CONSULTING SERVICES

BDC LABORATORIES

A Tentamus Company

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CMDC
CARDIOMED DEVICE CONSULTANTS
A Tentamus Company

FROM CONCEPT TO MARKET

Serving medical device manufacturers worldwide, BDC Laboratories and CardioMed Device Consultants deliver comprehensive support across the total product lifecycle of Class II and III medical devices.

UNIQUELY COMPREHENSIVE SERVICE

Medical device manufacturers worldwide have relied on BDC Laboratories and CardioMed Device Consultants to navigate every stage of the product lifecycle, from concept through device approval and market launch. Few partners can offer this breadth of regulatory and testing support under one roof. With more than 200 years of combined experience, our teams support medical device development with a rare pairing of technical precision and regulatory insight — all under one coordinated engagement.

Our collaboration means:
We work with your team throughout the full product development cycle.

From early design through submission, CardioMed leads the regulatory consulting and develops a testing approach and plan, drawing on a team of former FDA employees who know the ins and outs of the approval process.

BDC works from initial feasibility testing through regulatory submission and into production tests. Active participation in AAMI, ISO, and ASTM standards committees gives the BDC team unique insight into developing plans and protocols for FDA and CE Mark submissions.

WE BECOME AN EXTENSION OF YOUR TEAM

CardioMed + BDC acts as a force multiplier. With large organizations, this means we work with in-house regulatory and R&D teams. With small companies and startups, CardioMed + BDC become the team that takes care of regulatory strategy and testing services.

Our combined expertise and experience make us agile in bringing novel technologies to market.

Novel devices carry distinct regulatory complexity and can take three to ten years to reach market depending on risk class and device classification. You need a team who has seen it all to help guide you through this complex process.

We serve a wide range of customers, from start-ups to multinational corporations.

Organizations with vastly different resources have different requirements for regulations and testing support. We understand the obstacles you will face and the best ways to overcome them.

COMPLEMENTARY EXPERTISE

CardioMed Device Consultants

- FDA regulatory strategy and submission support
- Guidance on FDA preclinical testing requirements (Class II and Class III)
- Expertise from former FDA CDRH reviewers
- Specialized support for startups and international manufacturers
- Broad spectrum of technologies, including endovascular devices and digital health solutions

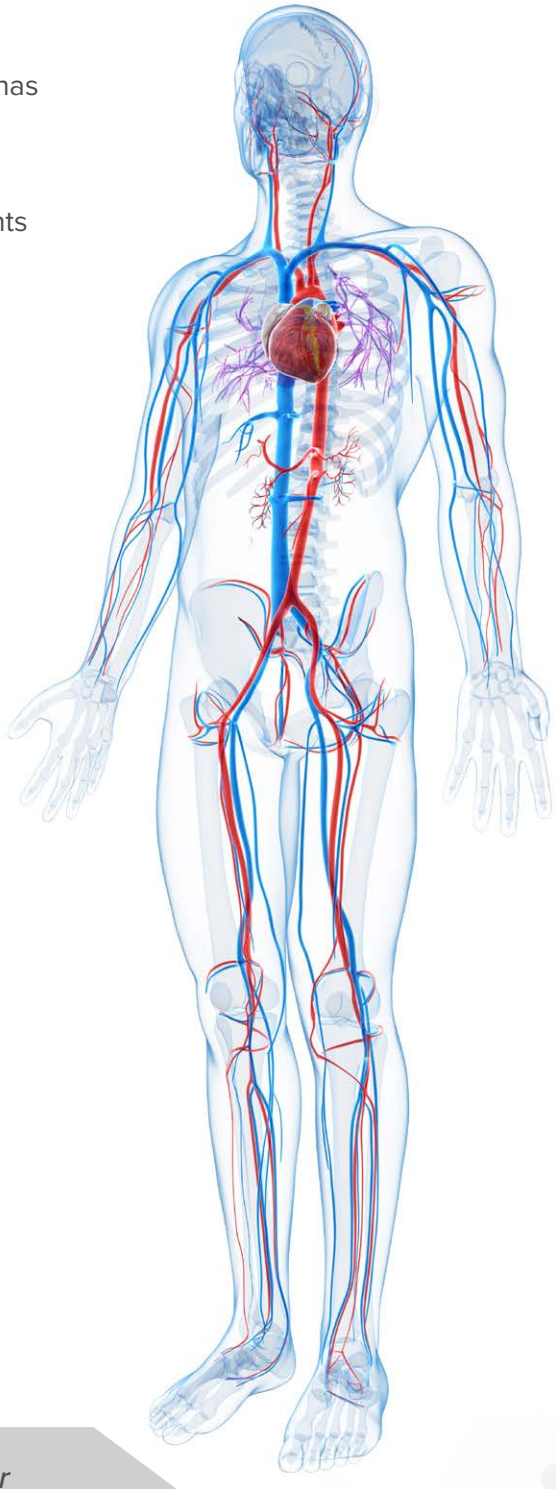
BDC Laboratories

- Mechanical and functional device testing
- Regulatory submission testing (Class II and III)
- Custom test protocols, equipment and simulation systems
- Comprehensive device testing reports
- GLP compliant
- ISO/IEC 17025 accredited

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 turnkey 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

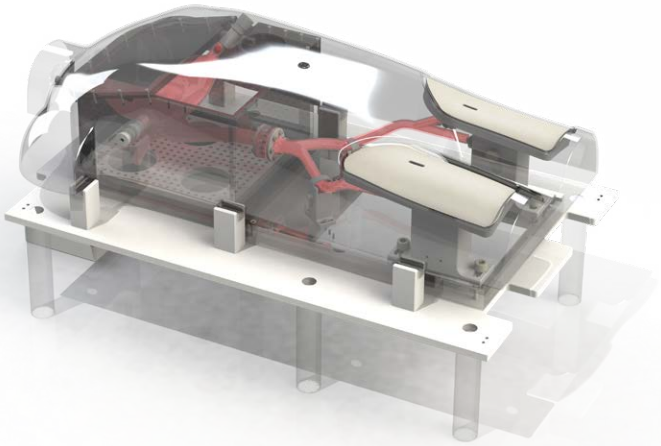
With BDC's customized simulation solutions, you can deliver tailor-made training programs on new devices and procedures to educate and build confidence in clinicians through hands-on training in a realistic setting.

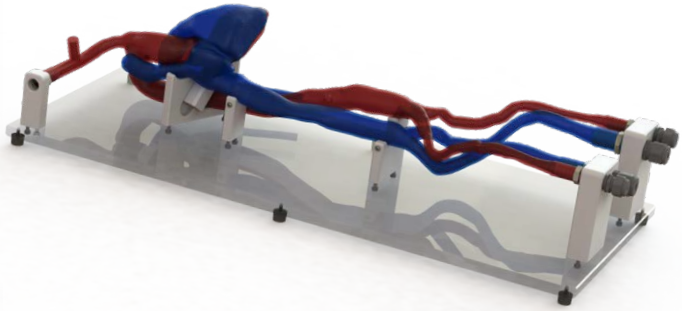
"BDC's expertise with hemodynamics is a great asset to our catheter development efforts. Furthermore, their desire and ability to help troubleshoot issues ensures they are not just another contract lab that performs testing and returns reports; instead, BDC is a true partner with our R&D team."

— Testing Services

Custom Simulation Solutions

BDC Laboratories is the world's leader in designing and building custom simulated use solutions, with each solution built to your specific simulation objectives and requirements. Whether the application is for proof of concept, design verification, design optimization, training clinicians, or sales & marketing activities ... if you can imagine it, we can build it!





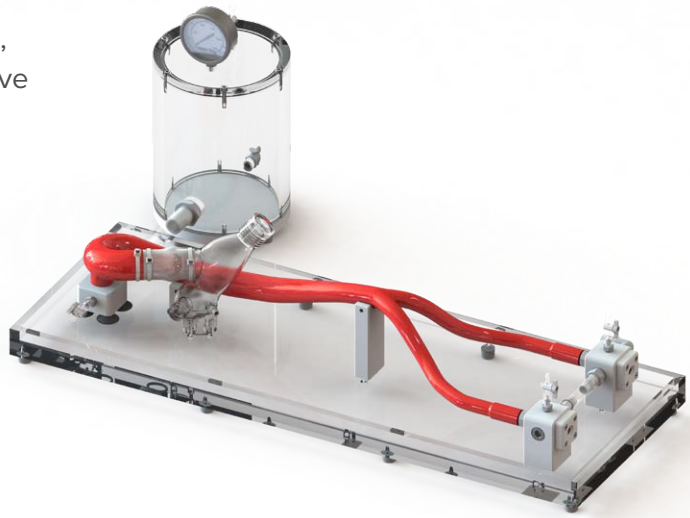
BDC offers innovative simulations solutions for virtually any transcatheter technology, including endovascular implants, prosthetic heart valves, heart valve repair devices or general catheter applications. Custom simulated use systems for novel and complex applications are our specialty, and we provide the design and fabrication expertise you need to transform your idea into the perfect solution.

APPLICATIONS

- Endovascular device studies (aortic, peripheral, carotid, neurovascular, femoral, venous, and pulmonary)
- Aortic Valve, Mitral Valve, Pulmonary Valve, Tricuspid Valve or Valve Repair Device evaluations
- Total Artificial Hearts (TAH) and Ventricular Assist Devices (VAD)
- Veterinary cardiovascular flow studies
- Research for device-pressure-flow interaction

Aortic Valve Simulation Solutions

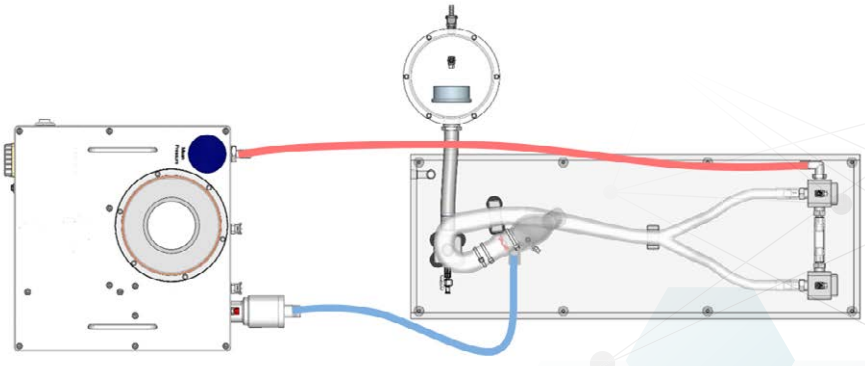
The Transcatheter Aortic Heart Valve Simulated Use Solutions from BDC Laboratories provide a complete, turnkey platform to evaluate Transcatheter Aortic Valve Replacement (TAVR/TAVI) devices and procedures for the treatment of aortic valve stenosis.



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

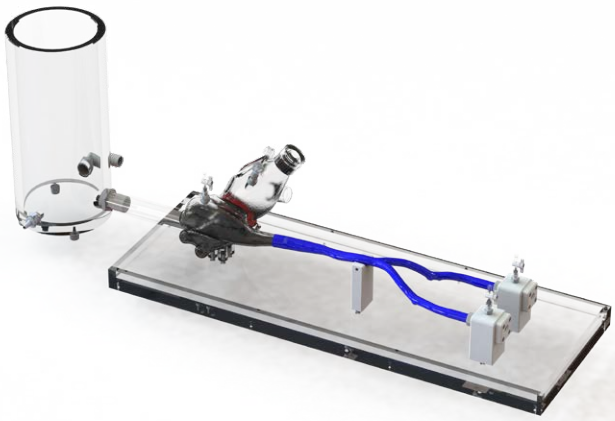
- Clinically relevant bench model for development activities, education and physician training
- Clear heart model and aortic valve allows visibility of the aortic valve and implant and clear, compliant silicone anatomical model allows direct visibility of the delivery system
- Functional silicone aortic 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



Scan this code for more information

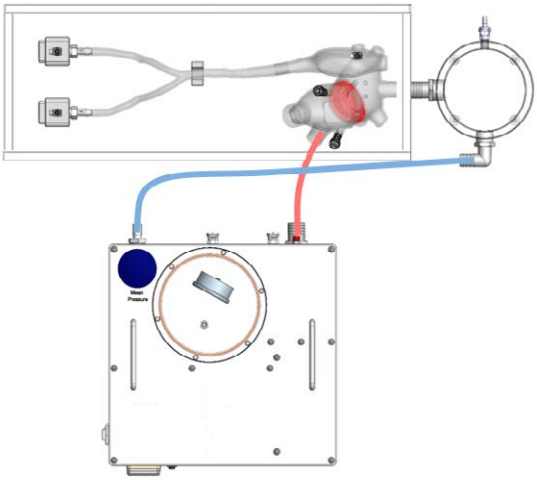
Mitral Valve Simulation Solutions

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



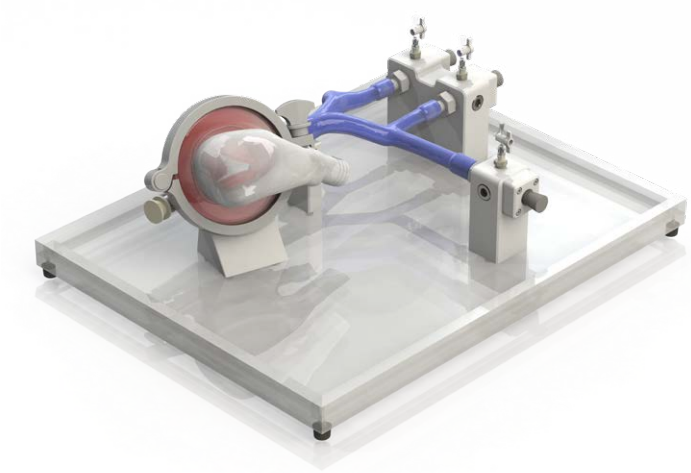
- Clinically relevant bench model for development activities, education and physician training
- Clear heart model allows visibility of the mitral valve and the replacement/repair implant and clear, compliant silicone vasculature allows visibility of the delivery system
- Functional silicone mitral valve 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

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Tricuspid Valve Simulation Solutions

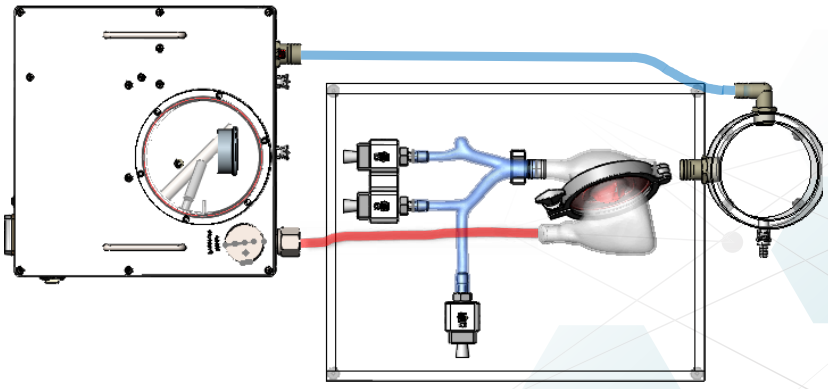
The Transcatheter Tricuspid Heart Valve Simulated Use Solutions from BDC Laboratories provide a turnkey platform to evaluate both Tricuspid Valve Replacement (TTVR) and Tricuspid Valve Repair technologies.

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

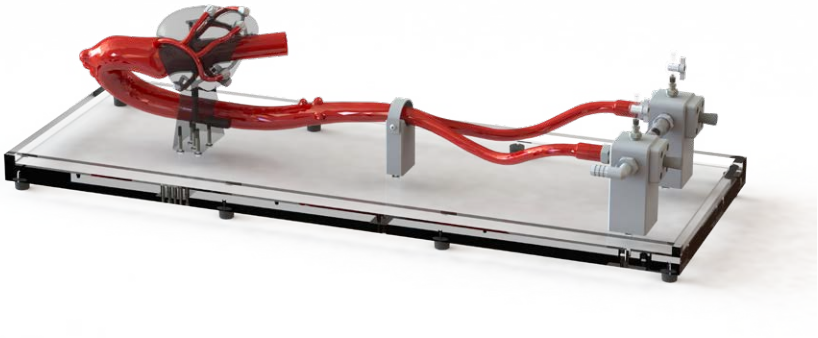
- Clinically relevant bench model for development activities, education and physician training
- Clear heart model allows visibility of the tricuspid valve and the replacement/repair implant and clear, compliant silicone vasculature allows visibility of the delivery system
- Functional silicone tricuspid 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



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Coronary Artery Simulation Solutions

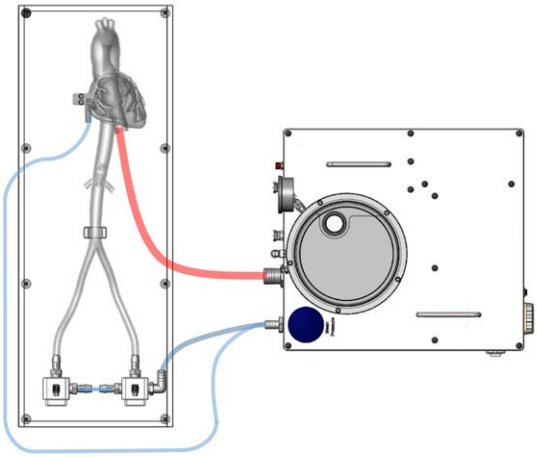
The Coronary Artery Simulated Use Solutions from BDC Laboratories provide a complete, turnkey platform to evaluate coronary intervention procedures and interventions.



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.

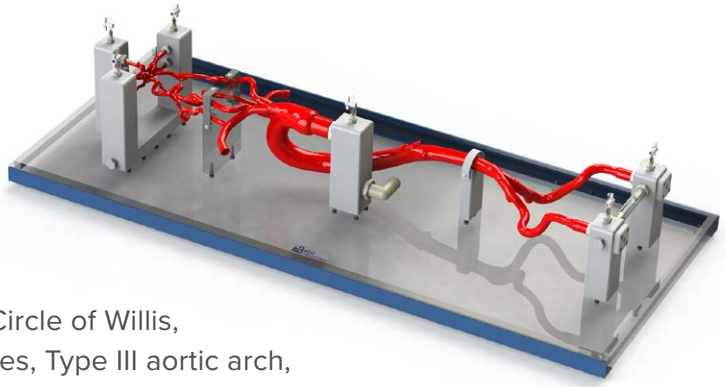
BENEFITS & FEATURES

- 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



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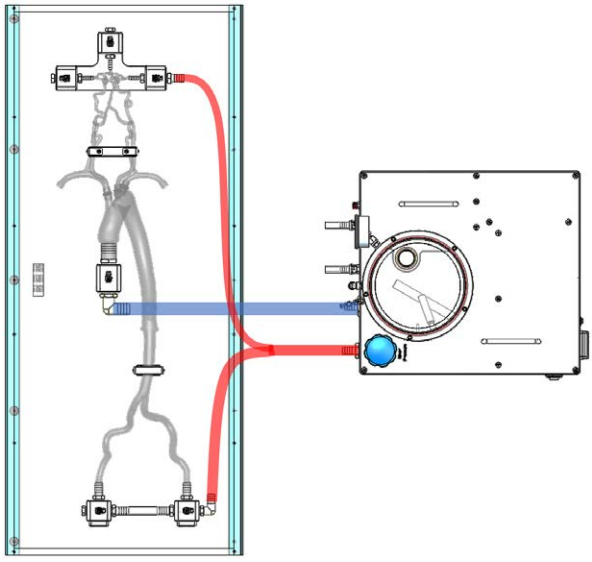
Neurovascular Simulation Solutions



The customizable neurovascular simulated use solutions from BDC Laboratories provides a complete, state-of-the-art, turnkey platform to evaluate neurovascular procedures for intravascular interventions, such as placing a flow diverter, embolic coils or other neurovascular devices.

This neurovascular simulation solution consists of a Circle of Willis, internal carotid arteries (ICAs), common carotid arteries, Type III aortic arch, descending aorta and femoral arteries. Within BDC Laboratories' silicone vasculature catalog, there are **five different neuro models available** that each have different levels of tortuosity that can be utilized / exchanged within this model. The simulated use solution has access ports with integrated hemostatic valves at the femoral arteries to facilitate insertion, advancement and delivery of neurovascular interventions. Additional, custom access approaches through the radial artery can be further integrated into these simulation systems.

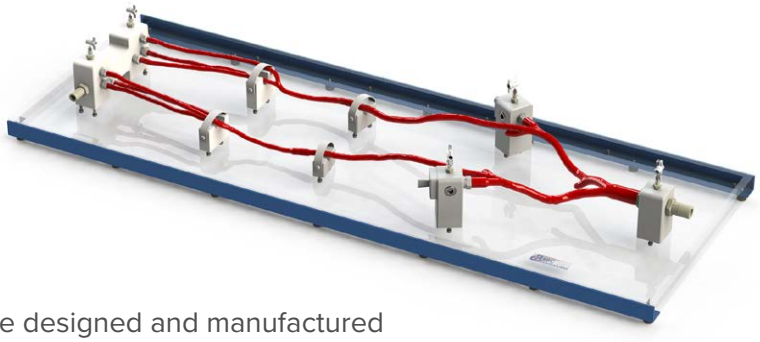
BENEFITS & FEATURES



- Clinically relevant bench model for development activities, education and physician training
- Exchangeable neurovascular vessels available with different levels of tortuosity
- Vascular aneurysm(s) integrated within the neuro vessels upon request
- Flow through all 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 neurovascular intervention simulations
- Silicone vasculature supports ensures the anatomical model retains its 3D configuration during procedures
- Portable, with optional rugged, hard-sided travel case for air-travel
- Optional PD-0500 Portable Pulse Duplicator offers temperature-controlled, clinically relevant pulsatile environment

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Leg Simulation Solutions

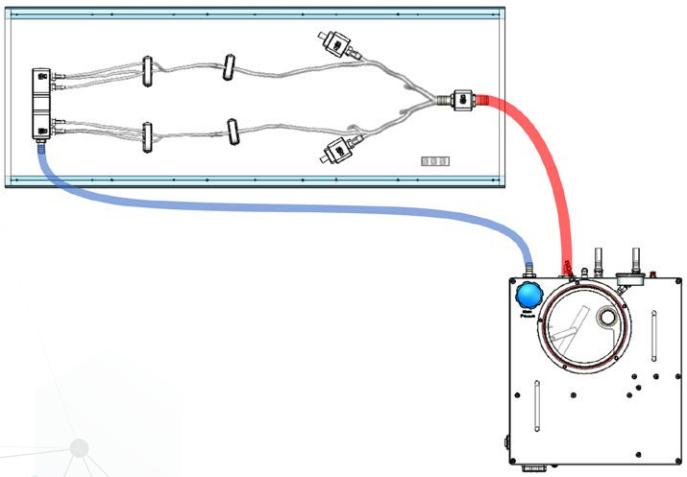


The customizable leg simulated use solutions from BDC Laboratories provides a complete, state-of-the-art, turnkey platform to evaluate lower extremity procedures for intravascular interventions, such as placing a stent, stent graft, catheter or cannula.

BDC's lower extremity simulation solutions can be designed and manufactured with both left and right femoral access to facilitate insertion, advancement and delivery, or just one leg's access for contralateral procedures. Both arterial and venous vasculature can be included in these simulated use systems, with the model including the aortic bifurcation down to the tibial / fibular artery region. Upon request, the BDC team can integrate a custom calcified lesion(s) into the vasculature at any location(s).

BENEFITS & FEATURES

- Clinically relevant bench model for development activities, education and physician training
- Femoral access for same leg or contralateral procedures
- Custom calcified lesion(s) can be integrated into the vasculature upon request
- Flow through all 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 neurovascular intervention simulations
- Silicone vasculature supports ensures the anatomical model retains its 3D configuration during procedures
- Portable, with optional rugged, hard-sided travel case for air-travel
- Optional PD-0500 Portable Pulse Duplicator offers temperature-controlled, clinically relevant pulsatile environment

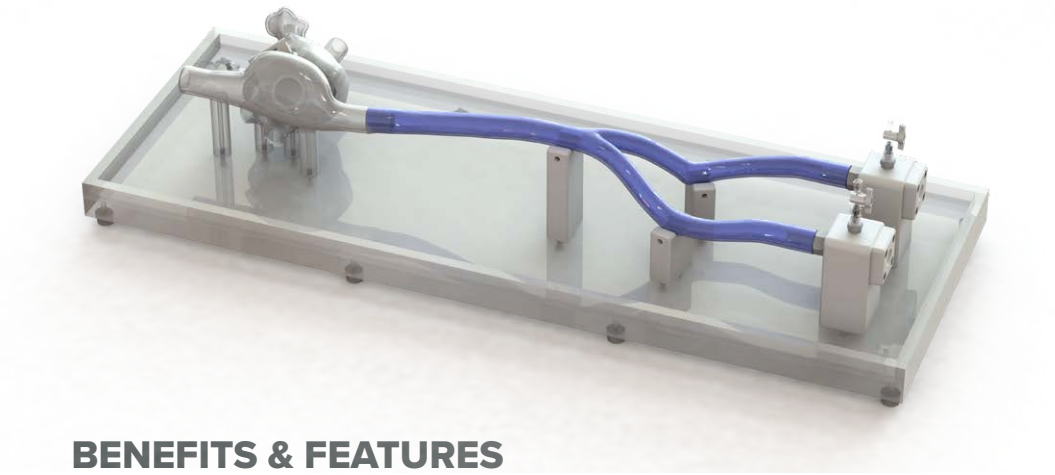


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Left Atrial Appendage & Septal Crossing Simulation Solutions

The Transcatheter Left Atrial Appendage (LAA) and Septal Crossing Simulated Use Solutions from BDC Laboratories provide a turnkey 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

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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...

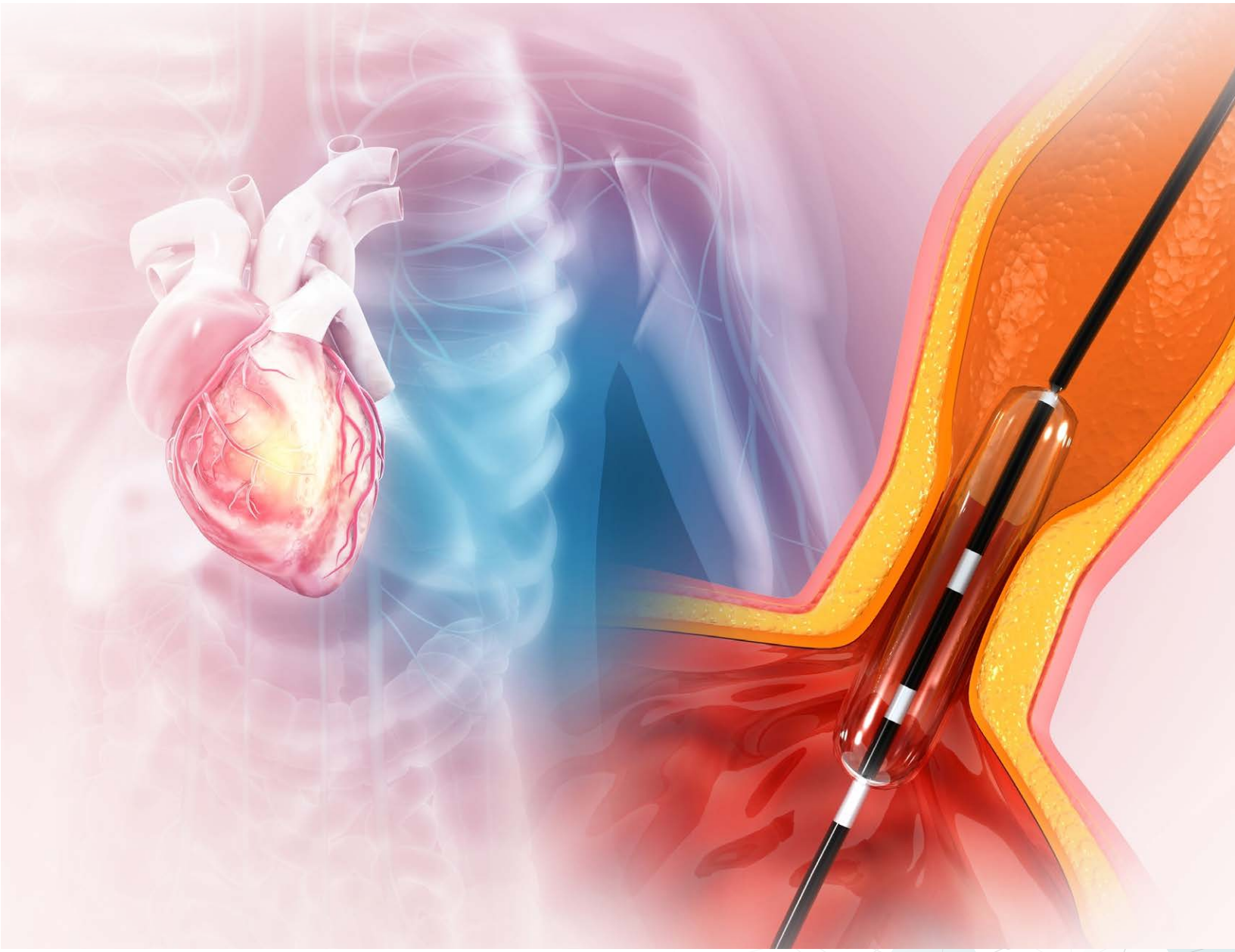
BENEFITS & FEATURES

- 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

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Simulation Solutions for Sales & Marketing

Take your sales and marketing efforts to the next level using a custom simulated use system from BDC Laboratories. Our models are beautifully engineered to not only look great, but to provide exceptional functionality and clinical realism. When coupling our silicone vasculature, and our clinically relevant proprietary SLIC™ friction reduction surface treatment, with our engineered model housings with integrated hemostatic valves … our simulated use systems are a great way to highlight your product and show its clinical advantages and unique performance features.



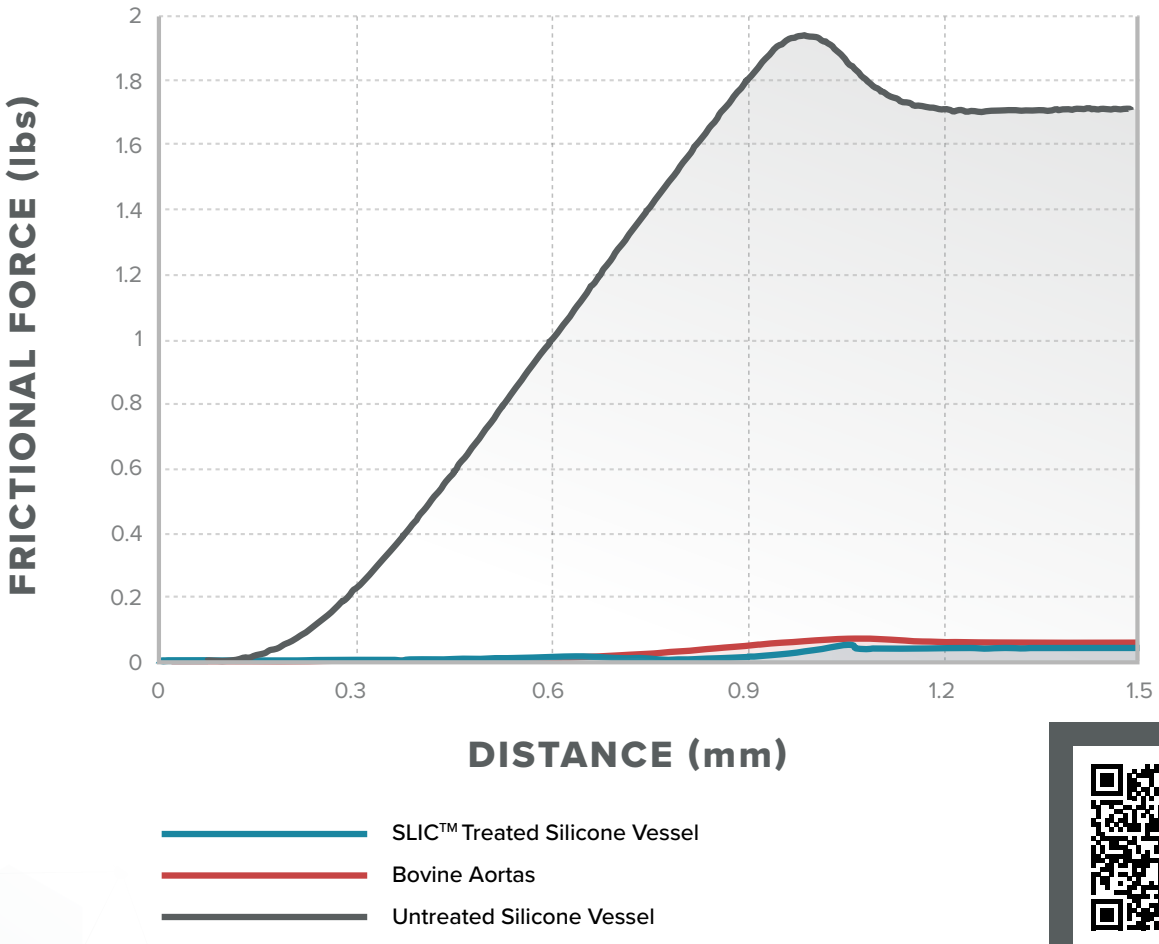
SLIC™ Friction Reduction Coating

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



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CAPABILITIES



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



CARDIOMED

Regulatory, clinical, pre-clinical and quality system consulting for Class II and Class III medical devices through the complete product life cycle

To learn more about BDC's full range of capabilities and equipment, visit **BDCLabs.com** or call **303.456.4665**

Questions?

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