

Silicone Vessels

- TESTING SERVICES
- TEST EQUIPMENT
- SIMULATION SOLUTIONS
- CONSULTING SERVICES

BDC LABORATORIES
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CMDC
CARDIOMED DEVICE CONSULTANTS
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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

Vasculature for All Applications

With over 15 years of experience in fabricating compliant silicone mock vessels and clinically accurate anatomical models of human and animal vasculature, BDC Laboratories leads the world in engineered silicone vascular solutions. BDC uses several proprietary methods to fabricate our silicone models for nearly all the world's leading cardiovascular device companies.

DEVICE DEVELOPMENT & EVALUATION

The development process for transcatheter structural heart and endovascular devices, as well as catheter-based therapies, greatly benefits from test platforms that accurately represent the clinical environment. With over 40 years of direct experience in the development and evaluation of these technologies, BDC Laboratories is in the highly unique position of being able to apply this extensive experience to all our silicone vascular models, yielding superior platforms for device evaluation. Moreover, with internal capabilities to certify the dynamic radial compliance of our mock vessels, BDC can provide certified vessels for durability studies, or other applications that require a specific dynamic radial compliance.

PHYSICIAN TRAINING & EDUCATION

BDC Laboratories specializes in engineered solutions to each of our client's needs, which becomes indispensable when procuring silicone vasculature-based simulation solutions for physician training. Beyond the ability to design and manufacture the silicone vasculature for your training needs, BDC has an entire team focused on both standard and custom simulated use solutions for the training and education of transcatheter structural heart and endovascular technologies. Furthermore, with our proprietary SLIC™ friction reduction coating, BDC's models do not require the use of surfactants or lubricants to create a clinical experience in either a wet or dry model, providing physicians with the most realistic experience available.

MARKETING & SALES

Differentiating and showcasing your technology is key to expanding market presence and sales volume. BDC Laboratories partners with each of our client's to fully appreciate the strengths of their technology and what differentiates it within the marketplace. With this distinctive approach to our silicone model solutions, BDC is able to provide the ultimate platform to highlight your device and demonstrate its benefits and key attributes. With our proprietary SLIC™ friction reduction coating, BDC's models do not require the use of surfactants or lubrication in either a wet or dry models, providing a superior ease-of-use and demonstration experience.

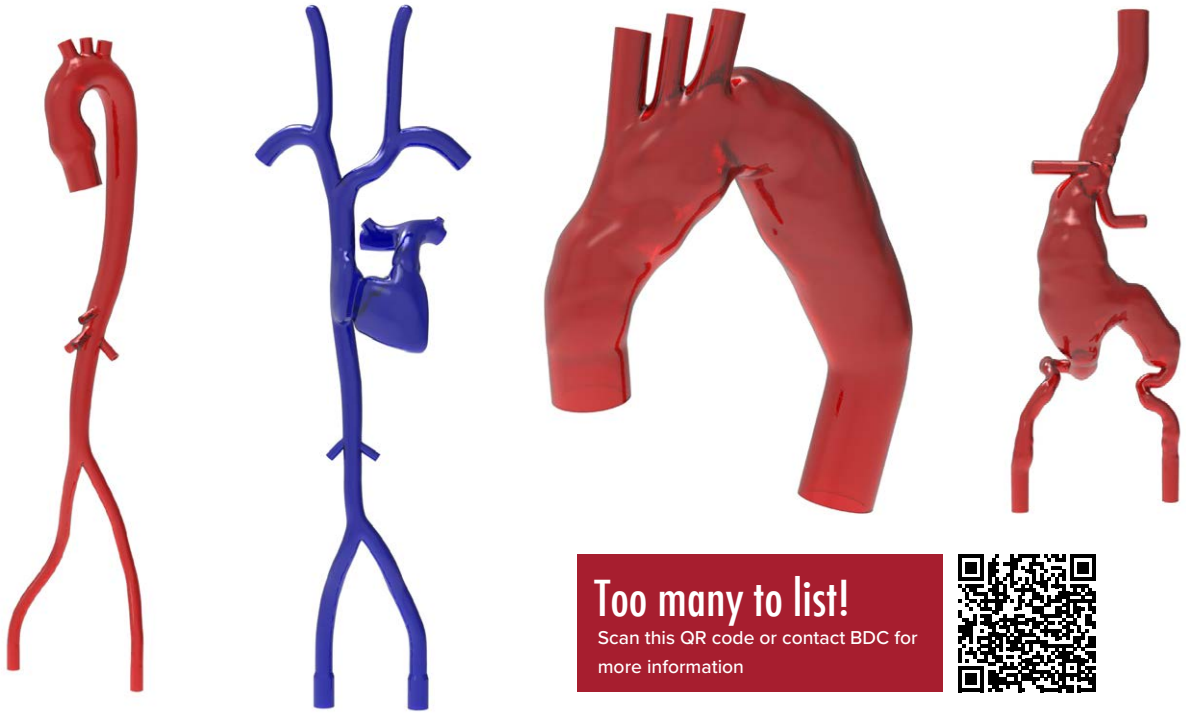


Anatomical Models

BDC Laboratories has an ever-growing internal database of patient-based vasculature acquired from computed tomography (CT) that be leveraged in the design and development of your specific model. Or if preferred, you can submit your patient-based dataset for us to use in the manufacture of your silicone anatomical model. BDC's highly experienced and talented engineering team uses advanced CAD software that further provides the ability for absolute customization of any dataset's attribute prior to build; therefore, we can manipulate the native anatomy's geometry to change diameters, lengths, tortuosity, and angulations, as well as the ability to introduce, mitigate or eliminate the presence of disease within the vasculature.

HEALTHY & DISEASED VASCULATURE

BDC Laboratories' models can be designed and manufactured to replicate healthy or diseased vasculature. Building from either our in-house patient-based datasets or a dataset provided by you, the BDC team can create and modify various states of disease, providing the most realistic platform for product evaluation, physician training, marketing and sales demonstrations. Our manufacturing experience and capabilities include not only diseases that affect geometry, such as aneurysms, dissections, coarctations and structural heart defects, but also diseases that impact the local vessel's state, such as calcification.



Too many to list!
Scan this QR code or contact BDC for more information

"BDC Labs is a knowledgeable and experienced team in testing medical devices. Our collaboration on equipment design and testing for simulated clinical use and device durability has been valuable in the development of the Nellix platform."

— Testing Services, Test Equipment, Silicone Vessels, Simulation Solutions

SLIC™ Friction Reduction Coating

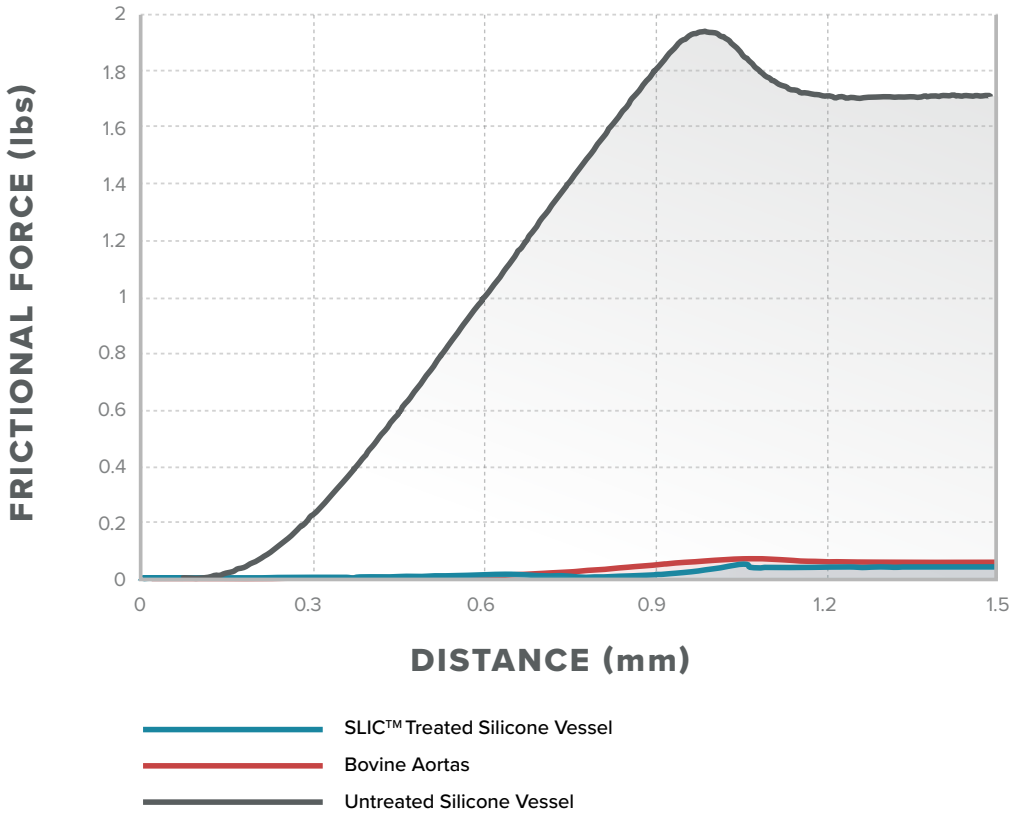
The use of silicone for manufacturing complex anatomical models and simple arterial/venous vessels is common and advantageous for its transparency, stability and durability. However, the inherent tackiness of the final product causes challenges in the model's use when tracking catheters, delivery systems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



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. The SLIC™ 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.

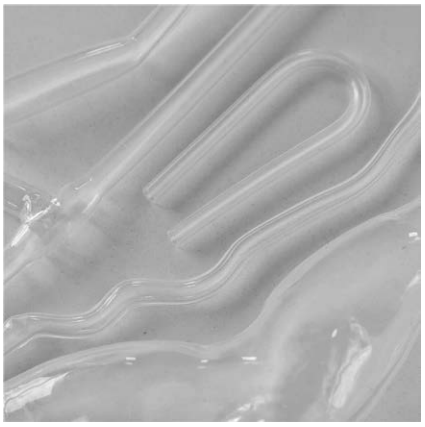
We can coat any of our simulation solutions' silicone anatomical models with SLIC on request!

SLIC™ Coating Friction Reduction



Scan this QR code to learn more about SLIC™ Coating

Silicone Mock Vessels



BDC Laboratories manufactures silicone mock vessels in nearly any configuration and below is an abbreviated list of our most common models. In addition to these items, our team can provide models with simulated vascular diseases integrated within the wall, as well as include flanges and imbedded rigid rings at the model's ends for mounting into a larger test apparatus when appropriate.

Silicone vessel capabilities include:

- Diameters from 1.5mm to exceeding 50mm
- Straights, Bifurcations, & Trifurcations
- Aortic Arches with Branch Vessels
- Silicone Heart Valves
- Atriums & Ventricles
- Coronary "U" Vessels

Scan this QR code to learn more about Silicone Mock Vessels

When ordering silicone mock vessels, our models are built custom to your specifications and requirements; therefore, the following details should be considered when placing an order: model geometry, target inner diameter and associated pressure, target diametric compliance and associated conditions or target wall thickness.

Quality & Product Certification

At BDC, we don't 'test' for quality, we build quality into every silicone mock vessel and anatomical model. Our silicone manufacturing team utilizes fully defined work instructions for the various operations, yielding a highly controlled build process. Moreover, through our precise manufacturing environment, BDC's clients appreciate superior repeatability when ordering multiple vessels and reproducibility when re-ordering products at a future date.

When your silicone vessels and anatomical models require an additional level of quality and control, such as when manufacturing vessels for durability testing and design verification bench testing, BDC Laboratories can measure the vessel's key attribute(s) and provide a Certification of Compliance with delivery. Dynamic radial compliance and pressurized inner diameters are determined using our fully validated dynamic compliance test system. When multiple vessels are ordered, the BDC team will test every one to assure each meet the required specifications.

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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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