

Silicone

MOCK VESSELS & ANATOMIES



TESTING SERVICES



TEST EQUIPMENT



SIMULATION SOLUTIONS

BDC
LABORATORIES



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**

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!

Please 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

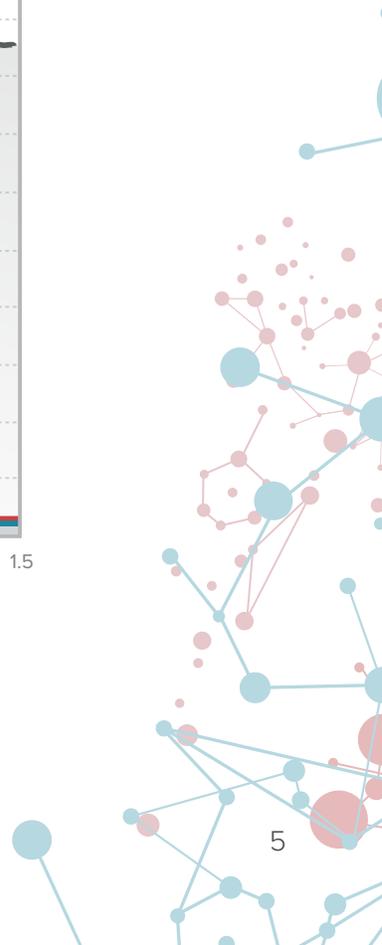
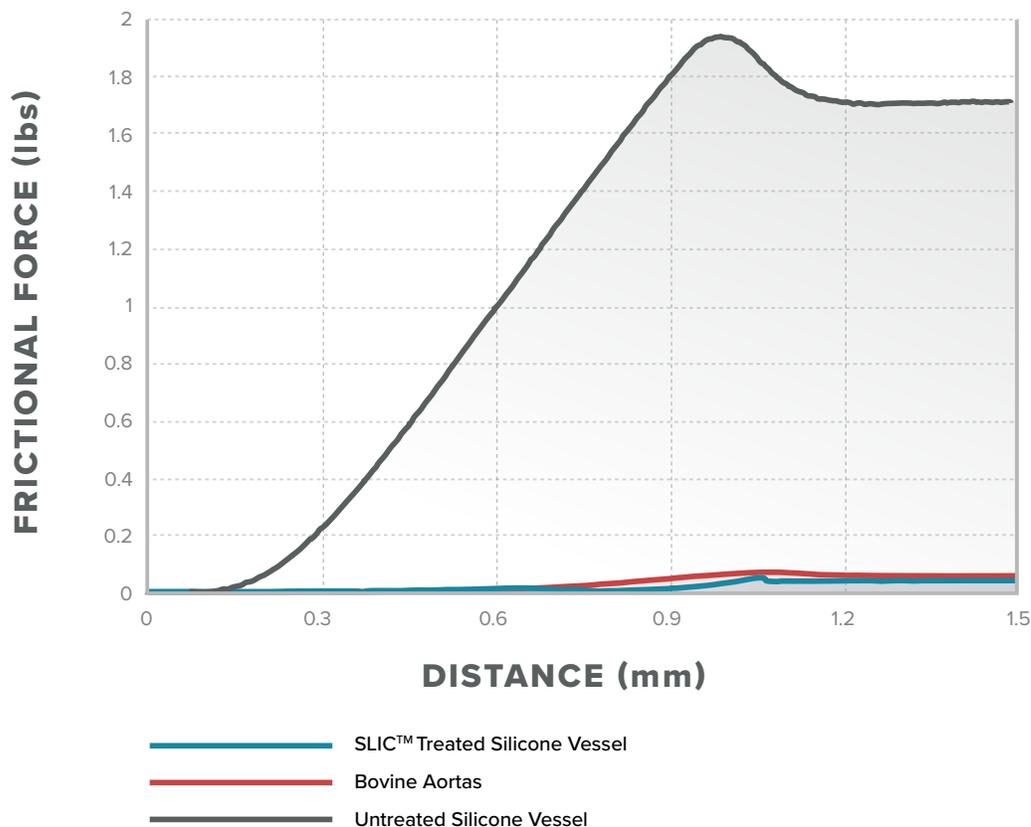
The use of silicone for manufacturing complex anatomical models and simple arterial/venous vessels is common and advantageous for its transparency, stability and durability. However, the inherent tackiness of the final product causes challenges in the model's use when tracking catheters, delivery systems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





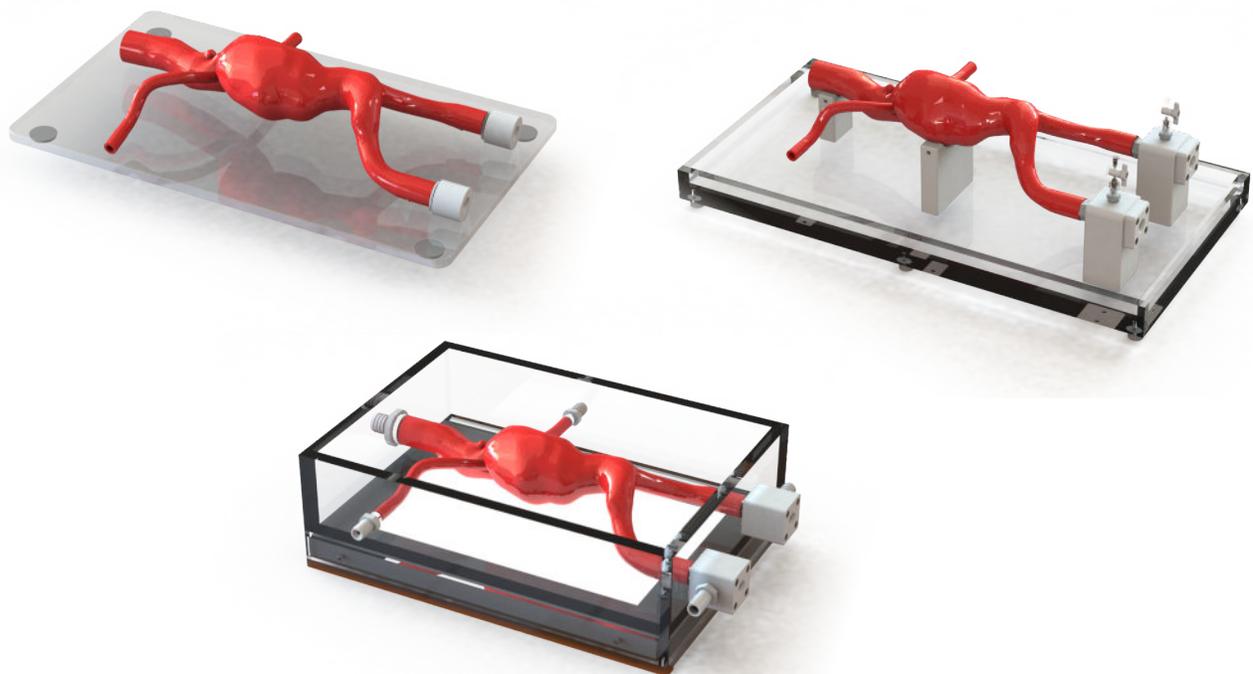
Quality & Product Certification

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.

Anatomical Model Housings

In addition to providing our silicone anatomical models as stand-alone vasculature, BDC Laboratories can design and build a housing that meets your end-use needs. Three different types of model housings are available: a simple acrylic sheet, an acrylic drip tray with vessel supports to maintain 3D geometry, and an acrylic tank with through-wall fittings and vessel supports. Furthermore, BDC's housing solutions include integrated hemostatic valves for seamless introduction of guidewires, catheters and delivery systems when the model is used under fluid pressure or pulsatile flow.





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 BDCLabs.com or call **303.456.4665**

Questions?

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