

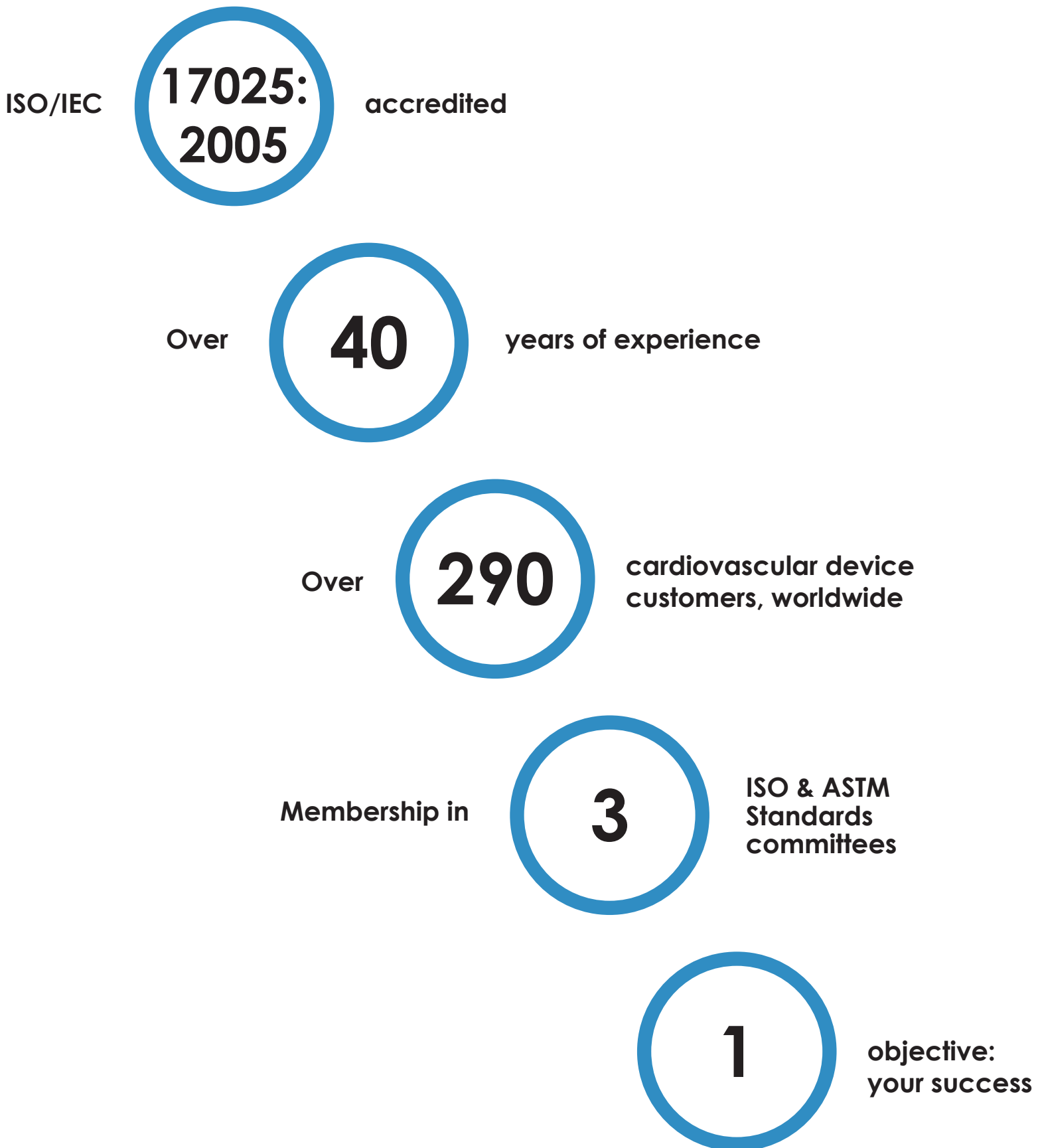
# Testing and Evaluation Services



- Heart Valve Testing
- Stent/Stent Graft Testing
- Vascular Graft Testing
- Coating and Particulate Studies
- Catheter and Balloon Testing
- Simulation Studies with Mock Anatomies
- Custom Test and Evaluation Services



# By the numbers: Why the world's leading medical device companies partner with BDC Labs...



# Testing and Evaluation Capabilities

BDC Labs is focused on the testing of Class 2 and Class 3 medical devices. The BDC team actively participates in AAMI, ISO and ASTM Standards Committees, developing regulations as they are being implemented and likely to impact our clients' testing requirements. We execute independent studies and present impartial, confidential test reports. Working closely with you, BDC Labs delivers the following cost-effective and accurate testing solutions designed to meet and exceed regulatory requirements:



## **Stent/Stent Graft and Vascular Graft Testing**

Comprehensive stent/stent graft and vascular graft testing solutions compliant with ISO 25539, ISO 7198 and FDA Stent Guidance Document. Chronic Durability and Acute Phase studies. Testing to Success and Testing to Failure modes.

## **Catheter and Balloon Testing**

Catheter and balloon testing programs compliant with ISO 10555, ISO 11070 and FDA Guidance Document.

## **Heart Valve Testing**

Heart valve durability and hydrodynamic testing compliant with ISO 5840.

## **Coating and Particulate Studies**

Coating and particulate studies compliant with ISO 25539, ASTM 2743, FDA Guidance for Stents and FDA Guidance for PTCA Catheters. Technologies include: delivery systems for stents, stent grafts and transcatheter heart valves, along with guidewires, catheters, endovascular filters, and other medical devices.

## **Simulation Studies with Mock Silicone Anatomies**

Simulation testing of stent/stent grafts, heart valves, heart valve repair devices and cardiothoracic vascular procedures using accurate silicone anatomies with pulsatile pumps to replicate in vivo cardiovascular hemodynamics and hydrodynamic loading.

## **Custom Product Testing**

From feasibility studies to full-bore customized testing programs for your unique medical device, BDC Labs design and engineering insight reduces risk, helps you catch design flaws early and reduces rework to speed you towards regulatory approval.

# Extraordinary expertise & resources driving accurate, timely, and cost-effective testing & evaluation services.

The medical device market presents challenges in terms of demanding regulatory requirements and the need for timely, accurate results. Couple these with the need to minimize product risk and shorten time to market, and you have the perfect storm. When you're driving product evaluation, don't experiment: contact BDC Labs. At BDC Labs, we know that you're not just looking for data, but you're looking for the most cost-effective, fastest, and accurate testing solution available with an engineering level of support to interpret results.

**Comprehensive Portfolio:** BDC Labs offers testing solutions across the breadth of cardiovascular applications: stents/stent grafts, vascular grafts, heart valves, catheters, vascular patches, coating and particulate studies, ventricular assist devices, simulation studies with mock silicone anatomies and custom solutions to support your unique testing requirements.

**Domain Expertise:** Testing solutions at BDC Labs are driven by a deep, broad expertise in all facets of cardiovascular technology. Regardless of whether you're testing a standard stent or a custom heart valve with a unique geometry, BDC Labs brings world-class performance to the table every time.



**Quality Results, Every Time:** BDC Labs has been providing cardiovascular testing solutions to the world's leading medical device companies for over 40 years for regulatory submissions. We are accredited to ISO/IEC 17025:2005 and welcome audits of our Quality Assurance program by our customers.



# Capabilities & Services

During the testing of stents/stent grafts, vascular grafts, catheters, and heart valves, BDC Labs offers several appropriate standard and optional services as part of the protocol, including the following:

- Sample deployment
- Pressure-based and deflection-based stent and stent graft durability testing
- Visual inspection of the sample device
- Optical microscope analysis
- Periodic motion verification
- Laser deflection measurements
- High speed video imaging & measurements
- Boundary condition definition
- Tracking pathway development
- Coating and particulate analysis
- Protocol development and validation
- Custom fixture development
- Comprehensive, confidential report submission
- SEM analysis
- X-ray analysis
- GLP audit of protocols



## Test Platform Versatility

BDC Labs gives you the option of performing any durability test on our test systems, or on a test system owned by you at our facility. Many customers choose to have their testing performed on instruments that are owned by them, but operated by us in our laboratories because of several advantages:

- Rental fees on instruments owned by the customer are eliminated
- When you own the instrument, you do not need to train your own technician to operate it, nor develop the infrastructure to execute studies
- We are ready to start testing whenever your protocol is ready since your instrument is used for your testing exclusively
- We can perform all QA and validation procedures on your unit
- Your instrument is operated by highly-trained personnel, in an ISO/IEC 17025:2005 accredited laboratory
- It is more cost-effective to purchase the unit, when you are performing multiple tests
- You save on your internal lab space since the unit is housed at our facility
- You benefit from the same outstanding level of service that all BDC Labs customers always receive

# Not Just Data

BDC Labs has been partnering with leading medical device companies as well as startups for over 40 years, and we know that testing is not just about data. Our vast experience in dealing with medical devices, our technological expertise, our highly trained staff and our regulatory insight have helped hundreds of medical device companies around the world obtain regulatory approval. For your next test, pick up the phone or email us, and experience the BDC Labs difference.

## Converting data into confidence for over 40 years.



Medical Device Testing & Equipment •  
Simulation Platforms • Silicone Vessels

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