Interventional cardiology entails transcatheater utilization of medical devices to treat structural heart and vascular disease via peripheral vascular access. Over time, the field of interventional cardiology has expanded from placement of coronary stents and peripheral stents to include techniques such as transcatheter valvuloplasty and deployment of thrombectomy devices. These minimally invasive procedures provide the advantage of minimizing pain and post-operative complications when compared to traditional open procedures.

CBSET has extensive expertise in the placement, assessment, imaging and histopathological evaluation of a wide variety of interventional devices, including:

- Coronary and peripheral stents
- Balloons
- Stent grafts
- Thrombectomy devices
- Transcatheter heart valves
- Filters
- Local drug delivery systems

CBSET’s state-of-the-art cardiac catheterization lab includes a fixed-panel GE Innova 2100 fluoroscope, and our staff includes multiple interventionalists with decades of experience in performing device evaluations. Beyond this, imaging capabilities enable the visualization and quantification of device placement and flow properties.

Thorough characterization of the safety and efficacy of interventional devices requires histopathological evaluation of any tissue responses. CBSET has pioneered histological methods for processing of complex devices, ranging from bare metal stents to bioabsorbable stents made of novel polymers or biomaterials to complex thrombectomy devices and others. CBSET’s board-certified veterinary pathologists have in-depth expertise in qualitative and quantitative evaluation of tissue response, including inflammation, injury and adverse effects such as restenosis. On-site SEM capabilities enable imaging of the luminal vessel surface and histomorphometric evaluation of endothelialization.

Computational modeling can also be applied to the in silico evaluation of drug elution characteristics from drug-eluting stents and drug-coated balloons, including prediction of local pharmacokinetic profiles and correlation with pharmacodynamics, such as receptor binding. Similar approaches can be used to characterize dissolution of bioabsorbable devices.

CBSET’s capabilities and expertise can allow optimal and efficient evaluation of interventional devices, ranging from initial acute assessment of prototype devices to definitive GLP studies for regulatory approval.
ABOUT CBSET

CBSET is an AAALAC accredited, not-for-profit, pre-clinical research organization dedicated to research, education, and the advancement of early-stage biomedical technologies. Our mission is to assist in methodologies uniquely suited for novel and innovative treatments for complex diseases. We offer a full range of GLP and non-GLP services, ranging from early product evaluation through lead optimization and pre-clinical safety, to physician assessment and training courses. We specialize in the development and application of techniques in the fields of cardiology, electrophysiology, orthopedics, wound healing, regenerative medicine, endoscopy/laparoscopy, drug and device delivery and safety, cellular therapy, and diagnostic imaging. Our world-renowned regulatory and scientific expertise helps transform early-stage concepts into novel therapies.

CBSET EXPERTISE

Our professionally trained staff and consultants provide expertise for all phases of biomedical discovery and development research including regulatory consulting, veterinary medicine, surgery and minimally invasive surgery, imaging, pharmacokinetics and drug metabolism, drug and device safety, pharmacology, lead optimization, and specialized histopathology and pathology. These individuals provide the basis for successful scientific collaborations, rapid concept advancements, unparalleled consultation services, and expert dissemination of information and findings to regulatory and scientific bodies.

CBSET offers a full range of GLP and non-GLP services, from early product evaluation through lead optimization and pre-clinical safety, to physician assessment and training courses. Our expertise includes:

- Stents/balloons
- Novel catheters/wires
- Robotic-assisted surgery
- Vessel sealing/closure devices
- Heart valve replacement/repair
- Cardiopulmonary bypass
- Beating heart technology
- Electrophysiology devices
- Tissue ablation devices
- Endoscopic NOTES surgery
- Laparoscopic surgery
- Orthopedic devices
- Novel surgical instruments
- Wound healing devices
- GLP training and regulatory consulting

CBSET FACILITIES

CBSET offers an unparalleled, GLP-compliant, 30,000 square foot state-of-the-art facility within minutes of Cambridge, Boston, and Logan International Airport. Our facility includes vivariums, catheterization/imaging labs, and full surgical suites containing the latest equipment for fluoroscopy, echocardiography (TEE/TTE), electrophysiology, IVUS, optical coherence tomography (OCT), endoscopy/laparoscopy, orthopedic surgery, and surgical video recording. CBSET offers dedicated labs for GLP-compliant SEM, specialty histopathology/pathology, metabolism and pharmacokinetics.