



# SCANNING ELECTRON MICROSCOPY

## High-Resolution Imaging

High-resolution imaging can be a powerful tool in supporting product development and technology differentiation, and in fortifying regulatory submissions. CBSET offers Scanning Electron Microscopy (SEM) services that complement our other services, including in-life studies, pathology service and mechanical testing.

CBSET applies its advanced SEM techniques and experience in pathology and regulatory review to meet the critical needs of our clients, including assessment of tissue and material characterization after *in vivo* device treatments, investigation of device integrity and failure, and evaluation of cellular morphology or elemental analysis. CBSET applies SEM assessment to studies including, including:

### Intravascular or nonsurgical device implantation

- **Stents & Scaffolds:** Coating integrity, thrombogenicity, endothelialization and inflammatory response to bare metal stents and polymer scaffolds.
- **Drug coated balloons:** Coating integrity, surface mapping and quantification of acute arterial coating distribution, assessment of arterial injury.
- **Valvular implantation:** Assessment of delivery, biocompatibility and function of replacement valves.
- **Depot integration:** Characterization of composition and tissue response to subcutaneous polymer depots.

### Surgical device implantations

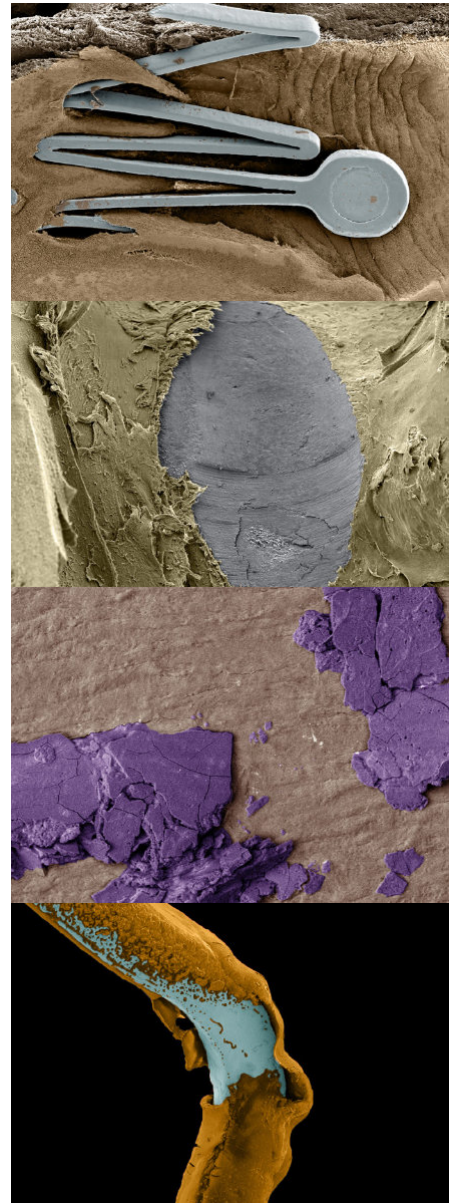
- **Vascular grafts:** Evaluation of drug coated grafts in peripheral artery bypass models.
- **Polymer meshes:** Histological evaluation of host inflammatory/fibrotic response and characterization of mesh contracture.

### Atherectomy and vessel preparation

Evaluation of plaque removal and stent damage after device-treatment, assessment of tissue morphology in control and treated arteries.

### Benchtop device evaluation

- **Vascular stents:** Assessment of coating thickness and defects, drug coating uniformity and coating microstructure.
- **Decellularized tissue implants:** Evaluation of microstructure and characterization of pore size.
- **Hemostatic agents:** Interaction of blood with test material.



## ABOUT CBSET

CBSET is a state-of-the-art translational research institute located in the greater Boston area of MA.

Our mission is to advance biomedical research, through innovative, high-quality services. We combine top-tier research with operational expertise. Since our inception, CBSET has continued to develop technical and scientific acumen through collaborative projects in the medical device, pharmaceutical and academic communities.

Our 40,000 square foot, GLP-compliant, AAALAC- accredited facility includes vivaria, procedure rooms, catheterization / imaging labs, surgical and necropsy suites, histopathology, SEM, and a range of other technologies.

## Why CBSET?

- **Credibility.** We are recognized as unbiased experts, bringing independent credibility to your regulatory filings.
- **Culture.** Our culture is based in science; we value new models and creative collaboration.
- **Mission.** Our motivation is to enable your success; your product is our mission.
- **Integrated resource.** Our multidisciplinary team includes board-certified veterinary, quality, biological and quantitative sciences expertise, as well as board-certified pathologists – all in one facility.

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## GLP-compliant Microscopy

CBSET is one of the few in the industry to perform microscopy under Good Laboratory Practice (GLP)-compliant procedures. To maximize the value of these critical imaging protocols CBSET maintains a fully-equipped microscopy laboratory utilizing current technology with a proven track record of satisfying regulatory review standards.

## State-of-the-art Equipment

We utilize a state-of-the-art Hitachi S-3400N-II, a fully automated, variable-pressure scanning microscope with digital imaging capacity. It is equipped with:

- Electron Detector (SE)
- Backscattered Electron Detector (BSE)
- Low Vacuum Secondary Electron Detector (ESED)

It can operate in High and Low Vacuum Mode and Variable Pressure Mode (VP) for observation of non-conductive samples.

Our SEM station uses a Deben-Peltier Cool Stage which allows observation of specimens in their natural state or in wet condition.

For an additional fee we can recolor images for greater contrast and use in presentations.

