

MECHANICAL TESTING OF BIOMATERIALS AND TISSUES

Mechanical testing of both biomaterials and biological tissues can be a critical component in both the design and evaluation of medical devices. Mechanical integrity of biomaterials being used in medical devices is a critical design consideration, and retention of mechanical properties after *in vivo* implantation can serve as an indicator of biocompatibility. Conversely, the decline in mechanical properties of biodegradable materials can contribute to understanding of the temporal and spatial characteristics of the degradation process. Beyond this, the maintenance or deterioration of mechanical properties of host tissues can be used to evaluate efficacy and/or safety of devices after *in vivo* implantation.

CBSET houses the Instron ElectroPuls E1000, an electrodynamic test instrument, which allows for a variety of testing solutions that are compliant with Good Laboratory Practice (GLP) regulations including:

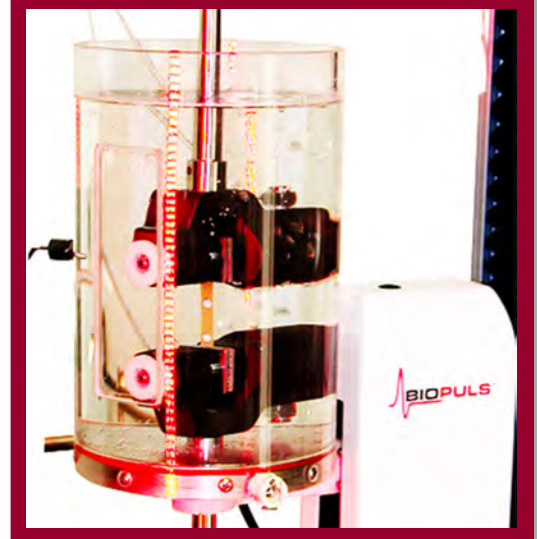
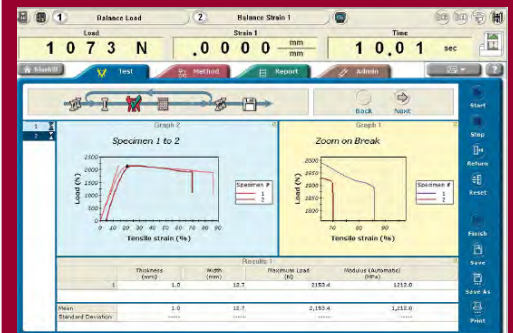
- Tensile testing
- Compression testing
- Bend/Flexure testing
- Fatigue testing
- Static/Monotonic testing
- Dynamic testing
- Environmental testing
- Custom testing design

Beyond standard testing of biomaterials, biological tissues and medical devices, CBSET will collaborate with partners in developing methodologies for novel testing and analysis. We can provide the expertise and equipment necessary for the successful evaluation of almost any type of sample. The versatile design of the ElectroPuls system allows the application of sub-Newton loads as well as physiological loads, offering the precision necessary for low-force testing of tissues and biomaterials, and the power necessary for high-force testing of bones and medical devices. CBSET also offers the option of using a BioPuls temperature-controlled bath, which provides a more optimal simulation of *in vivo* environmental conditions. Typical biomedical applications include static and fatigue testing of:

- Healing bone and bone/implant constructs
- Hernia meshes
- Stent materials and structures
- Polymeric and metal biomaterials
- Skin defects and wound repair
- Intact and repaired tendons
- Various other tissues and biomaterials

ElectroPuls E1000 Specifications:

- Dynamic capacity ± 1000 N (± 225 lbf)
- Static capacity ± 710 N (± 160 lbf)
- Stroke 60 mm (2.36 in)
- Daylight opening 610 mm (24 in) maximum
- Load cells: ± 2 kN, ± 250 N Dynacell™ load cells, ± 10 N static load cell
- WaveMatrix software for dynamic and fatigue testing
- Bluehill 2 software for static testing
- Compliant with Good Laboratory Practice (GLP) regulations



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
- Endovascular/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



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