



EVALUATION OF HERNIA REPAIR MESHES, FIXATION AND RELATED DEVICES

Hernia repair is one of the most common surgical procedures, and aims to close abdominal wall defects that tend to develop in the inguinal, ventral or umbilical areas. Prosthetic patches, meshes or plugs made from synthetic or biologically-derived materials are often used in the repair procedure, and serve to provide immediate hernia closure as well as a scaffold for formation of repair tissue. Hernia repair can be done either by open procedure or laparoscopically; the minimally-invasive approach is gaining popularity due to quicker recovery times, decreased pain and decreased risk of infection. Further advances in hernia repair procedures include incorporation of anti-infective agents into the devices and use of bioresorbable materials.

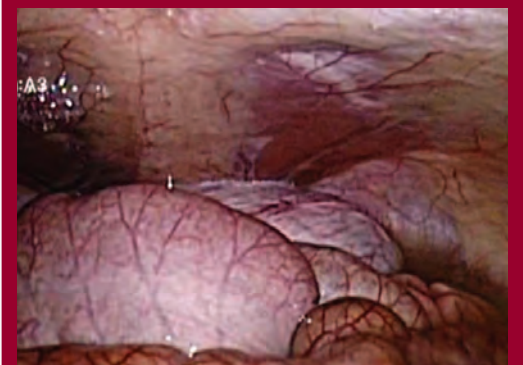
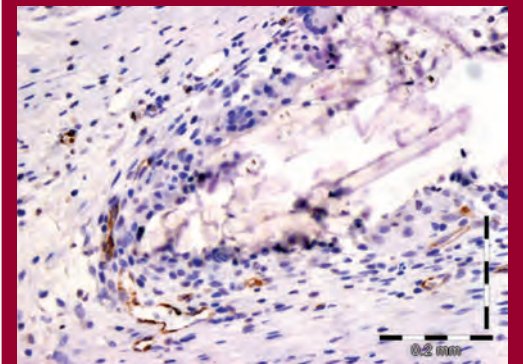
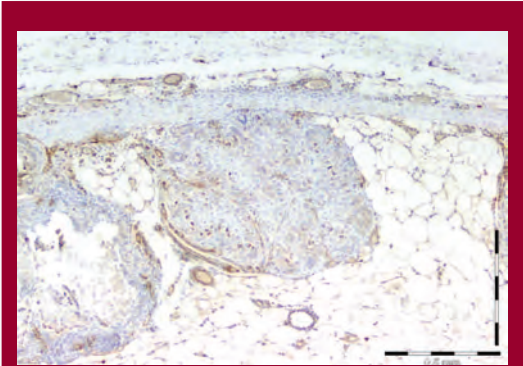
CBSET has experience evaluating the safety and efficacy of a variety of hernia repair technologies, including:

- Hernia repair patches and meshes
- Hernia plugs
- Suture or staple fixation
- Adhesive / glue fixation
- Infection prevention
- Wound drains

In addition to evaluating device safety and efficacy, CBSET also has experience in more advanced evaluation of these technologies, including characterizing novel materials, biomechanical testing of fixation strength and determining biodistribution of novel pharmacologic coatings.

CBSET is equipped with an Olympus EVIS EXERA II laparoendoscopic tower, including: VISERA PRO HD camera head, CO2 insufflation unit, 0° and 30° laparoscopes, dual-channel gastroscope, high-definition monitor, narrow band imaging technology and DVD/USB recording capabilities.

Our uniquely skilled surgical and technical staff has extensive experience with hernia repair model in small and large animals, including rat, rabbit, mini-pig or Yorkshire swine. In addition, CBSET's board-certified veterinary pathologists can evaluate and characterize tissue damage, repair, or response to implanted devices using histological methods.



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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