

SAFETY ASSESSMENT

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Capabilities and Expertise:

- Bone fracture/defect repair models
- Spinal fusion and non-fusion spinal models
- Joint/cartilage models
- Osteoinduction
- Craniomaxillofacial
- Dental implants and CMF models

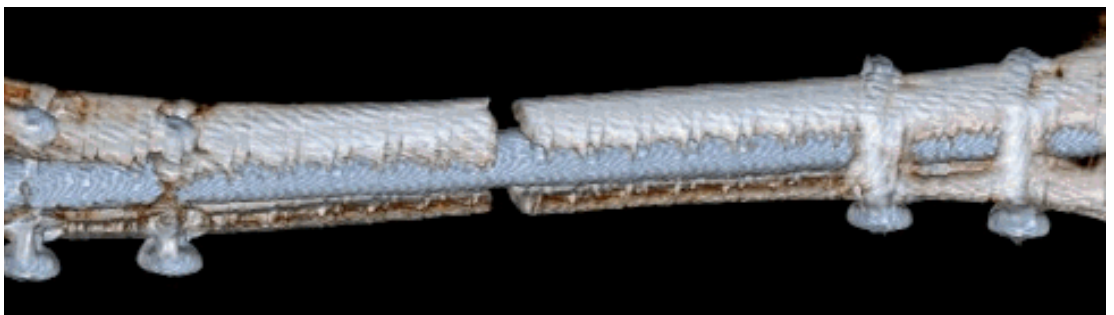
Orthopedic Models for Medical Devices

Preclinical Safety and Efficacy Assessment of Orthopedic Devices and Specialty Orthopedic Studies

Charles River provides evaluation services for orthopedic medical devices and biologics from the proof-of-concept to regulatory testing under GLP. State-of-the-art imaging modalities include computer tomography imaging (CT scanner), magnetic resonance imaging (MRI), high-definition radiography (Faxitron™), and micro-computed tomography (Micro-CT). Diverse histological end-points are quantitatively assessed using manual and software-guided automated histomorphometry. A full histopathological analysis and quantitative report is provided by experienced veterinary pathologists.

Bone Fracture/Defect Repair Models

Our bone repair models encompass orthobiologics and the evaluation of bone substitutes, long-bone femoral and tibial defects, press-fitted insertion and gap models, osteotomy repairs (e.g., critical-size segmental defects), bone apposition and the evaluation of bone implant contact (BIC), and osseointegration and bone ingrowth.



EVERY STEP OF THE WAY

Spinal Fusion and Non-Fusion Spinal Models

We offer a range of spinal fusion and non-fusion models, including intervertebral fusion cages, posterolateral lumbar intertransverse spinal fusion (PLF), disc arthroplasty, and nucleus pulposus replacement.

Joint/Cartilage Models

Our musculoskeletal expertise covers a range of joint and cartilage models, including knee articular cartilage repair, osteochondral defect repair, microfracture defects, osteoarthritis (OA) reduction, anterior cruciate ligament transection (ACL-T), reconstruction and fixation, as well as meniscal reconstruction.

Osteoinduction

Highly-specialized osteoinduction evaluations include ectopic bone formation and the muscular pouch model.

Craniomaxillofacial

Our range of craniomaxillofacial models include cranioplasty, parietal bone and mandibular defects, maxillofacial fracture fixation, alveolar ridge augmentation and dental implants.

Operating from our sophisticated orthopedics and biomaterials labs, our team is prepared to assist clients with the study design and the development of both short- and long-term animal studies that are fully compliant with regulatory agencies regarding the safety and efficacy evaluation of orthopedic medical devices and biologics. Charles River facilities are fully accredited by AAALAC international and CCAC, and successfully audited for GLP compliance by the US FDA.

