



SAFETY ASSESSMENT

Medical Device Preclinical Services and Facilities

- Implantation models
- Biocompatibility
- Pathology
- Imaging

Global capacity and multidisciplinary capabilities enable us to design a safety assessment program around what our clients value most. This is a representation of our safety assessment medical device portfolio, however additional services can be discussed with our experts as every Medical Device program is customized to specific client needs.

		Facilities						
		Boisbriand, Quebec, Canada	Laval, Quebec, Canada	Mattawan, Michigan, USA	Pathology Associates International, 3 Sites, USA	Senneville/Sherbrooke, Quebec, Canada	Spencerville, Ohio, USA	Veszprem, Hungary
Medical Device Safety and Efficacy								
Cardiovascular	Coronary and peripheral devices: drug-eluting stents, bioresorbable scaffolds, drug-coated balloons, stentgrafts	•		•				
	Structural heart: cardiac valves, occluders, closure devices	•		•				
	Electrophysiology: pacemakers, leads, ablation, neurostimulation	•	•	•				
	Heart failure: ischemia-reperfusion model, occlusive disease (permanent occlusion, ameroid constrictors), atrial fibrillation and atrial fibrosis	•	•	•				
Orthopedics	Orthopedic implants and biologics (general)	•	•	•		•		
	Bone fracture/defect repair models	•	•	•		•		
	Posterolateral (PLF) and intervertebral fusion	•		•		•		
	Osteoarthritis and osteochondral repair	•	•	•		•		
	ACL reconstruction and fixation models	•		•		•		
	Meniscal repair	•						
	Rotator cuff repair	•				•		
Dental	Osteoinduction and ectopic bone formation	•		•		•		
	Dental implantation	•	•	•				
	Alveolar ridge augmentation	•	•	•				
	Membrane guided bone regeneration (GBR)	•		•				
	Craniomaxillofacial (CMF) fracture repair	•		•				

EVERY STEP OF THE WAY

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Medical Device Safety and Efficacy (continued)								
Otorhinolaryngology (ENT)	Drug-eluting implants, drug-coated balloons	•						
Ototoxicology				•	•			
Ophthalmology	Oculoplasty	•	•	•				
Gastrointestinal	Colonic stents and clips, biliary stents, shunts (TIPS), endoscopic/laparoscopic instruments	•		•				
Oncology	Ablation systems (surgical and minimally invasive radiofrequency, microwave and cryoablation; percutaneous and laparoscopic)	•						
	Embolotherapy materials (bland and drug-eluting)	•						
Dermatology/Plastic surgery	Wound healing, dermal injections and breast implants	•	•	•				
Urogenital	Urinary catheters, vesical delivery systems and vaginal devices		•	•				
Histopathology and Other <i>Ex Vivo</i> Assessment								
	Scanning electron microscope				•			
	Transmission electron microscope				•			
	Elemental analysis with electron-dispersion x-ray spectroscopy				•			
	Paraffin histology	•	•	•	•	•	•	
	Plastic histology/ground sections	•			•	•		
	Histomorphometry	•		•	•	•		
	Image analysis	•		•	•	•		
	Immunohistochemistry	•	•	•	•	•	•	
	Medical device pathology	•	•	•	•	•		
	Peer review pathology	•	•	•	•	•	•	
	Toxicologic pathology		•	•	•	•	•	
	Whole slide scanning (Aperio)			•	•	•		
	Biomechanics			•		•		

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Cytotoxicity (GLP, ISO 10993-5)							
MTT assay							•
MEM elution assay							•
Neutral red uptake (NRU)					•		•
Genotoxicity (GLP, ISO 10993-3)							
Pretest to determine extraction method					•		•
Bacterial reverse mutation test (Ames)					•		•
<i>In vitro</i> mouse lymphoma assay TK					•		•
<i>In vitro</i> chromosomal aberration test					•		•
<i>In vitro</i> micronucleus test					•		•
<i>In vivo</i> rat micronucleus test					•		•
<i>In vivo</i> mouse micronucleus test					•		•
Hemocompatibility (GLP, ISO 10993-4)							
Hemolysis test			•				
Implantation (GLP, ISO 10993-6)							
Implantation (standard subcutaneous intramuscular or bone implantation)	•		•		•	•	•
Specialized Implantation	•		•		•		•
Sensitization (GLP, ISO 10993-10)							
Local lymph node assay (LLNA)			•				•
Buehler patch test			•			•	•
Guinea pig (maximization test) (GPMT)			•			•	•
Irritation or Intracutaneous Reactivity (GLP, ISO 10993-10)							
Skin irritation			•			•	•
<i>In vitro</i> skin irritation							•
Ocular irritation			•			•	•
Other irritation tests (vaginal, rectal, penile, oral mucosa)			•			•	•
Intracutaneous reactivity test			•			•	•

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Systemic Toxicity (GLP, ISO 10993-11)							
Acute systemic toxicity	•		•		•		•
Subacute toxicity (14-28 days repeat dose)	•		•		•	•	•
Subchronic toxicity (90 days repeat dose)	•		•		•	•	•
Chronic toxicity (9-12 months repeat dose)	•		•		•	•	•
Pyrogenicity (GLP, ISO 10993-11)							
Pyrogenicity study in rabbits			•				•
Imaging							
PET			•		•		
MRI	•		•		•		
CT scan	•						
Micro-CT	•		•		•		
Fluoroscopy	•	•	•				
Bioluminescence					•		
Fluorescence			•		•		
Ultrasound	•	•	•				
DXA scan			•		•		
Laser speckle (blood perfusion)			•				
Digital X-ray/Faxitron™	•	•	•		•		

For information on our other Medical Device Services in [Biologics Testing Solutions](#) and [QC Microbial Solutions](#), please [contact us](#).