

# Cardiovascular Studies



AppTec serves as a unique single-source provider for comprehensive medical device custom implant studies and materials testing. Testing services are offered through AppTec's associated facility, Integra Medical Research and Evaluation, located in Minneapolis, Minnesota.

## THE INTEGRA FACILITY

Integra is registered with the USDA and operates in accordance with the Guide for the Care and Use of Laboratory Animals. The facility has the capacity to house multiple species for implant studies, with modern, fully functional surgical suites and accompanying training suite.

Supporting equipment includes complete routine surgery equipment plus state-of-the-art fluoroscopy/angiography; echocardiography; Cryocor thermal ablation system; video imaging, recording and links to conference rooms; and a full engineering lab for customer use.

Staff scientists have over 30 years of cardiovascular device experience including stents, CRM, vascular, grafts and interventional devices.

## Program Features

Experience with all standard animal models, including: Rabbit • Dog • Sheep • Goat • Pig  
Experienced study director, research surgeon and QA auditor on site, plus physician access  
In-house chemistry, histology interpretation and clinical pathology evaluation  
Model development and evaluation  
Device and pharmaceutical performance and evaluation  
GLP, non-GLP and R&D device design and material testing  
Protocol development and reporting  
FDA/Regulatory guidance

## Implant Study Experience

- Cardiac device – permanent/acute (pacing & defibrillator leads, balloons, stents, atherectomy & CRM devices)
- Cardiovascular access
- Peripheral vascular access
- Site-specific organ access
- Electrophysiology
- Interventional procedures
- Fabric and vascular grafts
- Hemodynamics
- Heart failure
- Sensors and implantable monitors
- Right- and left-side catheterization

## Project Progression



*In addition to cardiovascular studies, AppTec offers other custom implant studies, plus complete biocompatibility/safety testing and toxicology studies.*

AppTec is a unique single source for comprehensive GLP/GMP-compliant testing, contract research and development, and specialized cGMP manufacturing services for biopharmaceuticals, medical devices, cellular therapeutics, and tissue-based products. We provide our clients the highest level of state-of-the-art science, regulatory expertise and individualized customer service.

For more information about our wide range of services, contact an AppTec Account Manager at 888.794.0077.

[www.apptec-usa.com](http://www.apptec-usa.com)