



MSI offers a broad array of services in support of medical device development, from study plan design and contract testing to lab time rental. Our staff has experience with a wide variety of device materials and configurations. Application technicians can assist with test development as well as perform the testing in an unbiased manner.

Within the testing lab we have top of the line testing equipment including the IDTE 2000™ Interventional Device Testing Equipment, RX550/650 Radial Force Testing Equipment, SR1000 Stent Securement Testing Equipment, Crescent Design burst test system, and Instron tensile testing system for comparatively and quantitatively testing performance features of percutaneous delivery and diagnostic devices. Test results can be useful for regulatory submissions, pre-clinical trial testing, competitive product testing, and product design.

## ***Medical Device Testing Services***

- **Stents.**
- **Guidewires.**
- **Guide catheters.**
- **PTCA/PTA catheters.**
- **Embolic protection devices.**
- **Endoscopic tools.**

# Contract Testing Services



## IDTE2000™ Interventional Device Testing Equipment

### Standard Testing Protocols

- Track force
- Push efficiency
- Lesion crossability force
- Insertion force measurement
- Torqueability
- Torque strength
- Rotational response
- Catheter / guidewire compatibility
- Stent flexibility
- Tip deflection

## RX550/650 Radial Expansion Force Testing Equipment

### Standard Testing Protocols

- Radial Stiffness for balloon expandable devices.
- Radial Strength for balloon expandable devices.
- Chronic Outward Force for self expanding devices.
- Radial Resistive Force for self expanding devices.

## SR1000 Stent Securement Testing Equipment

### Standard Testing Protocols

- Guide type securement test.
- Proximal or distal displacement of a stent.

## Relevant International Testing Standards

- ASTM F2394-07 for preconditioning of the stent on the deployment system prior to retention testing.
- ISO Standard 25539-1:2003(E) Titled "Cardiovascular implants - Endovascular devices -- Part 1: Endovascular prostheses".
- ISO Standard 25539-2:2008(E) Titled "Cardiovascular implants - Endovascular devices -- Part 2: Vascular stents".
- ISO/TS 15539:2000(E) Titled "Cardiovascular Implants - Endovascular Prostheses".
- FDA guidance document titled "Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems".