

The SR1000 Stent Securement Testing Equipment is designed to measure and record the force required to dislodge a balloon-expandable stent from its proper position on a balloon. The SR1000 is comprised of a multi-sectioned segmental head, including one segment that radially grips the balloon and another segment that captures the stent edge. These head sections separate to dislodge the stent proximally or distally from the balloon. The SR1000 utilizes stepper motor linear actuators for precise diameter control and smooth pull action. Test results can be used for regulatory submissions, competitive product testing, R&D device evaluation and inline manufacturing quality assurance.

MSI designed the stent securement tester to work as a standalone unit with an optional submersible configuration for testing in an aqueous, temperature-controlled environment. The system can also be purchased as an add-on to the MSI Interventional Device Testing Equipment (IDTE2000).

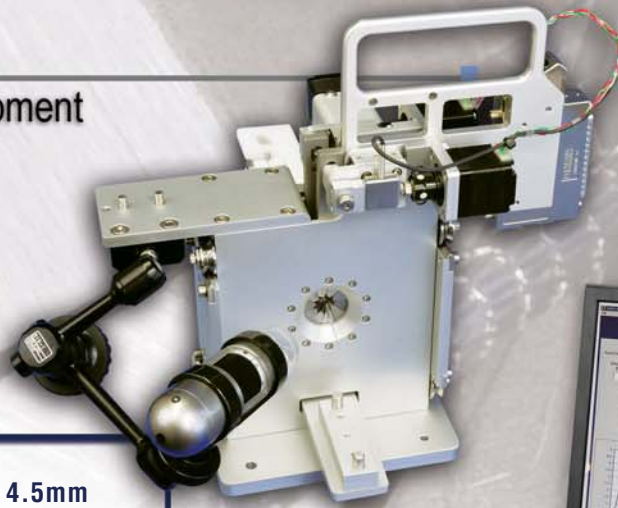
The SR equipment is designed with international testing recommendations in mind. These include: the FDA guidance document titled "Non-Clinical Tests and Recommended Labeling for Intravascular Stents, and Associated Delivery Systems", ASTM F2394-07 Guidance Document for Stent Securement, and ISO Standard 25539-2: 2008.

Stent Securement Features

- Guide-type securement test.
- Proximal or distal displacement of stent.
- High speed data acquisition system.
- Quick set up.
- Repeatable and reproducible data.
- Quick, simple software controlled calibration.
- Graphical displaying of force vs. displacement in real time.
- Diameter control and force feedback on capture segments.
- Video assist with sample alignment & video capture of test.
- Data output setup for spreadsheet analysis.
- Data output includes: profile parameters, peak force and associated displacement.

SR1000

Stent Securement Testing Equipment



Summary of Spec Data

<i>Capture Head Diameter Range</i>	0.25 - 4.5mm
<i>Capture Head Length</i>	0.5mm
<i>Gripper Head Diameter Range</i>	0.25 - 4.5mm
<i>Gripper Head Length</i>	6.0mm
<i>Diameter Accuracy</i>	0.02mm
<i>Diameter Resolution</i>	0.01mm
<i>Force Accuracy</i>	0.1N
<i>Force Resolution</i>	0.1N
<i>Pull Rate</i>	0.01– 30.0in/min
<i>Power Requirements</i>	110 or 220 VAC
<i>Capture Head Load Cell Size</i>	10lb
<i>Gripper Head Load Cell Size</i>	10lb
<i>Pull Load Cell Size</i>	5lb
<i>Temperature Controlled Water Bath</i>	Optional with submersible system
<i>General Warranty</i>	1 Year

SR1000 Equipment Specifications

Stent Securement Base

- Stainless steel ten segment design.
- Interchangeable handling system for proximal or distal pull.
- Stepper motor driven linear actuators.
- Standard S beam integrated load cells.

Control Module Specifications

- High speed motion control system.
- High speed data acquisition (100 samples/second).
- Ethernet PC to control module connection.
- Custom cable connection between control module and base.

Software Specifications

- Windows PC based software.
- Adjustable testing parameters include: head close speed, capture diameter, capture maximum force, gripper force, pull speed and pull distance.
- Pull force and distance are measured, displayed, graphed and written to a CSV (Comma Separated Variable) file.
- Unlimited profile creation and storage.

SR1000 Machine Dimensions

- Machine Weight: 8.8lbs (4.0kg)
- Height: 10" (254mm)
- Width: 13" (330mm)
- Depth: 12" (305mm)

SR1000 Control Module

- Machine Weight: 30lbs (13.6kg)
- Height: 17" (413mm)
- Width: 9" (229mm)
- Depth: 21" (534mm)