Medical Device Mechanical Performance Testing

Mechanical Performance Testing comprises a series of stress tests using calibrated equipment designed to establish the structural integrity and flexibility of a product, ensure that it can be used safely as intended, capture data regarding how the product responds to such stress, and they perform according to their intended use and labeling. We offer a list of the mechanical performance tests which are available for varieties of catheters and wires to ensure the mechanical integrity of a product. STEMart offers state-of-the-art technology and facilities to provide multiple balloon catheter testing according to FDA guidance document recommendations and ISO standards.

Our Mechanical Performance Testing:

Catheter Tensile Test

The catheter tensile test is designed to measure the tensile strength and elongation of the catheter joints and components including each tube, hub, connector, and junction. In another word, the catheter tensile test uses Zwick tensile test systems equipped with various load cells from 10N to 10kN to meet the ISO standards or customer-defined requirements, ISO 10555 specially asks for a measure of tensile force until a break occurs or until a junction separates.

• Micro Tensile Test

The Micro Tensile test is used to measure the tensile strength of small section samples within scanning electron microscope chamber. In addition, the test measures on the microscale to detect single plastic deformation mechanisms to meet the testing requirements of ISO standards or customer-defined requirements.

Catheter Kink Resistant Test

The Catheter Kink Resistant test is used to maintain a cross-sectional profile during deformation. In another word, this test measures kink resistance by placing a catheter segment between two plates and compressing the sample until it kinks to meet the ISO 10555 standard or FDA guidelines.

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With extensive expertise in medical device mechanical performance testing, **STEMart** can provide a full-service experience, support manufacturers to meet the regulatory goals, and minimize the compliance risks.

If you have any additional questions about Medical Device Mechanical Performance Testing or would like to consult with the experts at **STEMart**, please feel free to contact us.