

IDTE'S SOLUTION TO TORQUEABILITY AND TORQUE STRENGTH

A problem for many device companies is determining exactly how to best evaluate the mechanical properties of their Coronary and Peripheral Arterial Catheters. The FDA Guidance documents generally state that the mechanical properties, functional attributes as well as the performance characteristics described in the labeling and other instructions for use should be tested. The FDA does not give specific guidance on how to perform these tests. This is where the ASTM and ISO guidance documents and ASTM test methods are used to ensure appropriate and uniform testing across the industry.

Mechanical properties that companies tend to have difficulty testing is the torqueability and torque strength of their catheter systems including guide wires, guide catheters, catheters and other support devices. Torque Strength is defined by ISO as the torque required to break joints and or materials in the device. Torqueability is defined by the FDA as the correlation between rotation of the proximal end and the corresponding rotation of the distal end. The greatest challenge with the catheter systems is the very low torque values. For example the torque strength of most guide wires does not exceed 0.5 inoz.

Machine solutions has put significant effort into developing test setups for torqueability and torque strength for these low torque devices on the Interventional Device Test Equipment (IDTE). The torque package is one of the options customers can add on to the standard IDTE. Because the torque package is incorporated onto the IDTE all devices can be tested in a temperature controlled water bath through tortuous anatomy.

To evaluate torque strength there are two torque sensors on the system, one dynamic and one static. This allows the system to measure the torque at both the proximal and distal end continuously during the test and measure the failure in the product (a drop in torque force) even before the operator can visually see the failure in the product. This test can be performed on complete devices or subsystems to test the strength of specific joints. This system has the resolution to be able to see a 0.05inoz change in torque.

For torqueability the IDTE utilizes the dynamic torque sensor on the proximal end of the product and either an encoder or a low friction rotations out sensor on the distal end. Often the "WIP" of a product can either be masked or exaggerated by the method of measuring the rotations out on the distal end. Thus MSI has two methods of measuring rotations out. For light weight products such as guide wires the low friction rotations out sensor is used and it has the ability to measure the number of distal rotations without applying any load to the end of the wire. For larger diameter products with more stiffness, an encoder can be used on the distal end. The encoder has a greater resolution with 3600 counts per revolution and a very small amount of friction which is easily overcome by the stiffer products such as guide catheters.

With the optional Torque sensors the IDTE is an off the shelf system that can not only meet a companies need for torqueability and torque strength but also characterize deliverability, retraction and device compatibility.