

Dynatek delta

Leading the world in medical device testing

stent testing

FAQS

1. Where can I find the latest FDA Guidance Document for stent testing?

Follow this link: www.FDA.gov/cdrh/ode/guidance/1545.pdf

2. What are the FDA guidelines for stent testing?

Accelerated in vitro testing for approximately 10 years of equivalent real time should be conducted. A statistically significant sample of stents expanded to their largest intended diameter and dynamically cycled using simulated vessel conditions should be tested. A complete description of the test protocol and sample preparation used in this study should be provided.

3. At what frequency can the stents be tested? (i.e. How long does the test take?)

Using physiologically relevant load control protocols that have been shown to be predictive of clinical fractures and breakage, the frequency of the test is determined by the frequency response characteristics of the stent itself and of the mock artery with the stent deployed. Ideally, the frequency of the test would not surpass the sample system's ability to behave as it would in vivo. The LVP4 and SVP216 can be powered by several different mechanical systems which give testing speeds up to 50 cycles per second under ideal conditions (speed is determined by your device and pressures desired). However, as with most high speed durability/fatigue testing, the dynamic characteristics of the medical device itself will actually determine how fast the testing can be done. This determination of the frequency response of the device is usually accomplished on an instrument using protocols different than those used for the final high speed durability/fatigue testing.

4. Why is radial compliance important and at what compliance range should the device be tested?

The most common compliance is 5-7%; however, the mock artery should reflect the dynamic internal compliance of the target vessel of the stent. When testing intravascular products that must be mechanically evaluated inside of a mock artery, the internal compliance is important because it defines the amount of loading that the indwelling product will experience each cycle.

5. At what pressure range should the device be tested?

Stents should be tested under "worst case" scenarios. As most products are implanted in unhealthy patients, the minimum pressure range is usually chosen to be 160/80mm Hg.

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6. What size mock artery should be used to test the samples?

The mock artery should be sized to replicate the relative oversizing that a manufacturer suggests for any particular stent. When testing at nonphysiologic pressures and compliances, special attention should be paid to the stent/mock artery characteristics.

7. How does physiological pressure/compliance (also know as load control) testing differ from strain control testing?

Physiological pressure/compliance testing simulates what is happening in vivo. This technique had been shown to produce breakage and fractures in the same place and at a similar number of cycles as in clinical trials. Strain control testing, although usually carried out at higher frequencies, has not been shown to correlate with clinical results. The new ASTM standards will require verification that the outside of the stent follows the inside of the tube throughout the cycle. One method of verifying "vessel motion" is to measure the outside wall of the vessel and calculate the "inner motion". The problem with outside diameter measurements arises from two different sources. First, when a viscoelastic tube is pressurized and increases in diameter, the wall must thin out in order to circumscribe a larger diameter. This thinning of the wall means that the change in the inside diameter of the tube is never the same as the change in the outside diameter of the tube. If the tube has any porosity at all, then the problem magnifies, because wall compression can occur thereby causing an even larger difference between the change in the inside and outside diameters. The second source of trouble with respect to measuring outside diameter is that these are, by nature, pinpoint measurements. Cantilever, ultrasonic, and laser measurements, are only looking at a tiny fraction of the moving wall.

8. How many samples can be tested on Dynatek testers?

The number of samples depends on the size and shape of the mock artery and which tester is chosen. If testing on an SVP, twelve 1.5mm ID samples or up to eight 12mm ID samples can be tested. On an LVP twenty-four 4mm ID samples can be tested. Smaller numbers at larger ID samples (e.g. four 42mm ID) can be tested. Bifurcated and aneurized mock arteries can also be tested.

9. Can you design testing programs for new medical devices?

Since our inception in 1980, Dynatek has developed testers and protocols for a vast array of medical devices. Some of these are: septal defect closure devices, anastomotic staples, heart valve repair staples, heart valve implantation clips, various anastomotic devices, pulsatile tissue engineering incubators, LVADs, intra-aortic balloon pumps, and biological and synthetic vascular grafts. Dynatek designs all aspects of our testers, so modifying or designing new testers to fit new applications is done in a timely manner. Also, representatives from Dynatek are involved in ISO, ASTM, and AAMI standards committees that write test methods for new devices.

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10. What is the advantage of having one manifold that is bellows driven?

In order to measure the internal pressures that the devices are experiencing, the distal manifold has been designed with a pressure transducer port. This ensures that the pressure wave reaches completely through the mock artery. Having bellows on both manifolds prevents relevant pressure measurements while the tester is operational.

11. What are the advantages of having Dynatek do your testing?

Recently a number of articles have been published stating that companies are falsifying test data on their FDA submission documentation. Dynatek is an independent laboratory with a reputation for testing to the highest standards. By using Dynatek for your fatigue/durability testing, you are assured that all reports generated are submissible to any regulatory agency.

- We have the flexibility to meet ever changing needs and advancing technologies.
- We participate on the AAMI, ASTM, and ISO standards committees for writing new device test methods.
- You can enhance the effectiveness of your testing program by allowing you to focus on your core competencies.
- You obtain expertise, skills, and technologies that are not available anywhere else.
- Improved credibility in the test results; less encumbered in regulatory reviewing.
- Reduce investment in assets and free up resources for other purposes.