

# Dynatek delta

Leading the world in medical device testing

## graft testing

### FAQS

#### 1. What are the FDA guidelines and ISO standards for graft testing?

The FDA guidelines require a wide array of testing on grafts. Many of these tests can also be found in the AAMI/ISO standards. Dynatek offers both compliance and durability/fatigue testing. The AAMI/ISO test methods specify that instruments should be capable of applying reproducible dynamic internal pressure, maintaining  $37.0^{\circ} \pm 2^{\circ}$  C, measuring pressures up to 200 mm Hg (27.2 kPa)  $\pm$  2mm Hg (0.26 kPa), and measuring the diameter of the graft to an accuracy of  $\pm 0.02$  mm. Dynatek testers meet and exceed the aforementioned requirements. For a complete list, reference the ISO 25539-1:2003 Amendment 1, or contact us.

#### 2. How does Dynatek's testing conform to the standard requirements?

Dynatek testers exceed all requirements outlined in the standards. We are active in ASTM, AAMI, and ISO standards committees that write and review current test methods, so we are aware of new requirements.

#### 3. For prototype grafts, what initial tests are the most important?

Compliance, porosity, kink radius, blood compatibility and durability.

#### 4. At what frequency can the samples be tested (i.e. how long does the test take)?

The frequency of the test is determined by the material that the test specimen is made of, i.e., the frequency response of the graft material.

#### 5. What pressure ranges should be used to test the device?

To produce the most clinically relevant data, grafts should be tested at "worst case" physiological pressures (e.g. 160/80mm Hg).

#### 6. How does the testing differ for porous grafts versus nonporous grafts?

When testing a porous graft, a highly compliant liner is inserted. This allows for internal pressurization, but minimizes the effect of the insert on the durability (or compliance) testing of the graft.

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## graft testing cont.

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### FAQS

#### 7. What is the number of samples that needs to be tested? How do you choose the device size?

The minimum allowable sample population is three random samples per lot. In order to obtain the most clinically relevant data, one should test samples from each implantable size under the worst case scenario that the device would experience in vivo.

#### 8. How are abnormalities and failures reported to the customer?

For graft testing, unless otherwise requested, aneurysms and obvious failures are reported to the customer along with the conditions of the test (cycle count, temperature, etc). All other observations will be noted and reported in monthly reports and the final report.

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

Testing on Dynatek testers has proven to provide clinically relevant data. 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. Enhance the effectiveness of your testing program by allowing you to focus on your core competencies. Obtain expertise, skills, and technologies that are not available anywhere else. Improve credibility in the test results; less encumbered in regulatory reviewing.

Reduce investment in assets and free up resources for other purposes.