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## ***In-Vitro* Accelerated 85,000,000 Cycle Implantation Life Durability Test Protocol for Company Device**

Summary: This is a test plan for accelerated durability testing of Company. The Device mode tested was transverse compression inside physiological mock artery between two platens.

Device Manufacturer:

Approvals:

Protocol Author	Date
Lab Director	Date

March 22, 2006

## 1.0 Scope

This benchtop test is intended to provide empirical evidence for the continued structural integrity of the devices when subjected to mechanical fatigue such as that which they would receive *in vivo*. The test is designed to simulate the transverse compressive fatigue on a device due to the expanding and contracting of the vessel in which it was implanted. Eight (8) devices are deployed in silicone physiological mock arteries and will be tested within the same machine at one time. The test is accelerated in order to obtain results in a more reasonable time period than physiological rates would allow. The environment for the test is ambient air at 37°C +/- 2°C.

## 2.0 Objective

The objective of this testing is to demonstrate the safety of the device from mechanical fatigue failures. A device failure is defined as any broken or cracked strut visible at 30x magnification during or at the end of the test. The device manufacturer also will examine the devices post-testing and provide acceptance and/or failure criteria.

## 3.0 Sample Size and Identification

Samples are representative of devices prepared for commercial distribution. The table below may be used for device identification. Filters are placed in a radial configuration on a circular plate (see figure A below). The filter identification count starts from the mark on the plate in the clockwise direction.

Location on mounting disk	Filter ID
1	
2	
3	
4	
5	
6	
7	
8	

#### 4.0 Equipment

- 1.0 EnduraTEC ELF3230-001 test machine
- 2.0 EnduraTEC WinTest® Controls and Software
  - 2.1 Enduratec PC/PCI Series controller
  - 2.2 DAQ PC Control card
- 3.0 Computer ≥ 400MHz CPU
- 4.0 devices – provided by company
- 5.0 8-specimen test fixture for compression-compression fatigue – provided by company
- 6.0 The test fixture – a pair of platens -- was further modified to prevent sample migration and particulation. Physiological mock arteries were used to enclose the sample to prevent particulate generation owing to contact between filter devices and platens. Further, to prevent sample migration between the plates during test, small indentations were made into the two platens to hold the samples and physiological tubes. The indentations are approximately the thickness of the physiological tube itself.
- 7.0 Thermal chamber with thermal control – provided by MDTs

#### 5.0 Test Procedure Requirements

- 1.0 Mount base plate of thermal chamber into ELF. Adjust crossplate as required to accommodate the chamber. Also have heaters, rtd, and control box ready. Use impeller fans as needed.
- 2.0 Carefully mount test fixture into frame. Devices will be preloaded into the test fixture at Company. Devices shall be constrained from rolling or rotating by limiting movement of the double rings backbone as can be seen in figure A below.
- 3.0 Adjust positioning of the crossplate and also of the fixture as needed.
- 4.0 Install the chamber sides and top. Also position thermal control components as required so they do not interfere with the test rig.
- 5.0 Turn on Local Energy of the test system.
- 6.0 Slowly lower upper platens until they are at a position that is 22mm above the top surface of the bottom platen. This simulates the 22mm diameter, nominal diameter position of the device. The device shall be compressed from this position
- 7.0 Select Sine waveform.
- 8.0 Set level 1 and level 2 of the Sine wave to run between the max diameter position, 22mm, and a maximum compression position of 19.4 mm, giving a 3.6mm device compression.
- 9.0 Expected frequency for testing is 30 Hz. The device response shall be evaluated using a stroboscope to ensure a reasonable level of stability. The frequency may be adjusted to ensure stability.
- 10.0 Enter 85,000,000 cycles as total number of cycles in Sine waveform.
- 11.0 Check that chamber is at 37 degrees C.
- 12.0 Start test at zero counts.

**Monitor, measure and record values on a regular basis per below.**

#### 2.0 Regular Monitoring

Compression Protocol

- 2.1 Each weekday:
  - 2.1.1.1 monitor devices for migration,
  - 2.1.1.2 monitor and record peak/valley disp levels,
  - 2.1.1.3 record cycle count, and
  - 2.1.1.4 record temperature.
- 2.2 Every other weekday:
  - 2.2.1.1 Use a stroboscope to assist in inspecting for early device failures.
- 3.0 *Device removal from tester*
  - 3.1 After test has completed, examine visually and note any remarkable changes or device conditions.
  - 3.2 Carefully remove the fixture from the machine and package for return shipment to Company.

**6.0 Projected Schedule for Testing**

8 devices to 85 million cycles (33 days @30Hz)  
*Start Date*                    x/x/xx  
*Predicted Finish Date*    x/x/xx

The times reflect an estimate for the time to complete the various stages of the testing. As the test proceeds, more definitive dates may be established to account for setup, adjustments, data acquisition, problems, etc.

Revision History:

Version	Change	Date