TEST REPORT xxxx

ACCELERATED BENDING AND AXIAL COMPRESSION FATIGUE TESTING OF CUSTOMER DEVICES.

Device Manufacturer:
Customer
Contact:

Testing Facility:
Medical Device Testing Services
5929 Baker Rd Suite 430
Minnetonka, MN 55345
Test Engineer:
Job: MDTxxxxx
Date:

Scope

This benchtop test was intended to subject Customer's devices to simulated mechanical *in vivo* conditions and demonstrate the structural integrity. Testing was conducted under simulated physiological conditions: distilled water at 37°C +/- 2° fluid temperature and simulated bend and axial compression of the vessel surrounding it. The test was accelerated to obtain results in a shorter time period than physiological rates would allow. The testing objective was to characterize Customer's device mechanical properties over time (x years post implantation or x million cycles) in a physiologically relevant environment. Testing was conducted according to ASTM or ISOxxx..

Summary

x (x) devices were supplied by Customer and deployed in silicone tubes (xmm ID x xmm wall thickness, xmm ID x x wall thickness, xmm ID x xmm wall thickness) according to Customere's protocol (ID#xxx) and were subjected to x million cycles on an ELF3xx0x tester (ELF MDT-3xx0x-00x) in the MDT laboratory (7/25/2011 through 8/1/2011). Each cycle applied a bend and axial compression to the tubes to simulate mechanical conditions at the in vivo application site. Test duration simulated x years post implantation. Axial and angular displacement data were monitored daily. At the conclusion of the test, there were no signs of gross visible defects in any of the x devices. The tubes and devices were returned to Customer. Results only relate to the items tested, opinions and interpretations will be clearly marked as such in the test report.

Equipment

a) Bose Model 3300-AT Bose Test System – (ELF3300AT-002)
b) Bose WinTest® Controls and Software
c) Computer, ≥ 400MHz CPU
d) Required number of devices – 16, 4mm n=5, 6mm n=5, and 8mm n=6 (CSP#xxx1)
e) Silicone tubes 2.8mm ID x 1.0mm wall thickness n=5, 4.0mm ID x 1.0 wall thickness n=5, 5.3mm ID x 1.0mm wall thickness n=6
f) Multi Station Axial/torsional/bending test fixture provided by Medical Device Testing Service (PN 55060-101)
   (1) 16 Bending shoes (PN 51366-14 (5), PN 51366-15-B (5), PN 51366-16 (6))
   (2) 16 Bending Saddles (PN 51397-14 (5), PN 51397-15-B (5), PN 51397-16 (6))
g) 30x Microscope ISN 00217
h) Distilled water
i) Heating System

Procedures

The test followed test protocol (Doc. # xxx) agreed upon by MDT and Customer. Medical Device Testing Services (MDT) tests are conducted in accordance with *A2LA ISO/IEC 17025:2005, Certificate Number: 2783.01*.

Machine Calibration and Validations:

The ELF 3300 (MDT ELF3300AT-002) and temperature controller were verified to be up to date with all calibration schedules. Tester functionality was verified by running the tester without samples.

Fixturing:

Custom fixturing was designed, assembled and installed on the ELF 3300AT-002 according to protocol (Figure 1).

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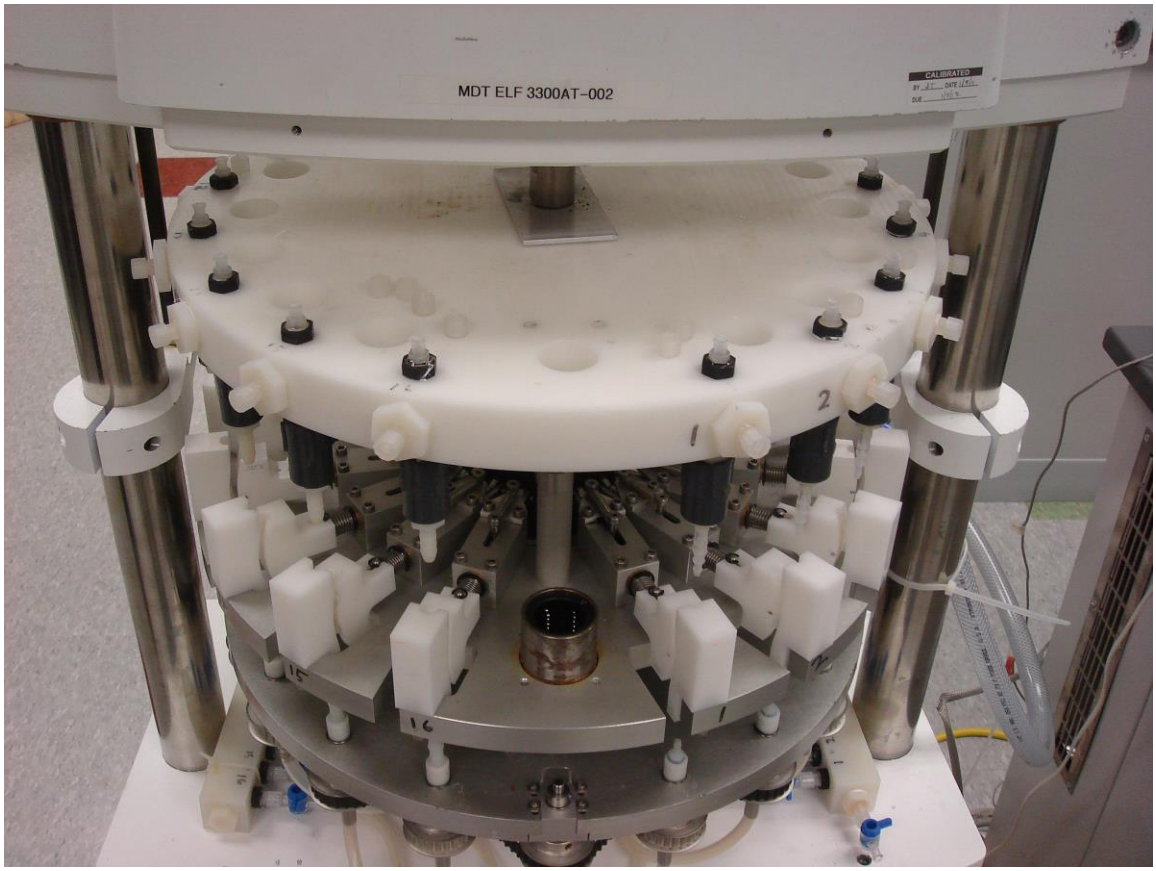

Figure 1: Fixture on ELF 3300AT-002-

Alignment:

Fixturing was aligned to achieve proper test conditions according to protocol.

Silicone Tube Conditioning:

Sixteen (16) silicone tubes were flushed with distilled water and were mounted on the ELF 3300AT EnduraTEC tester. The tester was filled with distilled water and then purged of air. The tubes were conditioned for 2 hours. Each tube was numbered and marked with top and bottom reference points.

Device Deployment/Installation:

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CUSTOMER Medical devices were deployed in conditioned silicone tubes while on the tester with the tubes in the maximum displacement condition, according to the protocol. The device position was marked on the silicone tube as a reference.

Accelerated Mechanical Testing:

The software parameters were identified based on the physiological inputs required by CUSTOMER (Table 1) and the EnduraTec ELF 3300AT (MDT ELF3300AT-002) was started on 7/25/2011. The autolog function was enabled. The cycle count, water temperature, axial displacement, rotation, were monitored and recorded daily. Additionally, a data scan at a single location is saved daily to the project file.

CUSTOMER Physiological Input	
Compression	x%
Bending	x mm Radius over x degree angle
Test Conditions	
Stretched tube length (mm)	x mm
Fixture fitting-to-fitting distance at top of stroke	x mm
Fixture fitting-to-fitting distance at bottom of stroke	mm
Tube length (unstretched)	x mm
WinTest Displacement Inputs	
Axial (total)	X
Axial (+/-)	X
Rotation input for bending (mandrels closing up at145°)	3° - 150°

Table 1: Test parameters to simulate physiological conditions for CUSTOMER device.

Disassembly:

At test completion the samples were carefully removed from the tester and labeled with a number corresponding to the order of testing.

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Results

The test parameters (axial displacement peak and valley for compression, rotation peak and valley for bending, (Figure 2, Table 2) were maintained within the Doc #228 protocol stipulations (Table 1).

RESULTS OMITTED FOR CONFIDENTIALITY

Descriptive Statistics	Displacement Peak (mm)	Displacement Valley (mm)	Rotation Peak (deg)-for bending	Rotation Valley (deg)- for bending
mean				
min				
max				
st. dev				

Table 2: 1 Million Cycle Fatigue Testing Data Descriptive Statistics for Test MDT11040 (MDT ELF 3300AT-002)

Disassembly:

Visual and 30x microscopic inspection at the conclusion of the test did not detect fractures in the 16 tested devices. The devices were picked up by CUSTOMER Medical for further inspection

Revision History:

Version	*Change*	*Date*

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Medical Device Testing Services (MDT) tests are conducted in accordance with *A2LA ISO/IEC 17025:2005, Certificate Number: 2783.01*. In compliance with this standard, MDT test reports include complete and accurate documentation of the test protocol and results. Information including the specific test conditions, statements of compliance or non-compliance with test protocol, statements of the estimated measurement uncertainty, and opinions or interpretations may be provided. Any test method deviations, additions or exclusions are documented and reviewed with the customer prior to beginning the test. Results only relate to the items tested, opinions and interpretations will be clearly marked as such in the test report. Additional information required by customer specific, or customer group specific, methods will also be noted.

Appendix A: Calibration Records

Equipment Calibration

No.	Component	Identification Number	Date Calibrated	Calibration Due Date
1	Enduratec ELF 3200 System Displacement (LVDT)	ELF 3xx0-00x		
2	Heater 0xx Temperature Box RTD Probe	 ISN ISN		

Table 1: Calibration schedule for the equipment used for MDT13xxx

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Appendix B: ISO 17025 Certificate

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Accredited Laboratory

A2LA has accredited

MEDICAL DEVICE TESTING SERVICES

Minnetonka, MN

For technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated 8 January 2009*).

Presented this 11th day of June 2015.

President & CEO
For the Accreditation Council
Certificate Number 2783.01
Valid to May 31, 2017

For the types of tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.

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Appendix C: Daily Data Monitoring

Date	Displacement Peak	Displacement Valley	Cycle (x.xx million)	Temp (°C)

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