

IN-VITRO ACCELERATED FATIGUE TESTING PROTOCOL

THIS IS A TEST PLAN FOR ACCLERATED, BENDING FATIGUE TESTING OF **COMPANY** STENTS. THE DURATION OF THIS TEST SIMULATES 1 AND 10 YEARS OF IMPLANTATION LIFE.

AUTHOR: **COMPANY**

DOCUMENT ID: 99129-MDT0xxxTP

GENERAL RENAL BENDING FATIGUE TESTING PROTOCOL FOR BALLOON EXPANDABLE STENT WITH STENT DEFLECTION CONTROL)

APPROVED BY:

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1.0 SCOPE

This benchtop test is intended to provide empirical evidence for the continued structural integrity of the devices when subjected to mechanical bending fatigue replicating *in vivo* conditions. The test is designed to simulate the device fatigue due to physiological strain at the *in vivo* deployment site. The test is accelerated to obtain results in a shorter time period than physiological rates would allow. The test is conducted under simulated physiological conditions with saline at 37°C +/- 2°.

The EElectroForce® (ELF) instruments operate with patented high-bandwidth, low-distortion motors. The ElectroForce 3200 series are rated to 250N (50 lbs) and perform precision materials tests including tension/compression, fatigue and dynamic materials characterization.

Testing will be conducted at Medical Device Testing Services Facilities, in Minnetonka, Minnesota, under the direction of trained Medical Device Testing Services personnel. All personnel who will be involved in the test set up and monitoring will be properly trained according to both **Company** and MDT's approved protocols.

2.0 OBJECTIVE

The testing objective is to meet the appropriate standard requirements for *in vitro* mechanical fatigue testing for the current test. The test will demonstrate the integrity of the device under mechanical bending fatigue for a minimum of 1 or 10 years post-implantation. Devices will be reviewed for any broken or cracked strut visible grossly or at magnification at the end of the test. The device manufacturer will also examine the devices post-testing and provide acceptance and/or failure criteria.

3.0 SAMPLE SIZE AND IDENTIFICATION

Samples will be representative of devices prepared for commercial distribution. The table below may be used for identification.

INSTRUMENT	TEST DESCRIPTION	SAMPLES LOT OR ID#
ELF3200	TEST 1 10MILLION	
ELF3200	TEST 2 10MILLION	
ELF3200	TEST 3 10MILLION	
ELF3200	TEST 1 10 MILLION	
ELF3200	TEST2 10 MILLION	
ELF3200	TEST 3 10 MILLION	
ELF3200	TEST 1 100MILLION	
ELF3200	TEST 2 100MILLION	
ELF3200	TEST 3 100MILLION	
ELF3200	TEST 1 100 MILLION	
ELF3200	TEST 2 100 MILLION	

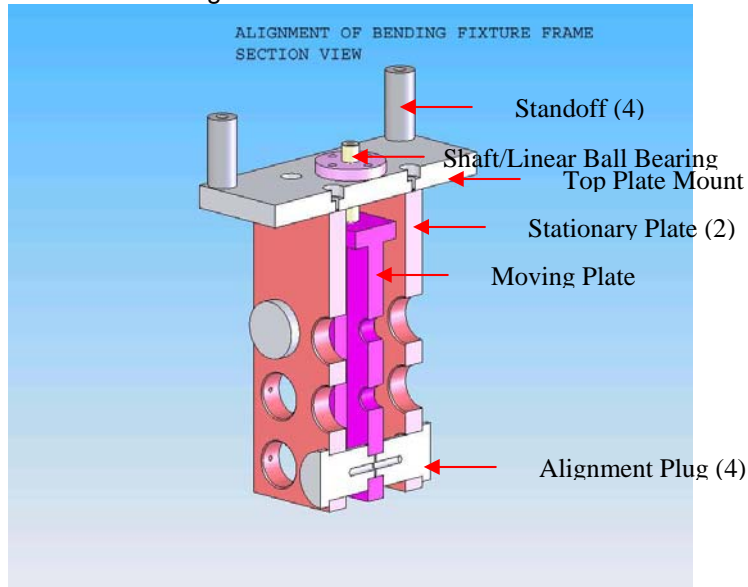
ELF3200	TEST 3 100 MILLION	
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4.0 EQUIPMENT

- a) Model ELF3200 EnduraTEC Test System
- b) EnduraTEC WinTest® Controls and Software
- c) Computer, ≥ 400MHz CPU
- d) Required number of devices – up to 12
- e) Multi Station bending fixture provided by Medical Device Testing Service (PN55058-103)
- f) Collet assembly (PN 55058-101)
- g) Load cell
- h) Saline Chamber
- i) Heating Circulator
- j) Isotonic Saline Solution (PBSS) :
 - (1) Water
 - (2) Sodium Chloride 0.85% w/v
 - (3) Dihydrogen Potassium Phosphate - trace
 - (4) Sodium Dihydrogen Phosphate Monohydrate - trace
 - (5) Ethylene Glycol Monophenylether – trace
- k) Associated Paper Work
 - (1) ELF Test Set Up Checklist
 - (2) Test Deployment Form
 - (3) Daily Data Sheets (Template 99127)

6.0 FIXTURE INSTALLATION

- a) Install the bending fixture frame on EnduraTEC ELF3200 test system.



- (1) Attach the two stationary plates to the top plate mount.

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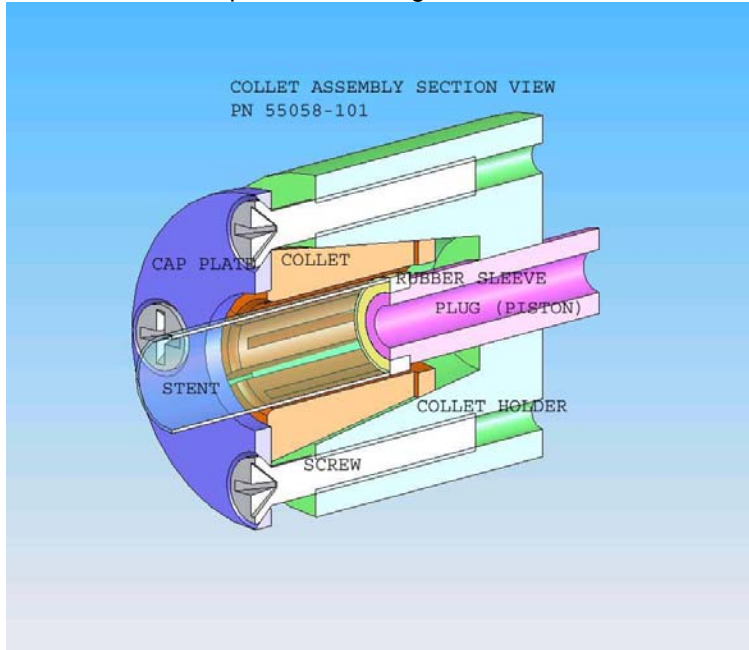
Rev. 3.0

- (2) Mount the top plate mount to the ELF3200 top plate through four standoffs.
- (3) Attach the shaft to the moving plate through stud.
- (4) Insert the shaft through the linear ball bearing mounted on the top plate mount.
- (5) Couple the shaft with the ELF3200 test system mover by stud and jam nuts..
- (6) Sandwich the moving plate with two pair of alignment plug by stud.
- (7) Secure the alignment plugs by setscrews.
- (8) Secure all the bending fixture parts in position.
- (9) Tare the displacement of the test system to "zero"
- (10) Remove the four alignment plugs from the fixture.

- b. Start the tester at the 60 Hz test frequency and adjust PID terms to achieve a stable sine wave.

7.0 DEVICE INSTALLATION

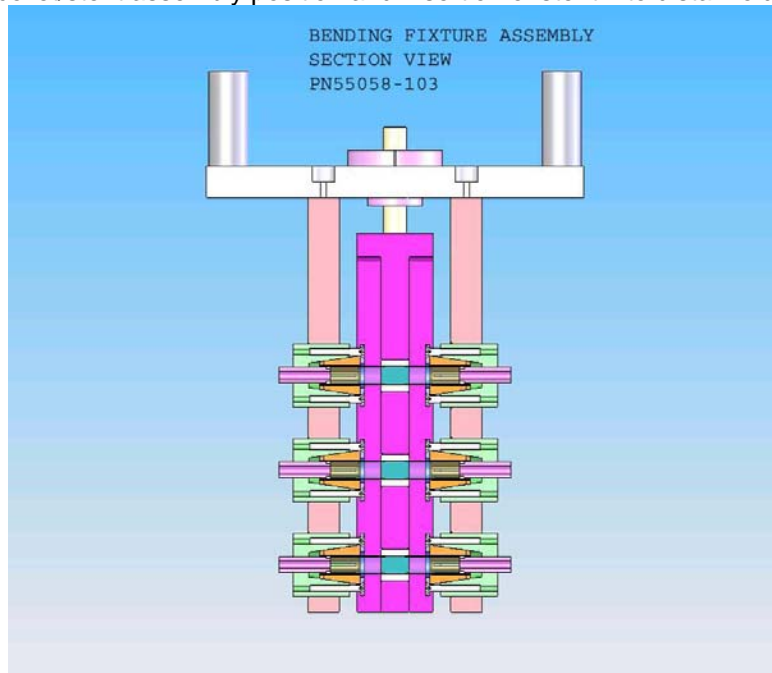
- a) Begin procedure with a spare stent to ensure proper set up per **Company** requirement in the protocol prior to full test device installation.
- b) Inspect sample integrity and notify **company** of any abnormalities.
- c) Pre-set collet ID using a pin representative of the stent OD.
- d) Assemble the collet / stent assembly (PN55058-101) per **company** specifications (**company** 10.3) to control the stent position and degree of contact between the stent and collet..



- (1) Position the stent partially within the collet, ensure 10.00mm of exposed stent..
- (2) Install plug with rubber sleeve.
- (3) Insert the plug with rubber sleeve into collet holder.
- (4) Insert the collet with stent into collet holder.
- (5) Attach the cap plate to collet holder with four screws.
- (6) Gradually adjust the four screws to press the cap plate down to secure the stent in the collet.

- (a) Ensure that the stent cannot be slid out of the collet.
- (b) Avoid over-crimping the stent, which could cause the sent OD to mismatch between the covered and uncovered areas throughout the test.
- (7) Lock the four setscrews in the collet holder radius to secure the plug that applies axial constraint to stent.

- e) Install bending fixture assembly (PN55058-103) per Company specifications to control the collet/stent assembly position and insertion of stent into distal holder.



- (1) Install the ring groove into the moving plate and secure them with setscrew.
 - (2) Turn on the local energy of the ELF3200 test system.
 - (3) Set the test system's displacement at "zero".
 - (4) Insert collet/ stent assembly into the stationary plate until the stent engages with the ring groove.
 - (5) Secure the collet assembly with setscrew
 - (6) Re-confirm the uncovered stent distance is 10mm +/- 0.1mm. .
- f) Verify the contact between stent end and distal holding ring groove during full range of displacement, assistance with load cell to measure the load history may be required. If the moving slug (where stent and holder loose contact while changing displacement direction) observed, estimate the slug distance and correspondingly adjust the total distal holder displacement to ensure the actual stent deflection level reaches the target (note this step should be performed with the spare sample from the test sample group).
- g) After setup verification repeat procedures a-b with all 10 fatigue stent samples.
- h) Number and mark the position and orientation of each holder/collet/stent corresponding to the fixture.
- i) Submerge the test samples in the saline bath 37C +/- 2C.

8.0 ACCELERATED FATIGUE TEST START UP

- a) Set distal holder alternating displacement to targeted level so that the displacement in the single direction equals the measured stent deflection by **Company** protocol
- b) Gradually increase the displacement frequency from low to the targeted test frequency (up to 60Hz)
- c) Set the target cycle count and start the test (10 million cycles or 100 million cycles according to Cordis test plan).

9.0 MONITORING

- a) Set and apply the appropriate limits to prevent damage to the tester due to fluctuations.
- b) Create a new job folder on the server. C/Data Files/ WinTest Data/ JOB#. All data concerning the current test should be stored here.
- c) Set up data acquisition to electronically capture displacement max/min and cycle count approximately every four hours.
- d) Manually record displacement max/min, cycle count and temperature. Document the information on the Daily Data Sheet.
- e) Daily Monitoring
 - i) Record pre-determined parameters on the Daily Data Sheet
 - ii) Observe devices for migration.
 - iii) Observe devices for failure.
 - iv) If an abnormal observation occurs, contact the Operations Manager or Director of testing.

10.0 TEST SHUTDOWN: PROTECTIVE LIMITS OR MALFUNCTIONS

- a) Retrieve the history from the show menu, record notes regarding shut down and contact the Operations Manager or senior lab personnel.
- b) The operations manager or lab personnel may resume the test and/or contact the customer at their discretion, based on the shut down specifications.

11.0 TEST COMPLETION

- a) Document the date of test cycle completion.
- b) Inspect the devices while still on the instrument.
- c) Inform the customer of the test completion and inspection results.

- d) Remove the test collet/stent assemblies from the fixture by sliding the ends of the assemblies from the collet holders.
- e) Inspect all samples for radial strut and flexible link connector separation with a 10-40x light microscope..
 - a. Inspect samples still installed on the collets
 - b. Inspect samples removed from the collets
- f) Return the test samples, physiological samples, and any remaining samples to customer.
- g) Send an electronic version or a cd containing all of the customer's raw data within 2 days of test completion.
- h) Prepare the test report.

12.0 PROJECTED SCHEDULE FOR TESTING.

SAMPLE NUMBER 10/TEST CYCLES_1) 10MILLION 2) 100 MILLION

FREQUENCY UP TO 60Hz

CYCLE START DATE: PHASE 1: TBD PHASE 2: TBD

PREDICTED CYCLE END DATE:

These 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 set up, artery adjustments, data acquisition, problems, etc.

Revision History:

Version	Change	Date
0.0		

