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Standard Guide for Active Fixation Durability of Endovascular Prostheses[1]

This standard is issued under the fixed designation F3374; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide addresses how to conduct *in vitro* durability testing on active fixation components (AFCs) and attachment mechanisms of endovascular prostheses. It does not address the durability of fixation systems that reside solely within the vessel lumen to resist device migration (e.g, radial force and friction, adhesives, or geometric fit).

1.2 This guide was developed to address active fixation durability for aortic stent grafts. It is not intended to address fixation durability for other endovascular prostheses such as inferior vena cava filters, transcatheter heart valves, barbed venous stents, ancillary fixation devices (e.g, staples or adhesives), or cardiac devices (e.g., left atrial appendage device or mitral repair device). However, some of the techniques and guidance within may be applicable to the *in vitro* testing of those other devices.

1.3 This guide does not directly apply to implants with absorbable AFCs although many aspects of this standard are applicable to those products.

1.4 This guide does not provide the *in vivo* physiologic loading conditions for endovascular prostheses. It is the responsibility of the user to determine the loading or deformation conditions for their particular device and indication. Typically, an axial loading (force or displacement) mode caused by hemodynamics is used, although other modes are possible and should be considered.

1.5 This guide does not recommend any specific test method or apparatus for evaluating active fixation durability. It is recognized that there are multiple valid ways to conduct active fixation durability testing and as such this guide provides general recommendations and topics to consider so that users can successfully develop a test plan for their device.

1.6 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (***S-N***) and Strain-Life (ε-***N***) Fatigue Data

F2477 Test Methods for***in vitro*** Pulsatile Durability Testing of Vascular Stents

F2942 Guide for***in vitro*** Axial, Bending, and Torsional Durability Testing of Vascular Stents

F3172 Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices

F3211 Guide for Fatigue-to-Fracture (FtF) Methodology for Cardiovascular Medical Devices

2.2 *Other Documents:*[3]

ASME V & V 40 Assessing Credibility of Computational Modeling and Simulation Results through Verification and Validation: Application to Medical Devices

ISO 25539 Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses

3. Terminology

3.1 *Definitions:*

3.1.1 *endovascular prosthesis, n*—vascular prosthesis (including modular components) which resides partially or completely within a blood vessel, or vascular conduit to form an

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

internal bypass or shunt between sections of the vascular system, delivered and deployed using a delivery system [from ISO 25539-1].

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *active fixation component (AFC), n*—the portion or sub-assembly of an endovascular prosthesis active fixation system (e.g., anchor, hook, barb of a suprarenal stent) designed to provide axial fixation which prevents device migration; these components pierce the native vascular tissue to provide fixation.

3.2.2 *active fixation system, n*—system or feature of the endovascular prosthesis that is comprised of active fixation components and attachment mechanisms and which is designed to prevent migration by embedding beyond the luminal surface of the vessel and by attachment to or integration with the endovascular prosthesis.

3.2.3 *attachment mechanism, n*—the connection(s) and/or structure(s) linking the AFC to the remainder of the endovascular prosthesis (e.g., connection of a barb to a stent via welding, suture or other bonding mechanism; suprarenal stent; or sutures connecting a proximal stent to graft material).

3.2.4 *load, n*—used to denote continuous and time-varying forces, stresses, strains, torques, deflections, twists or other parameters that describe the applied fatigue stimuli. Typically these fatigue stimuli are described by a mean value and an alternating value.

3.2.5 *mock vessel, n*—a simulated blood vessel typically manufactured from an elastomeric material.

4. Summary of Test Guides

4.1 This guide covers *in vitro* durability testing of active fixation components (AFCs) and attachment mechanisms. During development of an endovascular prosthesis, it is critical to test the AFCs and the attachment mechanisms because both are important to ensure active fixation system durability.

4.2 Depending on the test objectives, it may be preferable to test the durability of the AFCs and attachment mechanisms separately or simultaneously. Example fixturing for these three potential testing modes are presented in Appendix X1.

4.3 Determining the appropriate loading on the AFC and/or attachment mechanism is critical and may be determined by analytical force balance, computational modeling, clinical data, flow studies, or other means. Care should be taken to ensure that observed forces and/or motions are representative of the intended test conditions and do not introduce test artifacts.

5. Significance and Use

5.1 Once implanted, active fixation systems are subjected to cyclic loading that can be caused by blood flow, musculoskeletal motion, and other sources. The focus of this document is on axial loading caused by hemodynamics. However, depending on the device design other loading modes could influence AFC or attachment mechanism durability (e.g., radial dilatation could lead to longitudinal foreshortening and axial loading on an active fixation system). Damage to AFCs and/or attachment mechanisms may not necessarily lead to device malfunction, but could cause embolization of portions of the device, device migration, endoleaks, or other patient complications (**1-4**).[4] Therefore, durability testing of AFCs and attachment mechanisms is important to ensure that these components are capable of maintaining structural integrity for a defined lifetime.

5.1.1 A test method developed following this standard guide can be used to determine the durability of AFCs and/or attachment mechanisms under the desired loading which can be used to assess conformance to product specifications, consensus standards, and guidance documents as well as to support regulatory submissions, quality control, and manufacturing.

5.2 This guide provides examples and recommendations so that users can develop an appropriate active fixation durability test for their device design that mechanically challenges either the AFC, the attachment mechanism, or both simultaneously. It should be recognized that both AFCs and attachment mechanisms need to be evaluated to fully characterize active fixation system durability for design verification testing. While testing of the entire active fixation system may typically be preferable, this guide recognizes that there might be situations where this is not practical or desired and allows for independent testing of AFCs and attachment mechanisms. This guide does not contain an exhaustive list of test methods for active fixation durability and methods not included herein may be acceptable for evaluating active fixation durability. Furthermore, this guide does not include information on how to handle all patient complexities such as calcium deposits or weakened aortic tissue. For assistance regarding super-physiological testing, the user is referred to ASTM F3211.

5.2.1 The success of an active fixation durability test method depends on the ability of the test apparatus to consistently induce the desired loading (force and/or displacement) to the test specimen at the applied test frequency for the entire duration of the test.

5.3 For most devices, active fixation durability testing will need to be complemented by other types of durability testing such as pulsatile, axial, bending, or torsional. ASTM F2477 addresses pulsatile durability testing, ASTM F2942 addresses axial, bending, and torsional durability testing, and ISO 25539-1, in part, addresses general *in vitro* testing and durability testing of endovascular prostheses.

6. Specimen Size, Configuration, and Preparation

6.1 *Test Specimens*—Test specimens should be finished devices, appropriate components, coupons extracted from the device or component, or surrogate samples. Unless otherwise justified, test specimens should be representative of actual clinical devices or components made by the final manufacturing process, including sterilization. When deciding whether to test whole devices or portions of whole devices, it is important to consider the possibility of test artifacts from non-physiologic loading. Testing of full devices or the largest practical subassembly may help reveal unforeseen failure modes as well as

[4] The boldface numbers in parentheses refer to the list of references at the end of this standard.

characterize known failure modes. Because of the importance of the test specimen configuration (full device, surrogate sample, etc.), justification should be provided for its selection.

6.2 *Specimen Conditioning*—Unless otherwise justified, test specimens should be assembled with their delivery system and tracked through simulated anatomy at physiologic temperature, using applicable accessories (if appropriate), prior to placing the test specimen in the test fixture or mock vessel. If the test specimen and/or delivery system design does not permit assembly of the test specimen and the delivery system, the device assembly and tracking processes should be physically simulated. Given the unique fixturing needed for loading the test specimen, deployment through a simulated anatomy may not be possible.

6.3 *Selecting a Test Specimen Size*—Endovascular prostheses are typically manufactured in several sizes to accommodate different patient anatomies. Because *in vivo* loading and device design (e.g., number of AFCs) can differ among device sizes, justification should be provided when selecting which size test specimen to evaluate. This justification should be based on which AFC and/or attachment mechanism experiences the worst-case loading (the loading most likely to cause the most severe damage and/or failure) and may include analytical force balance, computational modeling, clinical data, flow studies, or other means.

6.3.1 Loading should be based on the loading experienced by AFCs and/or attachment mechanisms. This will depend on the number of AFCs and/or attachment mechanisms per device size, on the active fixation system design (e.g., if the AFC design varies with device size), as well as on anatomical and activity level variations within the intended patient population.

6.4 *Selecting a Number of Test Specimens*—The number of test specimens selected should be justified and sufficient to support any conclusions made based on the results. Although not directly applicable, ASTM F3172 and ASTM E739 might be useful in determining an appropriate number of test specimens. ASTM F3172, in particular, provides a statistical framework which incorporates risk into the sample size determination. Depending on how the user decides to conduct their testing, a test specimen could be a single AFC or a device with multiple AFCs and attachment mechanisms; this will have a large impact on the number of test specimens needed. The number of test specimens needed will depend on whether a test to success or a fatigue-to-fracture strategy is utilized. For assistance on creating a fatigue-to-fracture test plan, please reference ASTM F3211.

7. General Apparatus Requirements

7.1 *Measurement Devices*—Devices such as linear variable displacement transducers (LVDTs), lasers, high-speed cameras, and load transducers should be calibrated.

7.2 *Cycle Counting System*—The apparatus should include a cycle counting system for measuring the number of loading cycles applied to the test specimen. The cycle counting system should be verified at the test frequencies and the verification should be documented.

7.3 *Temperature Control System*—The apparatus should include a calibrated temperature control and measurement system to maintain the temperature of the test specimen at 37 ± 2°C unless otherwise justified.

7.4 *Inspection Equipment*—As appropriate to the test, a means of periodically inspecting the test specimen for damage during testing or during pauses in testing should be available. This could include an optical microscope, x-ray, load monitoring, resistance/conductivity measurements, visual inspection with a strobe light, borescope, ultrasonic measurements, or other system capable of observing damage such as AFC fracture, suture breakage, etc.

8. General Test Parameters

8.1 *Determination of Loading*—AFC and attachment mechanism loading *in vivo* is a function of the physiologic environment and the deployment orientation of the device. Selection of appropriate challenging loading conditions should include consideration of loading magnitude, angulation, test specimen configuration, and other characteristics as described below.

8.1.1 The loading on the AFC and/or attachment mechanism should be based on a severe physiological environment in the expected patient population (e.g., blood pressure and/or fluid flow) or other justified condition (e.g., super-physiologic loading in fatigue-to-fracture or replicating known clinical failure loads). It may be appropriate to consider whether the loads applied to the active fixation system are diminished by passive elements (e.g., friction between the vessel wall and the endovascular prosthesis resulting from chronic outward force). AFC and attachment mechanism loading can be determined by analytical force balance, computational modeling, clinical data, flow studies, or other means. An example of how to conduct an analytical force balance is provided in Liffman et al. (**5**). References (**5-11**) provide examples of loading determination in the abdominal aorta and References (**12**) and (**13**) provide examples of loading determination in the thoracic aorta. If computational modeling is used to determine loading, verification and validation activities should be conducted to assess the credibility of the computational model. ASME V & V 40 provides a risk-based framework for determining the credibility of computational models used in the development of medical devices.

8.1.2 The possibility of *in vivo* asymmetric deployment, incomplete AFC engagement into vessel wall, and vessel angulation should be taken into account when determining loading. In determining the expected loads, it is important to consider the interaction of the active fixation system with the native tissue as well as variation in physiological geometry, tissue properties, and loads based on the expected patient population. The relative direction of the loading input with respect to the active fixation system as well as input distributions among and along AFCs should also be taken into account. Deployment of a barbed proximal stent into vasculature with a high angulation, for example, may result in engagement of only the barbs along the outer curvature of the vasculature and cause a non-uniform, off-axis load distribution. To account for the presence of angulation on AFC and/or attachment mechanism

loading, it is acceptable to utilize test fixtures that allow for the direct testing of angulated test specimens. When testing angulated test specimens, it is important to consider that the loading on individual AFCs or attachment mechanisms may differ and that this may affect the number of test specimens needed. Alternatively, another method is to determine (e.g., analytically) the loading increase caused by angulation (or other conditions) and then apply that loading to test specimens in a straight configuration as shown in Appendix X1.

8.1.3 The AFC and/or attachment mechanism should be tested to a prescribed load level and direction. The load is typically applied in either force or displacement control. The area or point and direction of application of the force or displacement should reproduce the appropriate loading on the AFC and/or attachment mechanism. When testing multiple specimens in the same test system, care should be taken to ensure that the desired loading is applied to all specimens. This can be accomplished using individual load cells and/or displacement instrumentation.

8.1.4 When determining the loading magnitude, consideration should be given to alternating and mean blood pressures. Although higher mean blood pressures typically lead to higher forces, lower mean blood pressures could lead to higher displacements and higher abrasion, depending on the device design and indications. In some situations, such as when a worst-case load cannot be clearly identified, it may be appropriate to evaluate active fixation system durability under more than one condition to fully characterize performance.

8.1.5 Durability testing of active fixation systems has historically been conducted with constant amplitude loading even though loading is known to be variable due to changes in blood pressure, musculoskeletal motions, and other factors after implantation. When determining loading conditions, it may be appropriate to consider variable or multiple amplitude loading (e.g., potentially caused by stair stepping, low or high blood pressure spikes) that have differing magnitudes but lower frequencies than the loading from a typical cardiac cycle. For example, wear observed in sutures, graft material or the metal frame of a test specimen may lead to a reduction in strength such that a high magnitude loading event could lead to device failure even though the test specimen did not fail after the completion of a pre-determined number of loading cycles at lower magnitude. An evaluation of variable amplitude loading could be accomplished through block duty cycle testing where the test load inputs vary in blocks proportional to the number of cycles *in vivo*. A device may have different responses to a lower or higher magnitude input which might elicit different failure modes.

8.2 *Fixturing*—Fixturing will depend on the test method selected as described in Appendix X1 and as shown in Figs. X1.1-X1.6. Fixturing materials selection, stiffness, corrosion resistance, degradation and secure attachment to the test specimen need to be considered so that they do not adversely affect the testing. Fixturing of the test specimens should ensure that the intended input magnitude(s) and direction(s) are delivered to the AFCs and/or attachment mechanisms so that unintended forces and/or motions are not introduced.

8.2.1 *Use of a Mock Vessel*—If the test is to be conducted using a mock vessel as a constraint or means of loading the test specimen, the mock vessel should be capable of withstanding the test conditions and maintaining the desired loading throughout the testing. When AFCs and/or attachment mechanisms are tested using an endovascular prosthesis and a mock vessel, test specimens should be deployed in the mock vessel in such a manner so as to ensure the intended load distribution among AFCs and/or attachment mechanisms. Mock vessels for accelerated testing may not need a physiologically relevant radial or longitudinal stiffness, and stiffer or thicker walled mock vessels may be used to obtain the desired AFC and/or attachment mechanism loading. Stiffer mock vessels may allow for faster test frequencies and reduce the incidence of mock vessel tears, but may also limit the ability to reliably control test loads. A mock vessel selection rationale should be provided as part of the test system (machine and fixture) justification to demonstrate suitability for active fixation system durability testing. References **(14-17)** may be helpful in comparing physiological parameters (e.g., radial or longitudinal stiffness) to those of the mock vessels.

8.2.1.1 *Effect of Oversizing*—The mock vessel inner diameter should be appropriate for the deployed endovascular prosthesis's diameter and should maintain intended geometry (i.e., not drift substantially with time) over the duration of the test, unless otherwise justified.

8.2.1.2 *Mock Vessel and Active Fixation System Overlap*—Unless otherwise justified, the overlap between the mock vessel and the active fixation system should be minimized to ensure that the intended loading is applied to the AFCs and/or attachment mechanisms and not artifactually reduced by friction effects.

8.2.2 *Use of a Rigid Contact Test Interface*—If the test specimen is to be tested by deploying it against a rigid contact test interface (an example of which is shown in Fig. X1.1), the rigid contact test interface should be designed so as not to introduce non-relevant loading artifacts into the AFCs and/or attachment mechanisms. Loading artifacts and sometimes premature failure can occur due to stress concentrations or rubbing at the point of contact between the test specimen and rigid contact test interface. When AFCs and/or attachment mechanisms are mounted against a rigid contact test interface, test specimens should be deployed in such a manner so as to minimize any artifact due to unintentional misalignment so that the intended load distribution is obtained.

8.3 *Test Frequency*—The test should be run at a frequency that provides a consistent cyclic loading (e.g., with minimal secondary harmonics) that enables the desired loading (e.g., force or displacement) of the test specimen. Load cells, displacement sensors, strain sensors, or high-speed video may be used to verify that the loading conditions are within the tolerance of the intended loading conditions as described in section 8.6. Strain rate sensitivity of the specimen and fixturing should be considered when selecting a test frequency.

8.4 *Solution*—The test solution should be a phosphate-buffered saline (PBS) or equivalent, unless testing in a different environment can be justified. The rationale for testing in a different environment should be provided. Reference **(18)** may

provide useful information on the selection of a test solution when fretting wear is being evaluated. The pH of the PBS should be adjusted to 7.4 ± 0.5 with appropriate buffering chemicals, and pH should be verified at the beginning and at the end of the test. Since biological growth can affect the post-test specimen evaluation, a biological growth inhibitor (such as algaecide or chemical agent) may be used, unless the inhibitor would negatively impact the test.

8.5 *Temperature*—The temperature of the test specimen should be maintained at 37 ± 2 °C for the duration of the test. If a different temperature is used, rationale should be provided stating why the selected temperature is considered relevant. If the test specimen materials are temperature-sensitive (e.g., have temperature-induced phase transformations), have cyclic self-heating, or have stress-induced phase transformations, and especially if testing in air, consider the effect of the test rate on the test specimen temperature (**19**).

8.6 *Load Verification*—Applied loads from the test equipment to the fixturing will result in loading of the test specimen that may be affected by factors such as rigidity of the test fixturing and/or test specimen, gripping technique, length of mock vessel, slip between fixture components and/or test specimen, or inertial effects at elevated test frequencies. Thus, verification that each test specimen is subjected to the intended loading (e.g., force or displacement magnitude and direction) at the selected test frequency should be completed. The results of this verification activity should be used to establish the procedure for controlling the test specimen loading. It is recommended that load verification be conducted at regular intervals throughout testing or at a minimum near the beginning and end of the test to ensure that that the loading does not unintentionally change substantially over the course of the test (e.g., wear or creep of the mock vessel could affect the intended loading).

8.7 *Test Monitoring and Inspections*—Monitoring and inspections should be completed at appropriate intervals to ensure the intended testing environment throughout the study and to detect potential active fixation system damage with adequate cycle count resolution. It may be appropriate to select inspection intervals on a log scale to capture low-cycle fatigue fractures accurately.

8.7.1 Pre-test inspections should be done to ensure that all devices are deployed properly, and all AFCs and/or attachment mechanisms are intact.

8.7.2 Periodic monitoring during testing should be performed to verify that the test specimen achieves the desired loading throughout the test.

8.7.3 Periodic inspections during testing may be performed to detect AFC fractures, attachment mechanism and/or prosthesis damage, or irrecoverable axial displacement of the test specimen (e.g., the test specimen shifts axially inside a mock vessel after cyclic load application). Strobe light, high-speed video or other methods may be used for fracture detection while the test is running. Thorough evaluation of all specimens is recommended post-testing to determine any and all AFC fracture locations as well as any attachment mechanism, graft or other prosthesis damage.

8.8 *Test Termination*—The choice of the test end point may vary and is dependent on the purpose of the testing. The end of the test could be determined by a pre-specified number of loading cycles (e.g., 380 million cycles is commonly used to represent 10 years of cardiac loading) or by a certain event such as the first AFC fracture if subsequent fractures are not of interest.

8.9 *Acceptance Criteria*—Acceptance criteria, if appropriate, should be prospectively identified, based on the intended function of the test articles and associated risks, and will vary, depending on the test objective (e.g., no events such as AFC fractures, suture breaks, or graft material failure after completion of 380 million cycles). If the acceptance criteria permit a certain number or type of events, rationale of the clinical significance should be provided (e.g., the device can resist a particular migration force including increased loading per AFC with only a portion of the AFCs intact or failed portions of the AFC or graft material do not embolize).

9. Test Report

9.1 The test report should include a complete summary of the materials, methods, and results, including rationale(s) for choices within the test guide and deviations from the recommendations of this standard guide and/or the detailed test protocol. The effects of such deviations on the significance of the test results should be reported. All real, artifactual, and anomalous observations should be reported, including a justification for considering negative findings as artifacts or discounting their clinical significance.

9.2 Test reports should include:

9.2.1 Purpose/objective statement (e.g., design verification).

9.2.1.1 Scope statement regarding AFCs, attachment mechanisms, graft areas, stents and locations to which the testing is considered applicable.

9.2.2 Description of the test method with picture(s) or diagram(s), including justifications and rationales recommended by this guide.

9.2.3 Test specimen information including lot number(s):

9.2.3.1 Number of test specimens.

9.2.3.2 Size (diameter, length, or other relevant dimensions) of all test specimens.

9.2.3.3 Number of AFCs and/or attachment mechanisms per test specimen.

9.2.3.4 Rationale for the number of test specimens, the size and number of AFCs and/or attachment mechanisms per specimen used.

9.2.3.5 Sample preparation, conditioning and deployment/installation.

9.2.3.6 Statement that the specimens are representative of the finished product including crimping, tracking, and deployment. If the specimens are not representative of the finished product, appropriate justification should be presented.

9.2.3.7 Sterilization condition of specimens. Sterilization parameters and number of sterilization cycles applied to the test specimens.

9.2.4 Test parameters, acceptance criteria, and justifications:

9.2.4.1 Test parameters, such as: *(1)* Average minimum and maximum applied loading (axial bending, and/or torsional) for

each test specimen. *(2)* Average minimum and maximum applied loading for each AFC and/or attachment mechanism per test specimen as calculated from the applied specimen load. *(3)* Justifications for the applied axial, bending or torsional loads. *(4)* Test monitoring intervals to verify test sample deformations or loads. *(5)* If test loading blocks are used, provide average minimum and maximum values for each test block.

9.2.4.2 Acceptance criteria, if applicable (e.g., no evidence of AFC fractures, attachment mechanism damage, graft damage, or stent failure due to applied loads; no evidence of AFC release or irrecoverable axial displacement of the test specimen).

9.2.4.3 Verification of applied loads. As appropriate, provide verification of desired inputs (force, displacement, direction, etc.) for each test specimen.

9.2.4.4 Description of high-speed verification such as high-speed video evidence of mock vessel recovery or documentation of observations under a strobe light, vessel diameter measurements via laser micrometer, or AFC deformations via position sensors or cine x-ray images as a function of time during one or more loading cycles.

9.2.5 Materials and equipment used:

9.2.5.1 Test equipment and fixture(s).

(1) Any maintenance during testing.

(2) Calibration status of measurement equipment.

9.2.5.2 Mock vessels, if applicable.

(1) Mock Vessel geometry and sizing.

(2) Mock vessel material.

9.2.5.3 Test fluid/solutions.

9.2.5.4 Measurement devices.

9.2.5.5 Inspection equipment.

9.2.6 Description of and acceptability assessment of protocol deviations.

9.2.7 Storage location of raw data and associated documents (e.g., test reports, test qualifications, verifications).

9.2.8 Test results. Any deviations from acceptance criteria should be reported and rationalized. This may include the following:

9.2.8.1 AFC fracture and/or attachment mechanism damage (e.g., graft material hole, suture break, bond failure, integral stent fracture): *(1)* Report inspection intervals for AFC fracture and/or attachment mechanism damage. Report the number of cycles when the first fracture or damage was detected. *(2)* As appropriate, AFC fracture type should be described in the report (e.g., fatigue or overload). *(3)* Include the location of all AFC fractures and/or attachment mechanism damages on a diagram, plus representative photographs. If multiple fractures or damages occur within a single test specimen, the order should be reported, if possible. *(4)* Root cause assessment of fractures may be warranted. This type of analysis may include a comparison of fracture location to finite element analysis (FEA) predictions and fractography to detect the initiation site.

9.2.8.2 Irrecoverable axial displacement of the test specimen.

9.2.8.3 Fretting wear.

9.2.8.4 AFC pullout.

9.2.8.5 Mock vessel damage.

9.2.9 Test disassembly, sample post-test processing, storage and disposition.

9.2.10 Conclusions.

10. Precision and Bias

10.1 Intra-laboratory and inter-laboratory reproducibility has not been systematically determined.

11. Keywords

11.1 active fixation component; anchor; attachment mechanism; barb; durability test; endovascular graft; endovascular prosthesis; fatigue test; fixation system; hook

APPENDIX

(Nonmandatory Information)

X1. FIXTURING EXAMPLES

X1.1 AFC and Attachment Mechanism Combined

X1.1.1 Combined testing of AFCs and attachment mechanisms may be considered over testing each component in isolation as it allows for a greater understanding of the interactions between AFCs and attachment mechanisms and may provide a more physiologically relevant condition. However, if fatigue-to-fracture of the individual components is desired, individual testing of the AFC and attachment mechanism may be preferable. See Figs. X1.1 and X1.2.

X1.2 AFC in Isolation

X1.2.1 Testing of the AFC in isolation can be helpful, for example, when evaluating different designs and the attachment mechanisms to the remainder of the device are not expected to change. In addition, testing of the AFC in isolation can be helpful when device design considerations make it difficult to conduct a test that simultaneously and consistently mechanically challenges AFCs and attachment mechanisms and/or when attachment mechanisms make application of consistent loads to the AFC difficult. See Figs. X1.3 and X1.4.