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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.