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Standard Test Methods for *in vitro* Pulsatile Durability Testing of Vascular Stents and Endovascular Prostheses[1]

This standard is issued under the fixed designation F2477; 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 These test methods cover the determination of the durability of a vascular stent or endoprosthesis by exposing it to diametric deformation by means of hydrodynamic pulsatile loading. This testing occurs on a test sample that has been deployed into a mock (elastically simulated) vessel. The test is conducted for a number of cycles to adequately establish the intended fatigue resistance of the sample.

1.2 These test methods are applicable to balloon-expandable and self-expanding stents fabricated from metals and metal alloys and endovascular prostheses with metal stents. This standard does not specifically address any attributes unique to coated stents, polymeric stents, or biodegradable stents, although the application of this test method to those products is not precluded.

1.3 These test methods may be used for assessing stent and endovascular prosthesis durability when exposed to blood vessel cyclic diametric change. These test methods do not address other cyclic loading modes such as bending, torsion, extension, or compression.

1.4 These test methods are primarily intended for use with physiologically relevant diametric change, however guidance is provided for hyper-physiologic diametric deformation (that is, fatigue to fracture).

1.5 These test methods do address test conditions for curved mock vessels, however might not address all concerns.

1.6 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]

D1193 Specification for Reagent Water

F2514 Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading

F3067 Guide for Radial Loading of Balloon-Expandable and Self-Expanding 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 *ISO Standards:*[3]

ISO 7198:2016, A.5.9 Dynamic radial compliance—tubular vascular grafts only

ISO 14971 Medical Devices—Application of Risk Management to Medical Devices

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *cardiac cycle, n*—defined as one cycle from diastolic pressure to systolic pressure and back to diastolic pressure.

3.1.2 *compliance, n*—the change in inner diameter of a vessel due to cyclic pressure changes. Compliance, if calculated, shall be expressed as a percentage of the diameter change per 100 mmHg and defined per ISO 7198, A.5.9, or equivalently:

$$\%\text{Compliance/100 mm Hg} = \frac{(Dp2 - Dp1) \times 10^4}{(Dp1(p2 - p1))} \quad (1)$$

[1] These test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.30 on Cardiovascular Standards.

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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.

where:

$Dp1$ = inner diameter at the pressure of $p1$,
$Dp2$ = inner diameter at the pressure of $p2$,
$p1$ = lower pressure value (diastolic), in mmHg, and
$p2$ = higher pressure value (systolic), in mmHg.

3.1.3 *diametric strain, n*—a change in mock vessel or device diameter divided by the minimum diameter at the measurement location. This term does not equate to the mechanical strain seen in the device material. The diametric strain can be identified as:

$$\text{diametric strain} = \frac{(Dp2 - Dp1)}{Dp1} \quad (2)$$

that is,

$$\text{diametric strain} = \frac{(\text{maxID} - \text{minID})}{\text{minID}}$$

3.1.4 *endovascular prosthesis, n*—vascular prosthesis (including modular components) which resides partially or completely within a blood vessel, or vascular conduit to form an internal bypass or shunt between sections of the vascular system, delivered and deployed using a delivery system (from ISO 25539-1). Examples of endovascular prostheses are vascular stent grafts and covered stents.

3.1.5 *hydrodynamic loading, n*—causing a change in the diameter of a mock vessel by injecting a volume of fluid into a confined test volume inside and/or outside the mock vessel.

3.1.6 *mock vessel, n*—a simulated vessel typically manufactured from an elastomeric material. The mock vessel is made to approximate the ID and diametric change of a native vessel at physiological pressures (see A1.2.2 and A2.4.2) or at non-physiological pressures (see A2.4.4). Mock vessels with a simulated aneurysm may be used when evaluating the pulsatile durability of endovascular prostheses for aneurysmal exclusion indications. Mock vessels with a specified radius of curvature may also be used.

3.1.7 *native vessel, n*—defined as a natural blood vessel.

3.1.8 *strain control, n*—a term to describe control of diametric change, relative to an initial diameter of the mock vessel, not to be confused with controlling the strain in the device material.

3.1.9 *vascular stent, n*—a synthetic tubular structure that is implanted in the native or grafted vasculature and is intended to provide mechanical radial support to enhance vessel patency over the intended design life of the device. A stent is metallic and not covered by synthetic textile or tissue graft material. The term stent may also be used to describe the structural support component(s) of an endovascular prosthesis.

4. Summary of Test Methods

4.1 This document details two test methods that are currently used: Pressure Test Method and Diameter Control Test Method. These test methods cover fatigue/durability testing of vascular stents and endovascular prostheses that are subjected to hydrodynamic loading (internal and/or external pressurization) that simulates the radial loading and/or change in diameter that the stent or prosthesis is expected to experience *in vivo* due to the cyclic blood pressure changes of the cardiac cycle. The stent or endoprosthesis shall be deployed into a mock vessel that can be used to produce a cyclic diameter change of the stent or endoprosthesis. An endoprosthesis being evaluated for an aneurysm exclusion indication may use a mock vessel with a simulated aneurysm. Within the aneurysmal sac portion of the mock vessel, the endoprosthesis deformation is primarily due to cyclic pressure changes relative to the aneurysmal sac rather than the simulated aneurysm dimensional changes. Thus, the mock aneurysmal sac compliance is not critical and pressure monitoring of mock vessel might be needed.

4.1.1 *Pressure Test Method*—This test method (provided in Annex A1) requires the use of mock vessels that possess similar diametric compliance properties to native vessels (except within the mock aneurysm, if applicable) at specified physiologic pressures (applied externally and/or internally) at the testing frequency. The use of physiologic transmural pressure (that is, external to internal pressure differential) is important to ensure the test mimics physiological loading conditions. This test method may also be used with external physiologic pressures applied to thin non-physiologic mock vessels.

4.1.2 *Diameter Control Test Method*—(Sometimes called a strain control test method.) This test method (provided in Annex A2) requires the use of a diameter measurement system and mock vessels to ensure that the desired minimum and maximum device diameters, or the equivalent change in device diameter and mean device diameter, are being achieved at the test frequency. For conditions where a direct measurement of the device is not possible, measurements are typically made over the outside diameter (OD) of the mock vessel and a relationship is determined and justified for the ratio of the device OD versus measured mock vessel OD.

5. Sample Preparation, Device Labeled Size, Sample Configuration, Mock Vessels, and Number of Samples

5.1 Unless otherwise justified, samples selected for testing shall be taken from fully processed implant quality product. Sterilization should be required, unless it can be shown not to influence the fatigue/durability test results.

5.2 The number of samples tested for each device geometry should be sufficient to support any claims to be made based on the test results. The number of samples should also be justified in the context of the device risk assessment (see Guide F3172 and ISO 14971).

5.3 Fatigue/durability shall be evaluated for the worst-case labeled diameter, and a rationale shall be provided stating why the particular labeled diameter is considered worst case. See Guide F2514 for guidance in using finite element analysis for radial loading of stents.

5.4 *Mock Vessels:*

5.4.1 The choice of diameter of the mock vessel in contact with the device is critically important to the effectiveness of any durability test. The mean mock vessel diameter in contact with the device over a cardiac cycle should be consistent with the worst-case device diameter for the device being tested, over the full test duration.

NOTE 1—If implementing fatigue-to-fracture testing, see Appendix X3 for guidance regarding the use of a liner within the mock vessel.

5.4.2 See Annex A1 and Annex A2 for specific requirements.

5.5 The number of samples, in combination with other tests, animal and clinical tests, analyses such as FEA (Finite Element Analysis), and/or comparisons to predicate devices shall be sufficient to enable demonstration of an adequate justified reliability. In these test methods, one device or a pair of overlapped devices shall be considered one sample. The reliability justification may reference additional testing and/or analyses used to establish device durability.

6. General Apparatus Requirements

6.1 For test methods requiring precision measurement and control of pressure, dimensions, or cycle counts, verification of the dynamic performance of these systems at or encompassing the test frequency shall be performed and documented with justification of the means used.

6.2 *Pressure Measurement System*—Pressure transducers shall be chosen that allow for the accurate evaluation of the applied pressures at the frequency pressures are to be measured. See Annex A1 and Annex A2 for method specific requirements. The pressure measuring system must be calibrated.

6.3 *Cycle Counting System*—The apparatus shall include a cycle counting system for measuring the number of load cycles applied to the device/mock vessel combination.

6.4 *Temperature Control System*—The apparatus shall include a calibrated temperature control and measurement system to provide the testing temperature for devices being tested. If fluid temperature is measured to indicate device temperature, the relationship between the fluid temperature at the associated measurement location and the device temperature shall be justified.

7. General Test Parameters

7.1 *Temperature*—The temperature of the device shall be 37 ± 2 °C. Normally this can be accomplished by controlling the temperature of the fluid adjacent to the device. If other temperatures are to be used, a rationale shall be provided stating why the particular temperature is considered worst case or equivalent. The unit is to be stable over the intended period of the test and maintained within the established parameters.

NOTE 2—The presence of a mock vessel liner can induce a temperature differential between the fluid and device. This might require elevation of the fluid temperature.

7.2 *Solutions*—The test solution shall be physiologic pH buffered saline (for example, phosphate buffered saline) or equivalent unless testing in a different environment (such as in 0.9 % saline, modified simulated body fluid, or Specification D1193 Class IV distilled water) can be justified. Biological growth can inhibit post-test evaluation of the device surface characteristics. Use of a biological growth inhibitor (such as algaecides or chemical agents) may be used unless such use would negatively impact the test by unintended degradation of the device or the test setup. Rationale for use of a different environment shall be provided.

7.3 *Physiological Blood Pressures*—The cyclic pressures in the intended blood vessel. Selection of the systolic and diastolic blood pressures should be based on the patient population for which the device is indicated. For example, suggested systolic and diastolic values for hypertensive arterial blood pressures are 160 and 80 mmHg.

7.4 *Physiological Pulse Rate*—For the purposes of these test methods, determined to be 1.2 Hz or 72 beats per minute.

7.5 *Vessel Degradation*—Mock vessels made of materials that may degrade with exposure to environmental factors (such as UV light) shall be protected from such exposure.

7.6 *Device Deployment*—The device shall be deployed in the mock vessel, after tracking through a challenging simulated anatomy, in such a manner as to minimize end effects where the vessel is connected to the test apparatus. Unless testing is to be conducted with devices overlapped, or as otherwise justified, devices deployed in the same mock vessel shall be at a sufficient distance to avoid unintended interaction.

7.7 *Test Duration*—The test duration shall be justified. The number of cycles associated with an implantation time of ten years (for example, for arterial stents at least 380 million cycles) has been historically used.

7.8 *Test Frequency*—See Annex A1 and Annex A2 for test-specific details.

7.9 *Device Deformation Verification*—Differences in the contact between the device and the mock vessel (for example, no contact, too high friction, mock vessel conformability) compared to *in vivo* conditions can result in device deformation that is greater or less than intended. Thus, the investigator should demonstrate that during the cyclic displacement the device is subjected to the intended deformation (for example, similar deformation of device at 1.2 Hz) at the frequency and pressure used in the durability test. This may be done with a high-speed camera; however, a strobe light may also be used for qualitative verification. The high-speed camera may be used to measure the change of the OD of the mock vessel. Imaging the device inside of the mock vessel is problematic because of the refraction of light through different media (that is, air/silicone/water). See Appendix X2 for additional details regarding measuring the deformation of the device inside the mock vessel. Also, the proper functionality of a test method used to test a device inside a mock vessel depends on the device remaining in contact with the ID of the vessel throughout the diametric change of that vessel. This is also true for endovascular prostheses used to treat occlusive disease. If evaluating an endovascular prosthesis under aneurysmal conditions, the endovascular prosthesis should maintain contact with the mock vessel in the seal regions, but not in the aneurysmal sac region. Thus, the investigator shall demonstrate that the device or endovascular prosthesis to be tested maintains contact with the ID of the mock vessel to be used in the durability test throughout a test cycle, except in the aneurysmal sac region of mock vessel being used to evaluate an endovascular prosthesis under aneurysmal conditions. Device deformation verification is not required for every test sample. The

number of devices used for the deformation verification should be adequate and justified. The results of this verification activity should be used to establish the procedure for ensuring the intended deformation of the test samples (for example, utilize test frequency that provides intended deformation). For example, if it can be shown that the stroke and frequency of the pulsatile testing apparatus adequately correlates with the intended deformation of the device, further deformation verification activities might not be needed. The completion of the device deformation verification and any justifications shall be documented in the test report.

7.10 *Variation of Loading Along Length as Function of Frequency*—The investigator should be aware of the potential for pressure variations along the length of a mock vessel that may change in location and magnitude as the test frequency is changed. Typically, diastolic and systolic pressure levels are fairly uniform along the length of the mock vessel at physiologic frequencies, for example 1.2 Hz, but variation in the magnitude of either or both of these pressures along the length of the mock vessel can increase at hyper-physiologic frequencies. The test frequency, tester design and configuration, as well as the mock vessel compliance, length and diameter, and curvature can influence the magnitude of these pressure variations along the length of the mock vessel. The pressure variations typically cause diametric strain variations along the length of the mock vessel. Stiffer mock vessels may be used to reduce the diametric strain variations. However, in some cases prior to initiating cyclic fatigue, the investigator might find it difficult to identify a test frequency (for example, during a frequency sweep) that is sufficiently high for a practical test duration while maintaining acceptable pressure and/or diametric strain variability along the length of the mock vessel. In such cases, the investigator may choose to identify region(s) of interest on the test sample where test pressures and/or diameters are to be controlled, while other regions are only monitored. For example, the region(s) of interest would correspond to the location(s) that have been identified through analysis as having the smallest fatigue safety factor.

7.11 *Evaluation Procedure*—A detailed test protocol shall be written that describes all procedures unique to the device or endovascular prosthesis being evaluated. This protocol shall include any specific failure modes to be identified (for example, strut fracture, graft wear, fretting wear) and inspections to be performed to identify those failures. Note, a known test artifact is the artifactual wear that can occur from interaction of the prosthesis with the mock vessel material (for example, abrasion of graft material between silicone tube and device, rate-dependent abrasion properties of polymers) which tend to be more abrasive, due to higher friction and inability to mimic *in vivo* remodeling, than human arteries.

8. Test Report

8.1 The test report shall include a complete summary of the materials, methods, and results including any rationale for deviations from this standard. The effects of any such deviations on the significance of the test results shall be reported. All real, artifact, and anomalous observations shall be reported, including a justification for considering negative findings as artifacts or discounting their clinical significance.

8.2 Test reports should include:

8.2.1 Test parameters and acceptance criteria:

8.2.1.1 Test parameters (such as):

(1) Mock vessel attributes (for example, ID at pressure, compliance).

(2) Device temperature or fluid temperature that has been previously correlated to device temperature.

(3) Regions of interest for diametric strain control and associated rationale.

(4) Control parameters (for example, fluid pressure range and variability, desired change in vessel with device diameter).

(5) Minimum level and/or mean of control parameters (for example, diametric strain, pressure levels) across test samples.

8.2.1.2 Acceptance criteria (such as):

(1) Maximum number and location of failures to define acceptance.

(2) Allowable fracture grades (for example, SFA stent fracture grades).

(3) Minimum number of cycles required to define acceptance.

8.2.2 Test sample information:

8.2.2.1 Number of test samples.

8.2.2.2 Size (diameter, length, or other relevant dimensions) of all test samples.

8.2.2.3 Rationale for the number of test samples and sizes used.

8.2.2.4 Whether the samples are representative of the finished product.

8.2.2.5 Sterilization parameters and number of sterilization cycles applied to the test samples.

8.2.2.6 Traceability information.

8.2.2.7 Pre-conditioning status of samples (for example, loaded into a delivery catheter and tracked through a challenging anatomy).

8.2.3 Materials used:

8.2.3.1 Test equipment.

8.2.3.2 Mock vessels.

8.2.3.3 Test fluid/solutions.

8.2.3.4 Measurement devices.

8.2.4 Test protocol, including all justifications and rationales required by these test methods.

8.2.5 Control values (for example, diametric strain, mean ID, alternating and mean pressure, temperature) and associated tolerances.

8.2.6 Protocol deviations.

8.2.7 Mean, standard deviation, minimum, maximum of measured load condition at each location monitored or controlled for each sample at the specified measurement intervals (for example, 50 million, 100 million, 200 million, 380 million). For ease of understanding, the use of a plot to present the associated data relative to applicable limits may be used.

8.2.8 Durability reporting:

8.2.8.1 Report any fractures that occur during the test.

8.2.8.2 Fracture information should include: number and locations of all fractures along the length of the device, type of fracture such as transverse or spiral, with or without

dislocation, and any root cause analysis performed to determine the reason for the fracture. Report the number of cycles that were applied when the fracture was identified or if available, report the number of cycles when the fracture occurred.

8.2.8.3 Report durability observations other than fractures (for example, fretting wear between overlapped components).

8.2.8.4 For endovascular prostheses, report as applicable, observations of graft material wear, stent to graft attachment degradation (for example, suture wear), or other observations relevant to the durability of the endovascular prostheses.

8.2.9 Conclusions.

9. Precision and Bias

9.1 No information is presented about either the precision or bias of this test method for measuring durability since the test result is nonquantitative.

10. Keywords

10.1 durability test; endovascular cardiology; endovascular prostheses; fatigue test; interventional cardiology; intravascular device test; pressure control; pulsatile fatigue; stent durability; stent fatigue; stent test; strain control; vascular stent

ANNEXES

(Mandatory Information)

A1. PHYSIOLOGICAL PRESSURE TEST METHOD FOR PULSATILE FATIGUE/DURABILITY TESTING OF VASCULAR STENTS AND ENDOVASCULAR PROSTHESES

A1.1 Summary of Test Method

A1.1.1 With this technique, when the mock vessel is pressurized from the ID, a volume of fluid is injected into a fluid-filled mock vessel that has been manufactured to provide a targeted physiological dynamic diametric compliance. The injected volume is adjusted so that the measured cyclic pressure differential is equivalent to the targeted physiological pressure differential. The volume of fluid may also be injected into a fixed-volume chamber surrounding the mock vessel to pressurize the OD of the vessel. With external physiologic pressures applied, thin mock vessels may be used in lieu of physiological compliant mock vessels.

A1.2 Significance and Use

A1.2.1 This test method is used to characterize the durability of a stent or endovascular prosthesis under simulated vascular pulsatile conditions, to assess conformance to product specifications and guidance documents, and it may be used to support regulatory submissions, quality control, and manufacturing (for example, process changes).

A1.2.2 This method depends on the use of controlled physiologic pressures and either physiologic compliant vessels or with externally applied pressures mock vessels that are thin and do not appreciably inhibit intended cyclic diametric deformation of the device.

NOTE A1.1—With externally applied pressures and thin mock vessels, the cyclic diametric deformation to the device might be greater than the expected *in vivo* deformation.

A1.3 Apparatus

A1.3.1 See Section 6 for general apparatus requirements.

A1.3.2 *Fatigue/Durability Testing System*—The system must be able to deliver quantifiable pressures to the mock vessels at the desired test frequency and maintain the device temperature as specified (for example, 37 ± 2 °C).

A1.3.3 *Dynamic Compliance Measurement System*—The apparatus should include a diameter measuring system that allows determination of the ID and dynamic compliance of the mock vessels used in this method and is able to apply controlled cyclic physiologic pressures. This system may be the same apparatus as the fatigue/durability testing system. The system must operate such that the cyclic diameters and pressures can be measured at the test frequency.

NOTE A1.2—If direct measurement of the ID of the mock vessel is not possible with measurement system used, an empirical method may be used to relate the deployed device outer diameter (OD) with the measured mock vessel outer diameter (OD) as found in Appendix X2.

A1.4 Procedure

A1.4.1 When a physiologic compliant vessel is intended to be used, determine the ID and ID dynamic compliance of the mock vessel at the desired test frequency over the justified physiologic pressure range. The method (direct OD measurement only) outlined in ISO 7198:2016 clause A.5.9 may be used, with exception of the tension applied. The mock vessels should be tensioned uniformly (from vessel to vessel) and as they will be during cyclic testing. Length (pre and post tensioned) may be used to set the tension. Tensioning the mock vessel reduces the ID and increases the diametric compliance. The pressure transducer(s) shall be placed at the location of diameter measurements or a location that has been validated at the test frequency. The ID and dynamic compliance may be determined using one of the options in Appendix X2. These values are measured to ensure the desired radial loading is applied to the device.

NOTE A1.3—When external physiologic pressures applied and thin mock vessels are used, the compliance of the mock vessel does not need to be measured. However, the mock vessels must be thin enough to allow the applied external pressure to be transferred to the device as intended.

A1.4.2 Deploy the device in the mock vessel following instructions for use. For temperature-dependent devices, deployment at 37 ± 2 °C might be necessary to ensure a

clinically representative deployment. Leave enough length of the mock vessel extending beyond each end of the device such that the device will be in the region where the device deformation is unaffected by any end effects imposed by the fatigue/durability test system.

A1.4.3 Inspect the deployed stents in a systematic and objective manner, using appropriate instruments or techniques, and record the location and severity of any anomalies. Document the inspection locations for correlation to post-test inspection (see A1.6.2).

A1.4.4 Record proximal and distal locations of each installed device in the mock vessel prior to beginning the test.

A1.4.5 Establish the tolerances associated with the cyclic physiologic pressures. Tolerances may be set for the pressure amplitude and pressure mean, or alternatively the maximum and minimum pressure. Tolerances do not need to be bilateral.

NOTE A1.4—Tolerance cumulation should be considered when assigning tolerances. For example, when setting tolerances on the minimum and maximum pressure, the impact of tolerance cumulation on the pressure amplitude and pressure mean should be understood.

A1.4.6 Purge trapped air from the system. As appropriate, activate the temperature control system and allow the test system to equilibrate at 37 ± 2 °C (unless otherwise justified).

A1.4.7 Start the fatigue/durability test system and adjust the frequency to the desired rate and adjust the cyclic pressure range within tolerance of the justified physiological levels. Ensure the deformation of the device is as desired at the test frequency. If not, an alternative frequency may be needed.

A1.4.8 Zero the counter.

A1.4.9 Periodically monitor and document the cyclic pressures at prospectively specified intervals. Adjust the system as necessary to maintain the cyclic pressures within tolerance. If the cyclic pressures are out-of-tolerance, the cycles between the last in-tolerance measurement and when the system was brought back to within tolerance, for any given test sample, shall not be counted toward the number of cycles required for test termination.

NOTE A1.5—It can be prudent to specify an additional set of tighter tolerances for system adjustment to keep centered within the cyclic pressure tolerances (that is, warning limits).

A1.4.10 If desired, carry out periodic inspections of the device. If the device is removed from the mock vessel for inspection, care must be taken to remove and re-deploy it in a manner that does not destroy the integrity of the test. Periodic inspection shall be at the discretion of the device manufacturer.

A1.4.11 When a physiologic compliant vessel is intended to be used and the mock vessels have not been previously validated to have acceptable change in compliance and ID, periodically re-measure the ID and dynamic compliance of the mock vessel at the test frequency. The pressure transducer(s) shall be placed at the location of diameter measurements or a location that has been validated at the test frequency. This can identify any change in loading that can occur. If unacceptable changes occur, and if possible, without impacting the results of the test, replace the mock vessel (that is, move the device to a new mock vessel) preferably without re-deployment of the device. If moving the device to a new mock vessel is not possible, a new device and mock vessel might need to be tested.

A1.5 Test Termination

A1.5.1 Continue to test until the required number of the in-tolerance cycles (for example, at least 380 million cycles for a test representative of ten years implantation) has been applied.

A1.6 Post-Test Inspection

A1.6.1 When a physiologic compliant vessel is intended to be used and if the mock vessels have not been previously validated to have acceptable change in compliance and ID over the duration of the test, re-measure the compliance and the mean inner diameter of the mock vessel at the test frequency when the test is complete.

A1.6.2 Inspect all devices as required in the protocol.

A2. DIAMETER CONTROL TEST METHOD FOR PULSATILE FATIGUE/DURABILITY TESTING OF VASCULAR STENTS AND ENDOVASCULAR PROSTHESES

A2.1 Summary of Test Method

A2.1.1 The purpose of this test method is to reproduce the desired minimum and maximum diameters, or equivalent change in diameter at a mean, that the device would see *in vivo*. To reproduce these diameters, a volume of testing fluid is cyclically injected into a fluid-filled mock vessel that may or may not have a compliance that is physiologically relevant. Alternatively, the volume of fluid could be cyclically injected into a fixed-volume chamber surrounding the mock vessel to pressurize the OD of the vessel that contains fluid. Thick-walled (thicker than physiological tubing walls) mock vessels are commonly used in order to achieve the desired higher frequency levels. The injected volume is adjusted so that the minimum diameter and maximum diameter of the device is equivalent to the minimum and maximum diameters that the device would experience under physiological conditions. The desired primary measurements made with this test method are the OD (outer diameter) of the device, test frequency, cycle count, and temperature, if necessary. Measurement of the OD of the device using optical methods is problematic due to the lensing effect of the cylindrical mock vessel. Thus, the deployed device OD may be equated to the mock vessel inner diameter (ID) and a relationship between the OD and the ID of

the mock vessel may be used. Several methods for determining the relationship of the OD of the mock vessel to the mock vessel ID are provided in Appendix X2.

A2.2 Significance and Use

A2.2.1 This test method is used to characterize the durability of a stent or endovascular prosthesis under simulated vascular pulsatile conditions, to assess conformance to product specifications and guidance documents, and it may be used to support regulatory submissions, quality control, and manufacturing (for example, process changes).

A2.2.2 The success of this test method depends upon the use of a diameter measurement system that helps ensure that the desired minimum and maximum diameters, or equivalently, the desired mean diameter and change in diameter, of the devices are being achieved at the testing frequency.

A2.3 Apparatus

A2.3.1 See Section 6 for general apparatus requirements.

A2.3.2 *Diameter Measurement System*—The apparatus should include a diameter measuring system that allows the determination of the cyclic change in diameter of the devices at the area of interest within the mock vessel. The system must operate such that the cyclic diameters can be measured at the test frequency.

NOTE A2.1—If direct measurement of the OD of the device is not possible with the measurement system used, an empirical method may be used to relate the deployed device outer diameter (OD) with the measured mock vessel outer diameter (OD) as found in Appendix X2.

A2.4 Procedure

A2.4.1 Determine the minimum and maximum outer diameter of the device in the mock vessel under systolic and diastolic pressures to simulate the physiologic loading conditions. This can be done using one of three methods:

A2.4.2 *Method 1—Determination of Desired Minimum and Maximum Diameters Using a Physiological (Thin-Walled) Mock Vessel:*

A2.4.2.1 Create a mock vessel with physiological compliance behavior. The (thin-walled) mock vessel shall be engineered to simulate the dynamic (1.2 Hz) compliance and appropriate ID, at physiologic pressures (unless otherwise justified) for the device size (see X1.1).

A2.4.2.2 Measure the ID and the OD of the mock vessel statically to establish the basis for determining the mock vessel ID from OD measurements.

A2.4.2.3 Install the mock vessel onto the fatigue/durability test system. If multiple vessels are used, ensure that the mock vessels are mounted under uniform tension. Rationale: The mock vessel ID may be reduced and the compliance may be increased if the mock vessel were to be mounted under excess tension on the test system (see 7.5).

A2.4.2.4 Fill the fatigue/durability test system with the test solution. Purge trapped air from the system. Activate the temperature control system and allow the test system to equilibrate at the required test temperature, if appropriate.

A2.4.2.5 Run the test system at 1.2 Hz and adjust the pressure and bellows displacement to achieve the expected mean pressure plus/minus half the expected pressure differential for the intended use location (such as, 120 ± 40 mmHg; that is, 80 to 160 mmHg) (see X1.1). Determine and record the maximum and minimum ID of the mock vessel by direct measurement, or by using an appropriate equation (see X2.2 for example equations) for maximum and minimum OD measurements of the mock vessel.

A2.4.2.6 Deploy the device into the mock vessel following instructions for use. Leave enough length of the mock vessel extending beyond each end of the test device such that it is unaffected by any end effects imposed by the fatigue/durability test system (see 7.7).

A2.4.2.7 Run the test system at 1.2 Hz and adjust the pressure and bellows displacement to achieve the expected mean pressure plus/minus half the expected pressure differential for the intended use location (such as, 120 ± 40 mmHg; that is, 80 to 160 mmHg) (see X1.1). Determine and record the maximum and minimum OD of the device by direct measurement, or by using an appropriate equation (see X2.2 for example equations).

A2.4.3 *Method 2—Determine Desired Minimum and Maximum Diameters Based on FEA:*

A2.4.3.1 Determine the predicted minimum and the maximum diameter of the device using finite element analysis techniques to determine loading and boundary conditions that the device will experience.

A2.4.3.2 Determine the native vessel compliance based on clinical data or literature (see X1.1).

A2.4.3.3 Using the native vessel compliance, determine the minimum and the maximum diameters the combined device/vessel will experience.

A2.4.3.4 See Guide F2514 for guidance in using finite element analysis for radial loading of stents.

A2.4.4 *Method 3—Use Superposition to Determine the Minimum and Maximum Diameters:*

A2.4.4.1 In order to use this superposition method, diastolic and systolic pressures, vessel compliance (%C (%/100 mmHg)), the vessel mean internal diameter (D_{mean} (mm)) at the mean pressure, and the slope (s (mmHg/mm)) and intercept (i (mmHg)) of the device stiffness linear curve must be known. The slope and intercept of the device stiffness should be determined at relevant diameters and loading state expected *in vivo* (see Guide F3067). Example device stiffness curves are shown in Figs. A2.1 and A2.2 for nitinol and balloon-expandable devices, respectively. The vessel mean ID (D_{mean} (mm)) is typically the lower or upper limit of the recommended vessel diameter range for the device, whichever diameter results in a smaller fatigue safety factor.

NOTE A2.2—This method for determination of the minimum and maximum diameters might not be appropriate for all devices.

A2.4.4.2 Use Eq A2.1 to determine the diastolic diameter of the empty mock vessel (D_1 (mm)).