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Designation: ~~F2477 – 07 (Reapproved 2013)~~ F2477 – 19

Standard Test Methods for *in vitro* Pulsatile Durability Testing of Vascular Stents[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 by exposing it to physiologically relevant diametric distension levels by means of hydrodynamic pulsatile loading. This testing occurs on a stent test specimen that has been deployed into a mock (elastically simulated) vessel. The typical duration of this test is 10 years of equivalent use (at 72 beats per minute), or at least 380 million cycles.

1.2 These test methods are applicable to balloon-expandable and self-expanding stents fabricated from metals and metal alloys. It 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 do not include recommendations for endovascular grafts ("stent-grafts") or other conduit products commonly used to treat aneurismal disease or peripheral vessel trauma or to provide vascular access, although some information included herein may be applicable to those devices.

1.4 These test methods are valid for determining stent failure due to typical cyclic blood vessel diametric distension. These test methods do not address other modes of failure such as dynamic bending, torsion, extension, crushing, or abrasion.

1.5 These test methods do not address test conditions for curved mock vessels.

1.6 These test methods do not address test conditions for overlapping stents.

1.7 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.8 *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~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *General Caveat—This document contains guidance for testing as is currently carried out in most laboratories. Other testing techniques may prove to be more effective and are encouraged. Whichever technique is used, it is incumbent upon the tester to justify the use of the particular technique, instrument, and protocol. This includes the choice of and proper calibration of all measuring devices. Deviations from any of the suggestions in this document may be appropriate but may require the same level of comprehensive justification that the techniques described herein will require.*

1.10 *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 *Other Documents:*

ISO 7198: 1998(e), 8.10, Determination of Dynamic Compliance[2]

FDA Guidance Document 1545, Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, (issued January 13, 2005)[3]

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

Current edition approved ~~March 1, 2013~~June 1, 2019. Published ~~March 2013~~July 2019. Originally approved in 2006. Last previous edition approved in ~~2007~~2013 as ~~F2477 – 07.~~F2477 – 07(2013). DOI: ~~10.1520/F2477-07R13.~~10.1520/F2477-19.

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

[3] Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857, http://www.fda.gov. This document available at http://www.fda.gov/cdrh/ode/guidance/1545.pdf.

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3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *cardiac cycle, n*—defined as one cycle between diastolic and systolic pressures.

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 mm Hg and defined per ISO 7198, 8.10.5:

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

where:

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

3.1.3 *diametric strain, n*—a change in mock artery diameter divided by the initial diameter. This term does not relate to the mechanical strain seen in the stent 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 *distension, n*—the change in diameters; such as the inner diameter (ID) of a vessel due to a pressure change. The term "diametric distension" is meant to represent the change in inner diameter of a blood vessel during each pulse of blood circulation. As an example, the change in diameter between the diastolic and systolic pressure for each pulse of blood circulation.

3.1.5 *hydrodynamic loading, n*—causing a change in the inner diameter (ID) of a mock vessel by injecting a volume of fluid into the confined test volume.

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 distention of a native vessel at physiological pressures (see A1.2.2 and A2.4.2) or at non-physiological pressures (see A2.4.4).

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

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

4. Summary of Test Methods

4.1 These test methods cover fatigue/durability testing of vascular stents that are subjected to hydrodynamic loading that simulates the loading and/or change in diameter that the stent will experience *in vivo*. The stent shall be deployed into mock vessels that can be used to produce a cyclic diameter change of the stent. This document details two test methods that are currently used.

4.1.1 *Physiological 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 at physiological pressure and rate of pulsation as well as at higher testing frequencies.

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 stent diameters, or the equivalent change in stent diameter and mean stent diameter, are being achieved at the test frequency. For conditions where a direct measurement of the stent is not possible, measurements are typically made over the OD of the mock vessel and a relationship is determined and justified for the ratio of the stent OD versus measured mock vessel OD.

5. Specimen Size, Configuration, and Preparation

5.1 Unless otherwise justified, all 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 specimens tested for each stent geometry should be sufficient to support any claims to be made based on the test results. 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.

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