Designation: 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, health, and 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]

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:

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

[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.

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[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.

where:

$Dp1$ = inner diameter at the pressure of $p1$,