



# Standard Guide for *in vitro* Axial, Bending, and Torsional Durability Testing of Vascular Stents<sup>1</sup>

This standard is issued under the fixed designation F2942; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This guide includes three separate cyclic deformation durability guides related to vascular stents: bending, axial, and torsional.

1.2 This guide does not address flat plate, local crush durability, or multi-mode testing.

1.3 This guide applies to balloon-expandable and self-expanding stents fabricated from metals and metal alloys. It does not specifically address any attributes unique to coated stents (i.e., stent with a surface layer of an additional material(s)), monolithically polymeric stents, or absorbable stents, although the application of this standard to those products is not precluded.

1.4 This guide is applicable to testing of stent(s) (or a representative portion of a stent). While durability testing of coupon samples (e.g., a scaled-up portion of the stent structure) can provide useful information, it is not within the scope of this guide.

1.5 This guide applies to endovascular grafts (“stent-grafts”) and other conduit products commonly used to treat aneurysmal disease, peripheral vessel trauma, or to provide vascular access. The information provided herein does not address all issues related to testing of these devices.

1.6 This guide applies to *in vitro* modeling of stent durability from non-radial arterial motions. Such motions may arise from musculoskeletal activities, including walking and breathing, and cardiac motion. ASTM F2477 addresses pulsatile (i.e., radial) durability of vascular stents.

1.7 This guide does not provide the *in vivo* physiologic deformation conditions for a vascular stent. It is incumbent upon the user of the standard to develop and justify these boundary conditions (e.g., literature review, *in vivo* studies, cadaver studies, or modeling of stent vessel interaction) in these durability bench tests. Additional conditions that may be

considered include vessel calcification, vessel taper, eccentric lesions, loading excursions (e.g., exercise), and vessel remodeling.

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 and health practices and determine the applicability of regulatory limitations prior to use.*

## 2. Referenced Documents

### 2.1 ASTM Standards:<sup>2</sup>

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

### 2.2 Other Documents:

ASTM STP 588 Manual on Statistical Planning and Analysis, R.E. Little, 1975

ISO 25539 Cardiovascular Implants—Endovascular Devices—Part 2: Vascular Stents

FDA Guidance Document #1545 “Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems” (Issued April 18, 2010)

## 3. Terminology

### 3.1 Definitions of Terms Specific to This Standard:

3.1.1 *axial, adj*—compression or tension of a stent and/or mock vessel along its longitudinal axis.

3.1.2 *bending, adj*—deformation on the longitudinal axis of a stent and/or mock vessel to achieve a specified stent radius of curvature.

3.1.3 *fracture, n*—the complete separation of a stent structural feature.

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

3.1.5 *radius of curvature, n*—the inner, outer or centerline bend radius of a stent.

<sup>1</sup> This test method is 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 Aug. 15, 2013. Published September 2013. DOI: 10.1520/F2942-13.

<sup>2</sup> 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.

3.1.6 *specimen, n*—article consisting of an implantable device or a representative portion of an implantable device, that is tested according to this guide.

3.1.7 *torsional, adj*—twisting of a stent and/or mock vessel about its longitudinal axis.

#### 4. Summary of Test Guides

4.1 This guide covers *in vitro* durability testing of vascular stents using modes that represent those that might be observed *in vivo* such as bending, axial, or torsional deformation modes. Examples include, but are not limited to, the axial and bending deformation that occurs in the superficial femoral artery during the walking gait, the bending that occurs in the renal artery during respiration, and the bending that occurs in the coronary artery during the cardiac cycle. This guide provides details and guidance for separate tests for each deformation mode: axial, bending, and torsional. This guide allows the direct fixation of the ends of the stent or indirect fixation inside a mock vessel. Direct fixation of the ends of the stent allows better control of stent deformation; however, this can result in attachment-induced test artifact.

4.1.1 *Axial Durability Test Guide*—The purpose of this test is to subject the stent to a specified amount of cyclic axial deformation. The stent is deployed into a mock vessel, unless a justification is provided. This test guide is described in more detail in [Annex A1](#).

4.1.2 *Bending Durability Test Guide*—The purpose of this test is to subject the stent to a specified amount of cyclic bending deformation. There are three suggested bending guides presented in [Annex A2](#), [Annex A3](#), and [Annex A4](#), each involving placement of the stent inside of a mock vessel: column buckling, bending on a mandrel, and bending in an arc without a mandrel. In order to avoid test artifacts, these test guides recommend placement of the stent inside a mock vessel (stent ends not fixed) with subsequent cyclic bending of the mock vessel. When selecting the guide to conduct bending durability testing, consider the potential for the stent design under evaluation to be adversely affected by a particular guide and the ability of each test to simulate a particular clinical condition.

4.1.3 *Torsional Durability Test Guide*—The purpose of this test is to subject the stent to a specified amount of cyclic torsional deformation. This guide is described in more detail in [Annex A5](#).

4.2 Each test may utilize either ‘test-to-success’ (TTS) or the ‘fatigue-to-fracture’ (FTF) methodology.<sup>3</sup> The TTS methodology entails selection of a set of boundary conditions considered physiologically relevant, selection of a sufficient number of specimens, and application of the appropriate number of cycles. The successful completion of the TTS is based upon the number (if any) and type of stent strut fractures. The FTF methodology entails selection of the appropriate number of cycles considered runout (i.e., point to stop testing a specimen), selection of a sufficient number of specimens, and

characterization of the stent fatigue performance by applying multiple deformation levels (i.e., loading amplitude) and conducting periodic inspections of the stent during testing to obtain some test specimens with fractures and some without. For specimens that fracture, the number of cycles applied to cause fracture is obtained. The successful completion of a FTF test is based upon a comparison of stent fatigue performance, at the various deformation levels, to the physiologically relevant deformation levels. Selection of deformation levels to characterize the fatigue behavior of the stent may use the methodology described in ASTM STP 588.

#### 5. Significance and Use

5.1 It is important to consider the durability of stent designs in deformation modes that are intended to model *in vivo* conditions. The appropriate amplitude and number of cycles in each of the modes has to be determined independently for the particular clinical use proposed for the stent. These tests do not replicate all varieties and aspects of the deployment process and the *in vivo* mechanical environment so they cannot be proofs of durability. Instead, the tests provide evidence of durability. The durability tests can also provide a means of assessing design, material or processing changes.

5.1.1 This guide might be useful for development testing, specification acceptance testing, and regulatory submission testing and filings as it provides a basic assurance that the tests are designed, executed, and reported in a suitable fashion.

5.1.2 If the tests are conducted using a well-defined FTF methodology, they can be useful in:

5.1.2.1 Potential design improvement through identification of better and worse geometries, materials, and manufacturing processes;

5.1.2.2 Understanding product durability by estimating the effects of changes in geometry, materials, or manufacturing processes;

5.1.2.3 Estimating the safety factor relative to the amplitudes and other factors in use conditions; and

5.1.2.4 Validating finite element analysis (FEA) and fatigue life models.

5.1.3 As stated in the scope, this guide is not intended to provide the *in vivo* physiologic deformation conditions that a vascular stent can be subjected. Reliable clinical data characterizing cyclic vascular deformation may be lacking for some indications. The user should develop and justify the boundary conditions (e.g., literature review, *in vivo* studies, cadaver studies, or modeling of stent vessel interaction) for the chosen durability bench tests. Additional conditions that may be considered include vessel calcification, vessel taper, eccentric lesions, deformation excursions (e.g., exercise), and vessel remodeling.

5.1.4 Test methods other than those provided in the annexes of this document might be appropriate, depending upon stent design. However, these methods are beyond the scope of this guide.

#### 6. Specimen Size, Configuration, and Preparation

6.1 Unless otherwise justified, all specimens selected for testing should be taken from fully processed, implant quality

<sup>3</sup> Gong, X-Y, Chwirut, D. J., Mitchell, M. R., and Choules, B. D., Fatigue to Fracture: An Informative, Fast, and Reliable Approach for Assessing Medical Implant Durability, *Journal ASTM International*, Volume 6, Issue 7, July 2009.

product. Sterilization should be performed unless it can be shown not to influence the durability test results.

NOTE 1—Although sterilization may not directly affect the stent itself, it may affect the delivery system and, thus, the condition of the as-deployed stent.

6.2 Prior to durability testing, specimens loaded in or on their delivery systems should be tracked through a model representative of the vasculature to simulate clinical delivery.

6.3 To reduce the number of specimens to be tested, durability may be evaluated for the worst case justified device size/model. Alternatively, multiple sizes (length and/or diameter) at potentially multiple deployment diameters would need to be tested with an appropriate bracketing scheme (e.g., largest and smallest length and/or diameter or models).

6.3.1 *Stent Length*—The axial and torsional durability testing modes act to induce stent deformation normalized with length (length change per length, and transverse angle change per length, respectively). Thus, the fatigue resistance of a stent design with a repeating unit or cell design would also be independent of length and any length may be tested. In cases where the stent design is length-dependent (e.g., non-repeating unit cells), the length predicted or expected to perform worst should be justified (e.g., by finite element analysis or description of stent design).

NOTE 2—Because of the nature of these test methods, it may not be possible to test the longest stent length within a family of sizes, especially in the overlapped configuration. In such cases, other means may need to be implemented to justify the stent length tested or to allow extrapolation of test conclusions to the lengths not tested (e.g. justification based on finite element analysis).

6.3.2 *Stent Diameter*—The fatigue resistance of any specific stent design might be dependent upon the diameter. A rationale based on finite element analysis or an explanation as to why the particular diameter is predicted or expected to perform worst should be provided. If different labeled diameter stents within a family have significantly different strut patterns, each unique pattern should be considered separately.

6.3.3 *Deployment Diameter*—For each labeled diameter stent tested, the test stent should be deployed to the “worst-case” deployed diameter per the instructions for use (IFU) (see section 8.2 Mock Vessels). The diameter predicted or expected to perform the worst should be justified by means such as finite element analysis.

6.3.4 *Stent Overlapping*—When stents are expected to be overlapped in clinical use, durability testing of overlapped stents should be performed. An overlap length representative of clinical use should be selected. The relative position (rotation and overlap length) of the overlapped stents should be selected to ensure sufficiently challenging application of strain. Fretting and/or wear might lead to fracture of overlapped stents during durability testing. Thus, further analysis (e.g., scanning electron microscopy (SEM)) of the stents after durability testing might be necessary to determine the failure mode.

6.4 The number of specimens tested for each stent size and/or geometry should be sufficient to support any claims made based on the test results. The results of testing according to this guide in combination with other tests, animal and clinical tests, analysis (such as FEA), and/or comparisons to

predicate devices can be sufficient to enable demonstration of an adequate durability. In this guide, one stent or a set of two overlapped stents should be considered one specimen.

## 7. General Apparatus Requirements

7.1 The axial, bending and torsional dynamic displacements of the test equipment should be verified at the selected test frequencies. The dynamic stent deformation verification documentation should include justification of the verification means (see section 8.6).

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

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

7.4 *Temperature Control System*—The apparatus should include a calibrated temperature control and measurement system to maintain the temperature of the stents being tested.

## 8. General Test Parameters

8.1 Completion of the durability test for stents deployed within a mock vessel, in air alone, or in fluid alone, depends on the deformation mode (i.e., axial, torsional, or bending), the material used to construct the stent (i.e., self-expanding or balloon-expandable), as well as the test purpose. For example, cyclic axial tests that are being conducted to predict stent durability under *in vivo* use conditions are likely to be conducted in a mock vessel. For cyclic axial tests that are being conducted as part of a development process or as part of a FTF investigation, it may be possible to complete the testing without a mock vessel. Regardless of the test configuration, the user of the standard should provide justification for the test conditions. If testing is conducted in air, heating of the stent resulting from applied accelerated cyclic deformation might occur. In such a case, means (e.g., convection cooling) should be implemented to minimize heating and evidence provided that any remaining heating does not significantly increase the fatigue life.

8.2 *Mock Vessels*—The mock vessel should be durable, capable of withstanding the test conditions, and able to maintain the desired stent deformations. The inner diameter (ID) of the mock vessel is important to the outcome of the durability tests in this standard guide. The stented mock vessel ID should be appropriate for the selected stent deployed diameter as described in section 6.3.3 above, and should remain essentially constant (i.e. not drift with time) over the duration of the test. The wall thickness, coefficient of friction, and elasticity of the mock vessel might influence the testing results. For example, during the bending durability test, undesired kinking may result with an inappropriate mock vessel, or during the axial durability test the stent may not elongate or compress as intended if the friction between the mock vessel and stent is too high or too low. Measures to reduce excessive