



Standard Guide for *in vitro* Axial, Bending, and Torsional Durability Testing of Vascular Stents¹

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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 aneurismal 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:²

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.

¹ 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.

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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.