



Guide for Radial Loading of Balloon Expandable and Self Expanding Vascular Stents¹

This standard is issued under the fixed designation F3067; 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 This document provides guidance for developing *in vitro* test methods for measuring the radial strength or collapse pressure of balloon-expandable vascular stents and chronic outward force of self-expanding vascular stents.

1.2 This guide is applicable to balloon-expandable and self-expanding stents of tubular geometry. It covers both stent and stent grafts. It does not cover bifurcated stents. It does not cover stents with non-circular cross-sections or tapered stents.

1.3 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 This guide does not recommend any specific test method or apparatus for measuring the radial strength, collapse pressure, or chronic outward force. Instead, this guide provides examples of test methodologies and equipment that could be used and recommends the format for presenting test results.

1.5 This guide covers only *in vitro* bench testing methods. *In vivo* behavior might be different.

1.6 *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:

[E4 Practices for Force Verification of Testing Machines](#)

[E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods](#)

[F2079 Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents](#)

[F2081 Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents](#)

[F2477 Test Methods for *in vitro* Pulsatile Durability Testing of Vascular Stents](#)

3. Terminology

3.1 Definitions (alphabetically listed):

3.2 *balloon-expandable stent*—a stent that is expanded at the treatment site by a balloon catheter. The stent material is plastically deformed by the balloon expansion such that the stent remains expanded after deflation of the balloon.

3.3 *chronic outward force*—the minimum continued opening force of a self-expanding stent acting on the vessel wall at a specified diameter. The range of chronic outward force is defined by the unloading curve at the maximum and minimum indicated use diameters. Additional loading force considerations for self-expanding stents are evaluated as load excursions and described in [Appendix X2](#). Chronic outward force is not defined for balloon-expandable stents.

3.4 *collapse pressure*—the uniform radial load during testing with a hydraulic or pneumatic apparatus in which a balloon-expandable stent undergoes buckling over a specific region or the entire stent length.

3.5 *load*—a normalized, scalar value of force applied by the stent to the vessel and, at equilibrium, the vessel upon the stent. Load should be normalized by length (newton or millinewton per millimeter length) or by area (pascal or kilopascal).

3.6 *loading line*—for balloon-expandable stents, the line derived from the substantially linear portion of the radial loading curve during initial compression. The term is not defined for balloon-expandable stents tested using collapse pressure apparatus.

3.7 *radial force*—output of radial loading that equals the radial pressure times the stent cylindrical area. The relationship between radial force (F_R) and radial pressure (P) is given in the equation:

$$P = \frac{F_R}{A}$$

where:

P = radial pressure,

F_R = radial force, and

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.

Current edition approved Oct. 15, 2014. Published March 2015. DOI: 10.1520/F3067-14.