Designation: F3067 – 14 (Reapproved 2021)

Standard Guide for Radial Loading of Balloon-Expandable and Self-Expanding Vascular Stents[1]

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

1.7 *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 *ASTM Standards:*[2]

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:*

3.1.1 *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.

3.1.2 *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.

3.1.3 *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.

3.1.4 *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).

[1] This guide 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. 1, 2021. Published August 2021. Originally approved in 2014. Last previous edition approved in 2014 as F3067 – 14. DOI: 10.1520/F3067-14R21.

[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.

3.1.5 *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.

3.1.6 *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:

$$P = \frac{F_R}{A} \quad (1)$$

where:

P = radial pressure,
F_R = radial force, and
A = instantaneous stent cylindrical area:

$$A = \pi DL$$

where:

D = instantaneous stent expanded outer diameter, and
L = L_0 for length change less than 10 % and $L = L(D)$ for length change greater than 10 %. L:L_0 is the expanded stent length for balloon-expandable stents and unconstrained length for self-expanding stents. $L(D)$ is the instantaneous length of the stent as a function of the current instantaneous diameter. $L(D)$ may be either experimentally determined or computationally derived.

3.1.7 *radial loading*—a mechanical loading mode in which the load is directed perpendicular to the longitudinal axis of a cylinder and applied to the outer cylindrical surface of the stent. The load is applied to the entire outer surface or to at least three areas that are equally distributed around the outer circumference and extend over the entire cylinder length. Load might be expressed as radial force or radial pressure.

3.1.8 *radial loading curve*—the graph of radial loading output on the *y*-axis versus diametric deformation of a stent on the *x*-axis.

3.1.9 *radial pressure*—the area normalized output of radial loading equaling the average pressure applied to the stent by the loading fixture in the radial direction toward the stent cylindrical axis.

3.1.10 *radial resistive load*—the peak load during a compression excursion of a self-expanding stent. The excursion might be a single event or a cycle. A typical example is pulsatile cycling of an implanted self-expanding stent (refer to Appendix X2).

3.1.11 *radial strength*—a specific load on the radial loading curve that corresponds with a specific and clinically (practically) relevant amount of inward plastic deformation from the unloaded state. The term is defined only for balloon-expandable stents tested whose sole mechanism of expansion is by a balloon. Additionally, the term applies only to stents tested using a segmented head or sling type apparatus and not using a hydraulic or pneumatic pressure apparatus.

3.1.12 *self-expanding stent*—a stent that expands without the application of external forces or pressure, to a size and shape that is close to the desired final size and shape, when released from the delivery system.

3.1.13 *stent graft*—transluminally placed tubular vascular prosthesis, with one or more integral stent components to provide fixation or radial support, or both, residing partially or completely within a vascular conduit to form an internal bypass or shunt between sections of the vascular system.

3.1.14 *stent length*—unstressed length of the stent after deployment. If the stent has marker bands on non-radial force-producing components, the length is measured from the ends of the radial force-producing sections. The measured length of mounted or expanded stents should be measured by non-contacting instruments (profile projection, laser micrometer, and so forth) with a resolution of 0.1 mm or better (see Guide F2081).

3.1.15 *unloading line*—for balloon-expandable stents, the line derived from the substantially linear portion of the radial unloading curve. The term does not apply for balloon-expandable stents tested using collapse pressure apparatus.

3.1.16 *vascular patency*—a measure of the extent to which the vessel is open (unrestricted). Typically reported as a percent of the reference (unrestricted, adjacent) vessel diameter or cross-sectional area.

3.1.17 *vascular stent*—a tubular synthetic structure that is implanted in the native or grafted vasculature and that is intended to provide mechanical radial support to enhance vessel patency. For the purpose of this guide, a stent might be metallic or non-metallic. It might be durable or absorbable.

3.1.18 *zero compression diameter*—the diameter reference point required for the testing apparatus to fully engage the stent outer surface. Stent compression is calculated in comparison to this diameter.

4. Significance and Use

4.1 Upon deployment, at the site of the vascular stenosis, the stent establishes the patency of the lumen until vascular remodeling occurs. The radial load acting upon the stent is imparted by vessel and lesion stretch. Additionally, the vessel might be affected by excursions due to pulsation (systolic and diastolic variation), muscle-skeletal interactions due to patient movement, as well as external sources (e.g., patient is struck in the neck during a car accident). The excursions vary in magnitude and type based on the location of the vessel.

4.2 In order to maintain vessel patency, the stent has to withstand the forces acting on it without experiencing excessive deformation, migration, or sustained collapse; therefore, it is required that the stent possess adequate resistance to these loads.

4.3 Depending on the type of device and the clinical concern, the resistance to these loads can be presented through multiple test outputs: radial strength, collapse pressure, or chronic outward force.

4.4 The guidelines presented here can be used in the development of test methods to determine the radial loading properties of stents. This guide provides examples of different test apparatus (equipment and tooling), radial loading curves,