



Standard Guide for Three-Point Bending of Balloon Expandable Vascular Stents and Stent Systems¹

This standard is issued under the fixed designation F2606; 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 guide provides guidelines for quantitatively characterizing balloon-expandable stent and stent system flexibility using three-point bending procedures. Guidelines are provided for characterizing deployed stent flexibility, and for characterizing pre-deployment stent system flexibility in the region of the stent and balloon.

1.2 This guide is not recommended for test articles that cannot be appropriately evaluated using a span length to stent outer diameter (as tested) ratio of at least 4:1. Test articles that do not meet this requirement are likely to exhibit appreciable deformation by modes other than bending.

1.3 This guide does not provide procedures for characterizing the bending flexibility of self-expanding stents, self-expanding stent systems, endoprostheses (stent-grafts), or endoprostheses systems. However, some aspects of this guide may be useful for developing appropriate three-point bending characterization procedures for these devices. While this guide was developed with vascular stents and stent systems in mind, it may be useful for characterizing the bending flexibility of balloon-expandable stents and stent systems used in non-vascular applications.

1.4 The values stated in SI units are to be regarded as the standard. The values given in parentheses are mathematical conversions to inch-pound units that are provided for information only and are not considered standard.

2. Terminology

2.1 Definitions:

2.1.1 *bending flexibility*, n —a measure of the ability of a test specimen to bend.

2.1.2 *bending stiffness*, n —a measure of the ability of a test specimen to resist bending.

2.1.3 *conformability*, n —the degree to which a stent or stent system matches the native curvature of the vasculature.

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 March 1, 2014. Published April 2014. Originally approved in 2008. Last previous edition approved in 2008 as F2606 – 08. DOI: 10.1520/F2606-08R14.

2.1.4 *deflection*, n —displacement of the dynamic support (loading anvil) at any point in the test.

2.1.5 *delivery system*, n —catheter that is used to deliver and deploy a stent at the target site. A delivery system for balloon-expandable stents may be similar to a balloon-dilatation (angioplasty) catheter.

2.1.6 *midspan bending moment*, n —a linear estimate of the bending moment at the center of the span. See 8.5.

2.1.7 *midspan curvature*, n —a linear estimate of the curvature of the center of the span. See 8.5.

2.1.8 *span length*, n —distance between the centers of the supports.

2.1.9 *stent system*, n —delivery system with a pre-mounted stent.

2.1.10 *stent, vascular*, n —synthetic structure that is permanently implanted in the native or grafted vasculature and that is intended to provide mechanical radial support to enhance vessel patency.

3. Significance and Use

3.1 This guide can be used to obtain force versus deflection or midspan bending moment versus midspan curvature curves for stents and stent systems subjected to three-point bending conditions. Bending flexibility of a stent system may be a factor in its ability to track through the vascular anatomy, and may be a factor in vascular trauma along the delivery pathway distal to the guide catheter. Bending flexibility of a deployed stent may be one measure of its ability to flex with a vessel, or to conform to the natural curvature of a vessel. Bending flexibility of a delivery system may also be of interest if it is desired to assess the separate contributions of the delivery system and the mounted stent to the overall flexibility of the stent system.

3.2 This guide is not intended to determine material properties, stent system trackability (ability of a stent system to follow a guide wire and/or guide catheter through vascular tortuosity), or stent system deliverability (ability of a stent system to deliver a stent to the implantation site(s) or through particular level(s) of vascular tortuosity). While this guide does not determine stent system trackability or deliverability, it can provide quantitative insight into how stent system bending