



Standard Guide for Measuring Securement of Balloon Expandable Stent Mounted on Delivery System¹

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1. Scope

1.1 This guide provides guidance for the design and development of pre-test treatments, tests, and test endpoints to measure stent securement of pre-mounted, unsheathed, balloon-expandable stent delivery systems. This guide is intended to aid investigators in the design, development, and *in vitro* characterization of pre-mounted, unsheathed, balloon-expandable stent delivery systems.

1.2 This guide covers the laboratory determination of the shear force required to displace or dislodge a balloon-expandable endovascular stent mounted on a delivery system. The guide proposes a set of options to consider when testing stent securement. The options cover pre-test treatments, possible stent securement tests, and relevant test endpoints. An example test apparatus is given in 7.1.

1.3 This guide covers *in vitro* bench testing characterization only. Measured levels of securement and product design/process differentiation may be particularly influenced by selections of pre-test treatments, securement test type (for example, stent gripping method), and test endpoint. *In vivo* characteristics may also differ from *in vitro* results.

1.4 This guide does not cover all possible pre-test treatments, stent securement tests, or test endpoints. It is intended to provide a starting point from which to select and investigate securement test options.

1.5 This guide does not specify a method for mounting the stent onto the delivery system.

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 requirements prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

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.

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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.

E 1488 Guide for Statistical Procedures to use in Developing and Applying Test Methods

2.2 Other Documents:

ISO 10555-1 Sterile Sterile, Single-use Intravascular Catheters—Part 1: General Requirements³

Quality System Regulation, Part VII Dept. Health and Human Services, Food and Drug Administration, 21 CFR Part 820 Medical Devices; Current Good Manufacturing Practice; Final Rule. Federal Register, October 7, 1996⁴

3. Terminology

3.1 Definitions:

3.1.1 *balloon expandable stent, n*—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 *crimp, v*—to secure the stent on the delivery system by radially compressing and plastically deforming the stent onto the balloon.

3.1.3 *delivery system, n*—a system similar to a balloon dilatation catheter that is used to deliver and deploy a stent at the target site.

3.1.4 *displacement force, critical distance peak, n*—a stent securement test endpoint characterizing the maximum force required to displace the stent with respect to the balloon a critical distance. This critical distance is the minimum of the following two distances. The first is the distance at which the undamaged stent could overhang the balloon body resulting in a clinically significant, incomplete end deployment. The second is the length (distance) of stent compression or buckling that could result in a clinically significant, incomplete deployment of the stent against the vessel walls. (See Fig. X2.1.)

3.1.5 *displacement force, initial, n*—a stent securement test endpoint characterizing the initial force required to displace the stent with respect to the balloon such that the displacement is a non-recoverable movement (see definition below). (See Fig. X2.1.)

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

⁴ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.