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Standard Guide for Measuring Securement of Balloon-Expandable Vascular Stent Mounted on Delivery System[1]

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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 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined.

1.7 *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.*

1.8 *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]

E1169 Practice for Conducting Ruggedness Tests

E1488 Guide for Statistical Procedures to Use in Developing and Applying Test Methods

2.2 *Other Documents:*

ISO 10555-1 Sterile and Single-Use Intravascular Catheters—Part 1: General Requirements[3]

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, 1996[4]

EN 14299 Non Active Surgical Implants—Particular Requirements for Cardiac and Vascular Implants—Specific Requirements For Arterial Stents, May 2004[5]

CDRH Guidance, Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, January 13, 2005[6]

[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.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

[5] Available from British Standards Institute (BSI), 389 Chiswick High Rd., London W4 4AL, U.K., http://www.bsi-global.com.

[6] Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857, http://www.fda.gov/cdrh/ode/guidance/1545.pdf.

MAUDE Database[7]

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 and then removed.

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 3.1.15). (See Fig. X2.1.)

3.1.6 *displacement force, initial peak, n*—a stent securement test endpoint characterizing the first peak in force that occurs during or after stent displacement with respect to the balloon. (See Fig. X2.1.)

3.1.7 *dislodgment force, peak, n*—a stent securement test endpoint characterizing the peak or maximum force required to completely dislodge the stent from the delivery system balloon. During a test, this force will occur after or coincide with the initial displacement force. (See Fig. X2.1.)

3.1.8 *end flaring, n*—a distal or proximal outward conical opening of the diameter of the stent on the balloon. End flaring is a contributing factor to the probability that the stent may become caught during withdrawal into a guide catheter while tracking through a lesion.

3.1.9 *failure mode effect analysis (FMEA), n*—an analytical approach to methodically determine and address all possible product failure modes, their associated causes, and their criticality. Used to evaluate designs, prioritize testing, and track risk reducing improvements to the product.

3.1.10 *gauge length, n*—the initial unstressed length of catheter tubing between the proximal end of the stent to the grips which engage the catheter tubing.

3.1.11 *grips, n*—a means of applying force to the stent and balloon catheter to displace or dislodge the stent relative to the balloon. In particular, grips refer to the end of a device which makes the contact with the stent. Typical grips used to apply force to the stent include shims (as used in Figs. X2.5-X2.8); tape which sticks to the stent but not the balloon; an iris which can be narrowed down to allow the balloon to slip by but not the stent; or nubs which contact the stent but not the balloon.

3.1.12 *guide catheter, n*—a tube designed to transport the guide wire and the stent delivery system into the target vessel.

3.1.13 *guide wire, n*—a wire designed to aid in balloon, ultrasound, atherectomy, or stent placement during endovascular procedures.

3.1.14 *mandrel, n*—a wire that may be used as an alternative to the intended guide wire to provide support for the catheter guide wire lumen for some test procedures.

3.1.15 *non-recoverable movement, n*—a displacement of the stent relative to the balloon such that if the shearing force was reduced to zero, the stent would remain displaced in the direction of the shearing force relative to the initial placement on the balloon. The force at which non-recoverable movement begins is defined as the initial displacement force (see definition above).

3.1.16 *pre-test treatment, n*—a treatment of the stent delivery system prior to the evaluation of securement that simulates preparatory, environmental, mechanical, or other conditions that may be encountered prior to or during clinical use of the device. Examples include subjecting the devices to elevated shipping temperature/humidity, catheter preparation per use instructions, pre-soaking, bending treatments, tracking treatments (tracking fixture, see definition below), and tracking through lesion treatments (lesion fixture, see definition below).

3.1.17 *pre-test treatment tracking fixture, n*—a pre-test treatment fixture used to simulate an anatomical vasculature. Use of the fixture with a guide catheter, a guide wire, and the stent-balloon catheter delivery system is intended to simulate the bending and frictional forces of tracking the device to the lesion site that may be encountered in the clinical setting. See the engineering diagrams in Appendix X2. Note that these engineering diagrams simulate vessels with a moderately difficult degree of coronary tortuousity but do not include simulated lesions.

3.1.18 *pre-test treatment lesion fixture, n*—a pre-test treatment fixture used to simulate an anatomical vasculature and lesion. Use of the fixture with a guide catheter, a guide wire, and the stent-balloon catheter delivery system is intended to simulate the bending, frictional, and mechanical resistance forces of tracking the device across the lesion site that may be encountered in the clinical setting.

3.1.19 *securement test, guide-type, n*—a stent securement test that is similar to the clinical scenario of pulling an undeployed stent delivery system back into a guide catheter, arterial sheath, or hemostasis valve. Examples include guides, rings, or shims ideally designed to engage the stent end or body but not the catheter balloon. The shim securement test, described in Section 7, uses complementary thin, rigid plates with rounded "V" notches that are sized to circumferentially engage the stent end but not the catheter balloon. See the engineering diagrams in Appendix X2.

[7] http://www.fda.gov/cdrh/maude.html.