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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 may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

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 and health practices and determine the applicability of regulatory requirements prior to use.*

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 Sterile Sterile, 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]

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

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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.

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

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 the Appendix. 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 the Appendix.

3.1.20 *securement test, lesion-type, n*—a stent securement test that is similar to the clinical scenario of pushing or pulling an undeployed stent delivery system through or around a fibrous or calcified lesion. Examples include tape, nubs, protrusions or sandpaper ideally designed to engage the stent end or body but not the catheter balloon.

4. Significance and Use

4.1 The securement of the endovascular stent on the balloon is a critical parameter to ensure that the stent is safely delivered to or from the treatment site.

4.2 This guide is intended for use by researchers and manufacturers for the development and selection of pre-test treatments, tests and test endpoints to measure stent securement (displacement distances and dislodgment forces).

4.3 This guide may be used to investigate which practical combinations of *in vitro* tests best characterize clinical scenarios.

4.4 This guide should be used with discretion in choosing securement tests and evaluating results due to the myriad possible combinations of clinical conditions, failure modes, and stent delivery system designs.

4.5 This guide may be of use for developing a test for meeting parts 2 and 3 of the requirements of EN 14299, Section 7.3.4.4 on Trackability.

4.6 This guide may be of use for developing a test to meet section VII-C-8 of CDRH Guidance document.

5. Clinical Scenarios

5.1 There are two failure modes—the stent is dislodged from the catheter or the stent is displaced or deformed on the catheter such that balloon inflation delivery would not produce an acceptable stent shape at the proper location. Based on reported clinical incidents, there are three causes for these two types of failures:

5.1.1 Displacement or dislodgment of the stent while attempting to track through or position in tortuous bends, fibrous or calcified lesions, or previously implanted stents, or combination thereof.

5.1.2 Displacement or dislodgment of the stent on withdrawal of the undeployed stent delivery system back into the guide catheter, introducer sheath, or hemostasis valve. This failure type is usually associated with failure to cross tortuous bends, fibrous or calcified lesions, or previously implanted stents, or combination thereof. It is sometimes associated with less-than-ideal seating or angled placement of the guide catheter tip in the ostium of the vessel.

5.1.3 Displacement or dislodgement of the stent due to improper catheter preparation including mishandling or partial balloon inflation during preparation. This has been identified in a few cases where the loose, displaced, or dislodged stent was observed prior to use but may conceivably play a role in a small percentage of cases where dislodgment occurs in patients.

6. Test Method Considerations

6.1 *Flowchart*—See Fig. 1.

6.2 *Development and Evaluation of Securement Tests:*

6.2.1 Securement test development and selection is ideally begun through the initial use of a battery of tests measuring a variety of failure modes. These test methods may vary from a simple intuitive tactile impression of the securement forces through manipulation to clinically modeled situations with guide catheters and stenosis models to *in vivo* animal studies with representative anatomy and physician handling. From a safety-risk perspective, consider how securement challenges may occur in clinical situations, what may result from loss of securement, what the severity of the outcome is to the patient, what the frequency of these situations are, and then how to test to detect these occurrences. Factors to consider in evaluating securement tests include the following:

6.2.1.1 Review of the MAUDE database for reported problems with comparable devices.

6.2.1.2 Physician surveys for clinical relevance and problems with comparable devices.

6.2.1.3 Mechanical understanding of the tests' clinical relevance and limitations.

6.2.1.4 Mechanical and statistical understanding of the test reproducibility limitations due to device variation, pre-test treatments, various grips, and test conditions.

6.2.1.5 Ability to set accept/reject criteria by physician evaluation, by historical comparisons, or by other rational means.

6.2.2 The final securement test(s) selected must ultimately satisfy internal manufacturer quality standards. These standards may include clinical relevance, FMEA analysis, statistical assurance of characteristics, and challenge assurance of characteristics.

6.2.3 The final securement test(s) must also satisfy external regulatory body standards. For example, the FDA QSR 21 CFR Part 820, Oct. 7, 1996 states that each test used in the process of design and manufacturing of finished devices "is suitable for its intended purposes and is capable of producing valid results." For the statistical capability evaluation, Guide E1488 is very helpful.

6.3 *Pre-Test Treatments:*

6.3.1 Pre-test treatments may be conducted prior to the evaluation of securement to simulate preparatory, environmental, mechanical, or other conditions that may be encountered prior to or during clinical use of the device.

6.3.2 Pre-test treatments may include subjecting the devices to shelf life testing, sterilization, elevated shipping temperature/humidity, removal of the delivery system from the carrier tube, and other catheter preparation per use instructions, pre-soaking, bending treatments, tracking treatments, and tracking through lesion treatments.

6.3.3 Tracking treatments are intended to clinically simulate the bending and frictional forces of tracking the device through the guide catheter and vasculature to the lesion site. Considerations for tracking treatments include: tracking medium (for example, air, water, water with lubricants, saline, blood) and temperature; guide catheter and guide-wire selection; simulated vessel material (for example PMMA, silicone, glass, PTFE), tortuousity, dimensionality, length and diameter; speed of tracking; and number of repetitions to track. Angiograms or autopsies of human or similar animal vasculature may be particularly useful in developing alternative anatomical models. An example of a tracking treatment is given in Section 7. Two examples of tracking fixtures are given in engineering