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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.

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

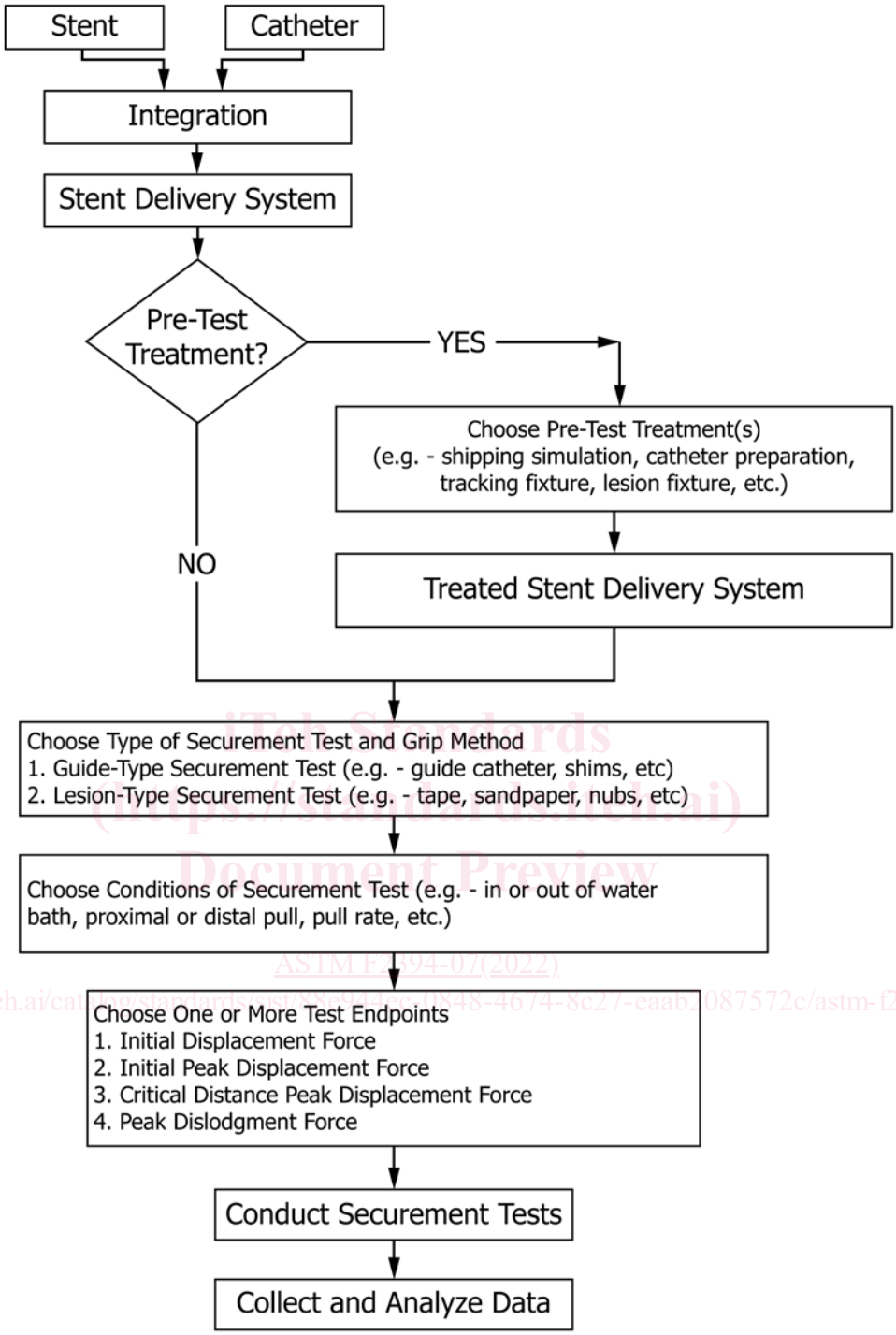

FIG. 1 Flowchart

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 diagrams in Appendix X2. Note that these engineering diagrams simulate vessels in 2D with a moderately difficult degree of coronary tortuousity but do not include simulated lesions.

6.3.4 Tracking through lesion treatments is intended to clinically simulate the bending, frictional, and mechanical resistance forces of tracking the device across the lesion site. Considerations include those of tracking treatments in addition to simulating the lesion material, type, and morphology. Lesion material encountered clinically may include calcium, fibrin,

collagen, fat, cholesterol, endothelial cells, smooth muscle cells, red blood cells, platelets, dead white blood cells, and macrophages. Lesion types may be calcified, fibrous, lipidic, thrombotic, or grumous. Lesion morphologies may be totally or partially occluded, concentric or eccentric, focal or diffuse, and of many possible shapes.

6.3.5 *Post-Track Test Evaluation*—To understand the effects of tracking on the probability that the stent delivery system may encounter securement challenges, the measurement of stent-balloon geometry changes post tracking may be a useful adjunct to force-measuring tests. In particular, the measurement of end flaring may be useful. While end flaring may increase the chance the stent will catch on a guide, previously placed stents, lesions, and so forth, end flaring does not in itself determine the force it takes to displace, dislodge, or deform the stent. End flaring and other geometrical changes also provide a measure of the effects of different track and lesion geometries and materials. End flaring may be measured by measuring the change in peak proximal and distal end heights relative to the longitudinal continuation of the nominal stent diameter.

6.4 *Securement Test and Grip Methods:*

6.4.1 There are two main categories of stent securement tests: guide-types and lesion-types.

6.4.2 A guide-type securement test simulates the clinical scenario of pulling an undeployed stent delivery system back into a guide catheter, arterial sheath, or hemostasis valve. Examples of grip methods used to simulate guide-type securement tests include guide catheters, 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 to circumferentially engage the stent end but not the catheter balloon. Engineering diagrams are included in Appendix X2.

6.4.3 A lesion-type securement test simulates the clinical scenario of pushing or pulling an undeployed stent delivery system through or around a fibrous or calcified lesion. Examples of grip methods used to simulate lesion-type securement tests include tape, nubs, protrusions, or sandpaper ideally designed to engage the stent end or body but not the catheter balloon.

6.4.4 For both types of tests, it may increase the understanding of the test to measure a baseline reference force by testing delivery systems without or with poorly secured stents. Such tests may provide measurements of slip forces, balloon and catheter deformation mechanics, and the lower limit to measurable securement forces.

6.5 *Test Conditions:*

6.5.1 Stent securement test conditions particularly important for hygroscopic balloon materials whose stent securement properties may change with varying exposure to water or other fluids include the following:

6.5.1.1 Tracking and test temperature,

6.5.1.2 Tracking and test medium (for example, air, water, saline, blood),

6.5.1.3 Tracking and test soak time (for fluid mediums), and

6.5.1.4 Time between track and test.

NOTE 1—Justification for the selection of the parameters should be part of the test history file.

6.5.2 Guide wire selection (or substituted test mandrel) may particularly influence pre-test track treatments and securement tests that include simulated tracking. A stiffer guide wire or test mandrel may place the stent delivery system under greater normal and frictional forces. Or, it may span and round out curvature in a track model, especially flexible models, and reduce the bending of the balloon and stent. Additionally, guide wire stiffness varies along the length (for example, flexible 50 mm tip, moderate 50 mm stent/balloon support, and stiff 500 mm shaft); guide wire materials may have strong nonlinear response and recovery from bending, and each different guide wire surface, typically chosen for lubricity and durability, may respond to different catheter lumen surfaces. Completing ruggedness evaluations using a variety of wires may be important to determine the optimal wire choice for the test. However, after choosing the optimal wire within the guidelines of the Instructions for Use for your stent, maintain consistency and simplicity by executing the remaining testing with the optimal selection.

6.5.3 The gauge length chosen may influence the pull rate transmitted to the stent. A shorter gauge length will have less longitudinal material deformation and transmit a less variable pull rate closer to the set pull rate. A 25 mm gauge length is a typical value.

6.5.4 The pull rate selected should allow meaningful discrimination and measurement of the chosen test endpoint(s) and, as possible, model the clinical situation. Slower rates may help visualizing pull-off mechanics in videotaped tests. Faster rates may be more repeatable. In a test modeling lesion dislodgment, set the crosshead extension speed (pull rate) to a slow rate such as at 0.5 in./min. In a test modeling withdrawal into the catheter, set the crosshead extension speed to a faster rate such as 10 to 30 in./min. Adjust the data sampling rate as appropriate; for example, increase the sampling rate for high pull speeds; have a high sampling rate for measuring peak forces.

6.5.5 The direction of pull (proximally, distally, or angled) chosen may depend on factors such as stent and delivery system design and clinical relevance. The product design may be more at risk for either proximal or distal displacement. Clinically, peak pull forces transmitted to the stent will exceed push forces. Also, the stent forces encountered clinically are seldom oriented purely proximally or distally tangent to the undeformed stent axis. Pulling in a non-tangential direction adds in normal forces which tend to increase the displacement and dislodgement forces. Thus, typically, the most challenging securement test pulls purely in the tangential direction of the undeformed stent. This is best confirmed through systematic variation of the pull direction.

6.6 *Test Endpoints:*

6.6.1 There are two main test endpoints for stent securement evaluations: displacement force and dislodgment force.

6.6.2 The displacement force is the force required to displace the stent with respect to the balloon in a non-recoverable movement. Clinically, displacement may result in the following:

6.6.2.1 Improper positioning upon deployment due to the movement of the stent with respect to the markerbands,

6.6.2.2 Incomplete stent end deployment due to movement of the stent off the body of the balloon, and

6.6.2.3 Incomplete or poor apposition of the stent to the vessel walls due to compression or buckling damage to the stent.

NOTE 2—There are at least four possible endpoints to measure displacement force: initial, critical distance peak, initial peak, and maximum sustained force. See Fig. X2.1 for graphical representation of the first three of these listed endpoints. The maximum sustained force (not seen in Fig. X2.1) may be relevant for some stent, balloon, and test combinations.

6.6.2.4 The initial displacement force is the initial force required to displace the stent with respect to the balloon. This is often difficult to distinguish from movement of the stent within but not out of its balloon imprint or movement of the intact stent and balloon with respect to, for example, the guide wire lumen and markerbands within the balloon. There may be operator variability in the assessment of the force at which initial displacement occurs. This endpoint is a conservative estimation of the force at which clinically significant negative outcomes may occur.

6.6.2.5 The initial peak displacement force is characterized as the first peak in force that occurs during or after stent displacement with respect to the balloon. A peak displacement force may often occur simultaneously with stent displacement and would therefore be equal to the initial displacement force. However, for some stent delivery systems, the stent may move a critical distance before a peak in force is reached. Therefore the initial peak displacement force is a conservative estimation of the dislodgment force.

6.6.2.6 The critical distance peak displacement force is the maximum force required to displace the stent with respect to the balloon a critical distance. This critical distance should be the minimum of the following two distances.

(1) The distance at which the undamaged stent could overhang the balloon body resulting in a clinically significant, incomplete deployment of the overhanging end of the stent, and

(2) The length (distance) of stent compression or buckling that could result in a clinically significant, incomplete deployment of the deformed stent against the vessel walls.

NOTE 3—The critical distance displacement force may often be equal to the initial displacement force. There may be operator variability in the assessment of the critical distance within which to determine the maximum force. Due to this operator dependence, there may be significant variance between operators.

NOTE 4—The clinical significance of incomplete deployment may depend on several factors, particularly time and the location at which the incomplete deployment occurs; for example, dislodgement during insertion into a coronary lesion is more critical than dislodgement on withdrawal through a hemostasis valve.

6.6.3 The peak dislodgment force is the maximum force required to completely dislodge the stent from the delivery system balloon. Clinically, if the stent is dislodged distally, this endpoint represents the stent embolizing in the vasculature. If the stent is dislodged proximally, the balloon can no longer be used to deploy the stent. The majority of reported securement problems are associated with stent dislodgement. Though peak dislodgment force is operator independent, it still may have significant variability, particularly for stent delivery systems with catch-points such as unfurled balloon cones or other raised profile components abutting the distal or proximal end, or both, of the stent. Since dislodgement occurs after displacement, the peak force is of secondary importance to the dislodgement distance prior to stent deployment and of primary importance if the stent/stent delivery system is being removed. Dislodgement force is a vital characteristic but is not a complete measure of securement.

7. Examples of Apparatus and Procedure

7.1 *Apparatus Example:*

7.1.1 *Pre-Test Treatment Tracking Fixture*—An example of the fixture is given in the engineering diagrams in Appendix X2, Figs. X2.1 and X2.2. Note that this model simulates a coronary vessel in a 2D plane with a moderately difficult degree of tortuousity but no simulated lesions.

7.1.2 *Securement Testing Machine*—A power-driven machine capable of the following:

7.1.2.1 Uniform crosshead speed (pull rate) within 5 % of set rate,

7.1.2.2 Measurement and recording of force exerted to a precision of 0.01 lbf, and

7.1.2.3 Measurement and recording of crosshead displacement to a precision of 0.01 in. or time measured to a precision of 0.1 s.

7.1.3 *Crosshead Catheter Clamp*—Wedge clamps or other clamps attached to the machine crosshead capable of holding the catheter beyond the securement endpoint without slipping.

7.1.4 *Fixed Shim Stent Grips*—An example of the fixed shim stent grips and associated tooling is given in engineering diagrams in Appendix X2, Figs. X2.5-X2.8.

7.1.5 *Water Bath*—Vessels used to immerse the tracking fixture and the securement test stent grips in 37 ± 2 °C water.

7.1.6 *Camera and Video Recorder*—Optional devices used during the securement testing to help determine the stent securement test endpoint.

7.2 *Test Specimens:*

7.2.1 To establish a sufficiently powered test, first determine the standard deviation. This can be established by running a trial to estimate the variation or by leveraging existing data. Further, calculate the required sample size with this standard deviation, the desired minimum detectable difference, minimum significance level, and minimum power level.

7.2.2 Unless otherwise justified, all samples selected for testing should be taken from finished, sterilized, clinical quality product. Cosmetic rejects or other non-clinical samples may be used for these tests if the cause for rejection is not related to securement.

7.2.3 Prepare the device in accordance with the Instructions for Use.

7.3 *Pre-Test Treatment Procedure:*

7.3.1 Set the tracking fixture, with the guide catheter and guide wire inserted, in the 37 °C water bath. Guide catheter and guide wire selection should be consistent with the devices used during medical procedures for the device tested.

7.3.2 Advance the delivery system through the guide catheter and the tracking fixture. Fully track the system into the

fixture in 2 to 8 s. Withdraw it at approximately the same rate. For a worst case in loosening the stent on the balloon, track the device three or more times.

7.3.3 Remove the system from the tracking fixture and store on a catheter rack at room temperature.

7.4 *Securement Test Procedure:*

7.4.1 Set up the shim stent grips within the water bath at a temperature of 37 ± 2 °C.

7.4.2 If used, set up the camera and video recorder to allow clear display of the stent/shim interface.

7.4.3 Set the crosshead extension speed (pull rate) at 2 in./min.

7.4.4 Insert a suitable guide wire or test mandrel into the catheter lumen so that it will extend at least from the catheter clamp point to the tip of the catheter.

7.4.5 Insert catheter through the open "V" of the shims and close the shims over the folded balloon at the proximal end of the stent.

7.4.6 Check shim size. Shims should be sized to allow the delivery system balloon to move freely while the stent remains blocked from moving through the shims. Remove and replace shims as necessary to obtain proper fit.

7.4.7 Secure crosshead catheter clamp at 1.0 ± 0.1 in. proximal to the proximal edge of the stent (1 in. gauge length).

7.4.8 Start video recorder, if used.

7.4.9 Start machine crosshead extension.

7.4.10 Monitor test to observe chosen test endpoint.

7.4.11 Record the securement endpoint(s), force, and mode (for example, stent slippage or buckling).

7.4.12 If the stent pulls through the shim ID, the peak force is a false representation of stent securement and should be recorded as invalid data. The stent delivery system should not be retested.

8. Test Report

NOTE 5—The following is a content recommendation for stent securement test reports. The documentation should be clear enough so that the study could be repeated.

8.1 *Test Report Identification:*

8.1.1 Report title; author, contributors, and their affiliations; name of organization presenting the results; date of publication; any additional document identifiers, such as a document number, as required by the organization or reviewing bodies.

8.1.2 Product(s) tested.

8.2 *Executive Summary:*

8.2.1 Summarize the nature and scope of the testing.

8.2.2 Summarize conclusions made as a result of the testing, especially claims pertaining to safety.

8.3 *Objective:*

8.3.1 Identify the types of specimens being tested:

8.3.1.1 Labeled stent length and diameter.

8.3.1.2 Monorail, over-the-wire, or other type of delivery system.

8.3.1.3 Devices with special characteristics or histories.

8.3.1.4 Actual or representative finished goods or special builds.

8.3.2 Identify the type(s) of testing being performed:

8.3.2.1 *Product Specification Testing*—Determine if the product performance meets the requirements of the product specification.

8.3.2.2 *Manufacturing Control Testing*—Determine if the performance of the product is within normal tolerance and if there is no significant trend towards being out of control.

8.3.2.3 *Other Types of Testing*—Predicate device comparison testing, design alternative testing, observational testing, test method development.

8.4 *Scope:*

8.4.1 Identify what the test will demonstrate:

8.4.1.1 Stent securement as a stand-alone characteristic;

8.4.1.2 The ability to retract the stent delivery system intact after stent securement is challenged;

8.4.1.3 The ability to deploy the stent after stent securement is challenged; and/or

8.4.1.4 Performance compared to historical data or against other stent delivery system designs, models, or sizes.

8.4.2 Test scenario:

8.4.2.1 Simulated use conditions.

8.4.2.2 Comparative bench testing which emphasizes repeatability and the ability to discriminate products and deemphasizes actual use conditions.

8.4.2.3 Challenge testing which combines two or more low-probability events/situations to create an unlikely condition in which it is likely the performance of the device will decrease.

8.4.3 Characteristics to be evaluated:

8.4.3.1 Stent securement performance.

8.4.3.2 Changes in stent geometry with tracking and/or securement testing.

8.4.3.3 Specific stent securement or safety mechanisms.

8.4.3.4 Conclusions to be made based on the results of the testing, especially accept/reject criteria.

8.5 *References/Supporting Documents:*

8.5.1 Test protocol (what is to be done), test method (how), test method development reports (how you know the test method is suitable and capable for intended purpose), and data sheets.

8.5.2 As required, reference equipment calibration and maintenance logs, and operator training records.

8.6 *Test Specimens/Materials/Traceability:*

8.6.1 Identification:

8.6.1.1 Stent—length, diameter, coatings or treatments.

8.6.1.2 Stent delivery system—if a balloon catheter, indication of balloon material characteristics (for example, compliant versus non-compliant); monorail, over-the-wire, combination device, or other; and the stent delivery system coatings or treatments.

8.6.1.3 Accessory devices used, for example, guide wires.

8.6.1.4 Traceability—provide sufficient information so that processing records can be found for the test specimens—as full assemblies, partial assemblies, the assembly processes, and sterilization/conditioning records, as appropriate.

8.6.2 Processing and conditioning of the stent, the delivery system, and the finished device.

8.6.2.1 Pilot line or production line manufacturing.