ASTM INTERNATIONAL

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

This standard is issued under the fixed designation F 2394; 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 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]

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 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]

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.)

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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.

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

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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 *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.

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

3.1.10 *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.

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

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

3.1.13 *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.

3.1.14 *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).

3.1.15 *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).

3.1.16 *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.

3.1.17 *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.

3.1.18 *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.

3.1.19 *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 selection of pre-test treatments, tests and test endpoints to measure stent securement (displacement and/or 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.

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.
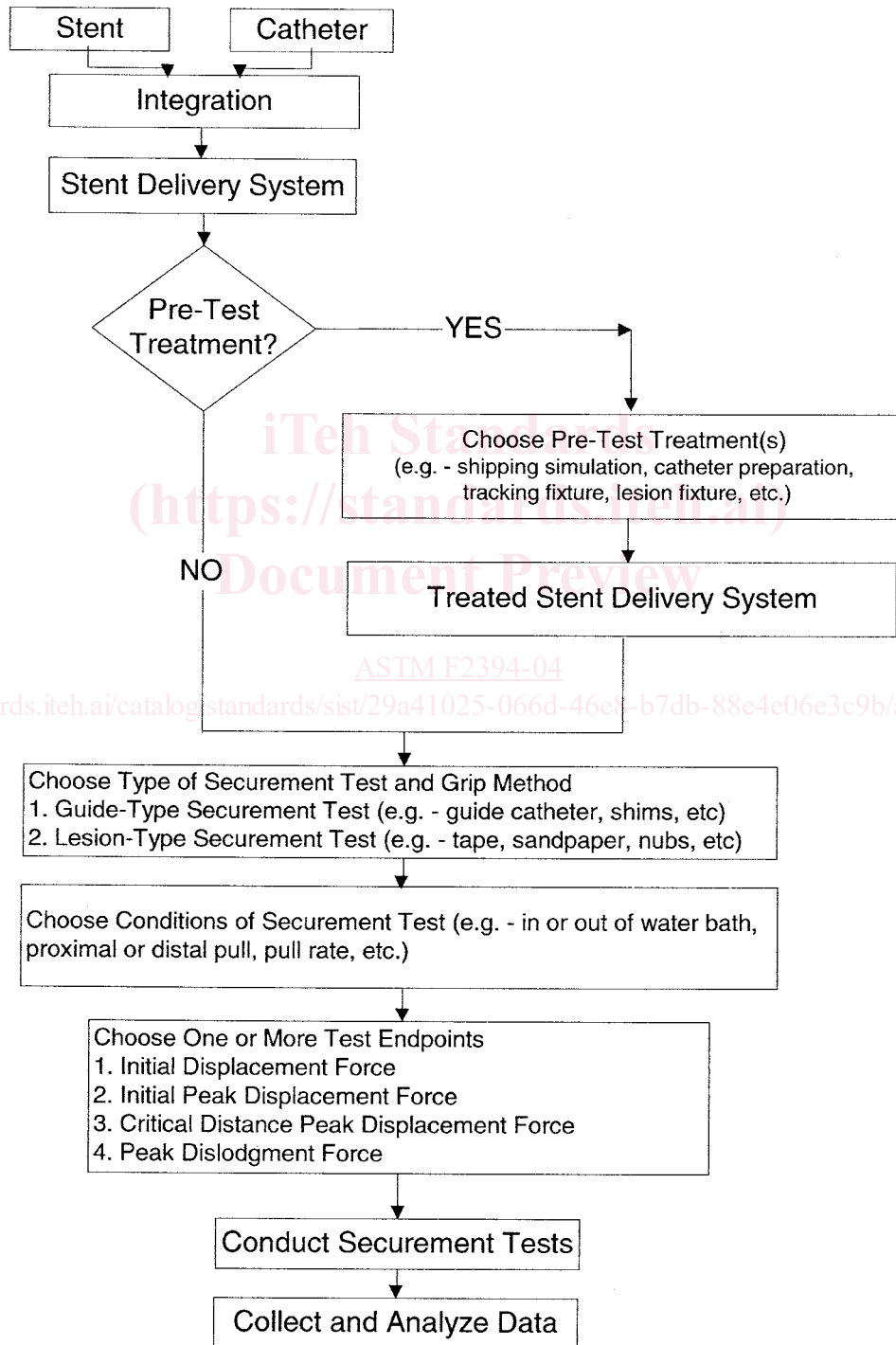
6.2 *Discussion*:

FIG. 1 Flowchart

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.

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, Guide E 1488 provides guidance.

6.2.4 This guide outlines the path from initial testing to final test method selection to provide assurance of stent securement characteristics.

6.2.5 The validation activities for a test method depend on the criticality and the complexity of the test method. That is, the more complex the test, the more work will be required to understand the method, sources of variation (test or specimen), and choose appropriate test parameters. The more critical the need for the test (that is, measured test characteristic that is merely annoying or potentially life-threatening), the more focused is the need for showing that the test method is relevant and predictive to the need for which it is intended.

6.2.6 Factors to consider in evaluating securement tests include the following. Physician surveys for clinical relevance. Mechanical and mathematical understanding of the clinical relevance and limitations as well as test reproducibility limitations of pre-test treatments, various grips, test methods and test conditions.

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, saline, blood) and temperature; guide catheter and guide wire selection; simulated vessel material, 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 mod-els. An example of a tracking treatment is given in Section 7. Two examples of tracking fixtures are given in engineering diagrams in the Appendix. Note that these engineering diagrams simulate vessels in 2-D with a moderately difficult degree of coronary tortuousity but do not include simulated lesions.

6.3.4 Tracking through lesion treatments are 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.

6.4 *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 the Appendix.

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 stents.

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 wires or test mandrel may place the stent delivery system under greater normal (and frictional) forces. However, it may also span and

round out curvature in a track model and reduce the bending forces delivered to the balloon and stent.

6.5.3 The gage length chosen may influence the pull rate transmitted to the stent. A shorter gage length will have less longitudinal material deformation and transmit a less variable pull rate closer to the set pull rate.

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 video taped 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 in./min.

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 proximal pull forces transmitted to the stent will exceed distal push forces. Also, the stent forces encountered clinically are seldom oriented purely proximally or distally. However, a securement test set up to pull without an angle will not impart a normal component of force on the stent with an uncertain increase in securement.

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 deployment of the stent to the vessel walls due to compression or buckling damage to the stent.

NOTE 2—There are three possible endpoints to measure displacement force: initial, critical distance peak, and initial peak. (See Fig. X2.1.)

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.

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. This endpoint may have high variability, particularly for stent delivery systems with catchpoints such as unfurled balloon cones or other raised profile components abutting the distal or proximal end, or both, of the stent.

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 the Appendix, Figs. X2.1 and X2.2. Note that this model simulates a coronary vessel in a 2-D plane with a moderately difficult degree of tortuosity 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 0.005 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 the Appendix, 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 $\pm$ 0.5°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 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.

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

7.2.3 If specimen preparation such as hand crimping is required prior to testing, this should be done 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 guidewire inserted, in a 37 ± 0.5°C water bath. Guide catheter and guidewire 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 ± 0.5°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. gage 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. Keywords

8.1 angioplasty; artery; dislodgment; displacement; medical device; retention; securement; stent; vascular

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 Beginning with an understanding of the clinical conditions which may lead to stent dislodgement or stent deformation, this guide describes a development process and many considerations in stent securement testing. The guide shows a method to develop one or more tests that are clinically relevant as well as repeatable and reliable. The guide asks the user to consider the many product life-history pre-test treatments of the test specimen that may affect the results. The guide also discusses some details of the test conditions and the detail of how to interpret numerical results from the test.

X2. ENGINEERING DIAGRAMS