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StandardTest Methods for *in vitro* Pulsatile Durability Testing of Vascular Stents[1]

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1. Scope

1.1 These test methods cover the determination of the durability of a vascular stent by exposing it to physiologically relevant diametric distension levels by means of hydrodynamic pulsatile loading. This testing occurs on a stent test specimen that has been deployed into a mock (elastically simulated) vessel. The typical duration of this test is 10 years of equivalent use (at 72 beats per minute), or at least 380 million cycles.

1.2 These test methods are applicable to balloon-expandable and self-expanding stents fabricated from metals and metal alloys. It does not specifically address any attributes unique to coated stents, polymeric stents, or biodegradable stents, although the application of this test method to those products is not precluded.

1.3 These test methods do not include recommendations for endovascular grafts ("stent-grafts") or other conduit products commonly used to treat aneurismal disease or peripheral vessel trauma or to provide vascular access, although some information included herein may be applicable to those devices.

1.4 These test methods are valid for determining stent failure due to typical cyclic blood vessel diametric distension. These test methods do not address other modes of failure such as dynamic bending, torsion, extension, crushing, or abrasion.

1.5 These test methods do not address test conditions for curved mock vessels.

1.6 These test methods do not address test conditions for overlapping stents.

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 limitations prior to use.*

1.8 *General Caveat—This document contains guidance for testing as is currently carried out in most laboratories. Other testing techniques may prove to be more effective and are encouraged. Whichever technique is used, it is incumbent upon the tester to justify the use of the particular technique, instrument, and protocol. This includes the choice of and proper calibration of all measuring devices. Deviations from any of the suggestions in this document may be appropriate but may require the same level of comprehensive justification that the techniques described herein will require.*

2. Referenced Documents

2.1 *Other Documents:*

ISO 7198: 1998(e), 8.10, Determination of Dynamic Compliance[2]

FDA Guidance Document 1545, Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, (issued January 13, 2005)[3]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *cardiac cycle, n*—defined as one cycle between diastolic and systolic pressures.

3.1.2 *compliance, n*—the change in inner diameter of a vessel due to cyclic pressure changes. Compliance, if calculated, shall be expressed as a percentage of the diameter change per 100 mm Hg and defined per ISO 7198, 8.10.5:

$$\%\text{Compliance/100 mm Hg} = \frac{(Dp2 - Dp1) \times 10^4}{(Dp1(p2 - p1))} \quad (1)$$

where:

$Dp1$ = inner diameter at the pressure of $p1$,
$Dp2$ = inner diameter at the pressure of $p2$,
$p1$ = lower pressure value (diastolic), in mm Hg, and
$p2$ = higher pressure value (systolic), in mm Hg.

3.1.3 *diametric strain, n*—a change in mock artery diameter divided by the initial diameter. This term does not relate to the mechanical strain seen in the stent material. The diametric strain can be identified as:

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

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

$$\text{diametric strain} = \frac{(Dp2 - Dp1)}{Dp1} \quad (2)$$

that is,

$$\text{diametric strain} = \frac{(\text{maxID} - \text{minID})}{\text{minID}}$$

3.1.4 *distension, n*—the change in diameters; such as the inner diameter (ID) of a vessel due to a pressure change. The term "diametric distension" is meant to represent the change in inner diameter of a blood vessel during each pulse of blood circulation. As an example, the change in diameter between the diastolic and systolic pressure for each pulse of blood circulation.

3.1.5 *hydrodynamic loading, n*—causing a change in the inner diameter (ID) of a mock vessel by injecting a volume of fluid into the confined test volume.

3.1.6 *mock vessel, n*—a simulated vessel typically manufactured from an elastomeric material. The mock vessel is made to approximate the ID and diametric distention of a native vessel at physiological pressures (see A1.2.2 and A2.4.2) or at non-physiological pressures (see A2.4.4).

3.1.7 *native vessel, n*—defined as a natural healthy blood vessel.

3.1.8 *strain control, n*—a term to describe control of diametric distention, relative to an initial diameter of the mock vessel, not to be confused with controlling the strain in the stent material.

3.1.9 *vascular stent, n*—a synthetic tubular structure that is implanted in the native or grafted vasculature and is intended to provide mechanical radial support to enhance vessel patency over the intended design life of the device. A stent is metallic and not covered by synthetic textile or tissue graft material.

4. Summary of Test Methods

4.1 These test methods cover fatigue/durability testing of vascular stents that are subjected to hydrodynamic loading that simulates the loading and/or change in diameter that the stent will experience *in vivo*. The stent shall be deployed into mock vessels that can be used to produce a cyclic diameter change of the stent. This document details two test methods that are currently used.

4.1.1 *Physiological Pressure Test Method*—This test method (provided in Annex A1) requires the use of mock vessels that possess similar diametric compliance properties to native vessels at physiological pressure and rate of pulsation as well as at higher testing frequencies.

4.1.2 *Diameter Control Test Method*—(Sometimes called a strain control test method.) This test method (provided in Annex A2) requires the use of a diameter measurement system and mock vessels to ensure that the desired minimum and maximum stent diameters, or the equivalent change in stent diameter and mean stent diameter, are being achieved at the test frequency. For conditions where a direct measurement of the stent is not possible, measurements are typically made over the OD of the mock vessel and a relationship is determined and justified for the ratio of the stent OD versus measured mock vessel OD.

5. Specimen Size, Configuration, and Preparation

5.1 Unless otherwise justified, all samples selected for testing shall be taken from fully processed, implant quality product. Sterilization should be required unless it can be shown not to influence the fatigue/durability test results.

5.2 The number of specimens tested for each stent geometry should be sufficient to support any claims to be made based on the test results. Fatigue/durability shall be evaluated for the worst case labeled diameter, and a rationale shall be provided stating why the particular labeled diameter is considered worst case.

5.3 *Mock Vessels:*

5.3.1 The choice of inside diameter of the mock vessel is critically important to the effectiveness of any durability test to be carried out. The mean non-stented mock vessel ID over a cardiac cycle shall be consistent with the worst case stent OD, for the stent being tested, over the full test duration.

5.3.2 See Annex A1 and Annex A2 for specific requirements.

5.4 The sample size, in combination with other tests, animal and clinical tests, analysis (such as FEA (Finite Element Analysis), and/or comparisons to predicate devices shall be sufficient to enable demonstration of an adequate justified reliability. In these test methods, one stent shall be considered one sample. The reliability justification may reference additional testing and/or analysis used to establish stent durability.

6. General Apparatus Requirements

6.1 For test methods requiring precision measurement and control of pressure, dimensions, or cycle counts, verification of the dynamic performance of these systems shall be performed and documented with justification of the means used.

6.2 *Pressure Measurement System*—Pressure transducers should be chosen that allow for the accurate evaluation of the pressures within the tubes at the frequency of the test. See Annex A1 and Annex A2 for method specific requirements. The pressure measuring system must be calibrated and justified.

6.3 *Dimensional Measurement Devices,* such as linear variable displacement transducers, lasers, and high-speed cameras must be calibrated and justified.

6.4 *Cycle Counting System*—The apparatus shall include a cycle counting system for measuring the number of load cycles applied to the stent/mock artery combination.

6.5 *Temperature Control System*—The apparatus shall include a calibrated temperature control and measurement system to provide the testing temperature for stents being tested.

7. General Test Parameters

7.1 *Temperature*—The temperature shall be 37 ± 2°C. If other temperatures are to be used, a rationale shall be provided stating why the particular temperature is considered worst case or equivalent. The unit is to be stable over the intended period of the test and maintained within the established parameters.

7.2 Actual temperatures and precisions shall be documented by the user with accompanying justifications.

7.3 *Solutions*—The test solution shall be phosphate buffered saline (PBS) or equivalent unless testing in a different environment (such as in distilled water or in air) can be justified. Rationale for use of a different environment shall be provided.

7.4 *Physiological Pressure*—The pressure change in the intended blood vessel. A suggested range for coronary stent pulsatile fatigue evaluation is 80 to 160 mm Hg.

NOTE 1—Selection of the systolic and diastolic pressures should be based on the patient population for which the stent is indicated.

7.5 *Physiological Pulse Rate*—For the purposes of these test methods, determined to be 1.2 Hz or 72 beats per minute.

7.6 Biological growth can inhibit post-test evaluation of the stent surface characteristics. Use of a biological growth inhibitor (such as algaecides or chemical agents) may be used unless such use would negatively impact the test by unintended degradation of the stent or the test set-up.

7.7 The ID of the non-stented mock vessel is to be empirically verified on the test instrument after the mock vessel(s) have been mounted in their initial test position.

7.8 *Vessel Degradation*—Mock vessels made of materials that may degrade with exposure to environmental factors (such as UV light) shall be protected from such exposure.

7.9 *Stent Deployment*—The stent shall be deployed in the mock vessel in such a manner as to minimize end effects where the vessel is connected to the test article and at a sufficient distance from other stents that may be deployed in the same vessel (see X2.5).

7.10 *Test Frequency*—See Annex A1 and Annex A2 for test specific details.

7.11 *Test Validation*—The investigator shall demonstrate that the stent to be tested maintains contact with the ID of the vessel to be used in the durability test throughout the cycle, when evaluated with the same pressures and frequencies to be used in the durability test. This is not required for every sample. This and any justifications shall be documented in the test report. Rationale: The functionality of a test method used to test a stent inside a vessel depends on the stent remaining in contact with the ID of the vessel throughout the distension cycle of that vessel.

7.12 *Acceptance Criteria*—A detailed test protocol shall be written that describes all procedures unique to the stent being evaluated. This protocol shall include any specific failure modes to be identified, and inspections to be performed to identify those failures in any acceptance/rejection criteria. (See Appendix for examples.)

8. Test Report

8.1 The test report shall include a complete summary of the materials, methods, and results including any rationale for deviations from this procedure. The effects of any such deviations on the significance of the test results shall be reported. All real, artifact, and anomalous observations shall be reported, including a justification for considering negative findings as artifacts or discounting their clinical significance.

8.2 Test reports should include:

8.2.1 Test parameters and acceptance criteria:

8.2.1.1 Test parameters (such as):

(1) Mock vessel dimensions.

(2) Fluid temperature.

(3) Fluid pressure range and variability, or desired change in stented vessel diameter.

8.2.1.2 Acceptance criteria (such as):

(1) Minimum level of pulsatile distention to define acceptance.

(2) Maximum number of failures to define acceptance.

(3) Minimum number of cycles required to define acceptance.

8.2.2 Test specimen information:

8.2.2.1 Number of test specimens.

8.2.2.2 Size (diameter, length, or other relevant dimensions) of all test specimens.

8.2.2.3 Rationale for the number of test specimens and sizes used.

8.2.2.4 Whether the specimens are representative of the finished product.

8.2.2.5 Sterilization parameters and number of sterilization cycles applied to the test specimens.

8.2.2.6 Traceability information.

8.2.3 Materials used:

8.2.3.1 Test equipment.

8.2.3.2 Mock vessels.

8.2.3.3 Test fluid/solutions.

8.2.3.4 Measurement devices.

8.2.4 Test protocol, including all justifications and rationales required by these test methods.

8.2.5 Protocol deviations.

8.2.6 Raw data.

8.2.7 Test results.

8.2.8 Data analysis

8.2.9 Fracture reporting:

8.2.9.1 Report any fractures that occur during the test.

8.2.9.2 Fracture information should include number of cycles to failure, number and locations of all fractures along the length of the stent, type of fracture such as transverse or spiral, with or without dislocation, and any root cause analysis performed to determine the reason for the fracture.

8.2.10 Conclusions.

9. Precision and Bias

9.1 Intralaboratory and interlaboratory reproducibility has not been systematically determined.

10. Keywords

10.1 durability test; endovascular cardiology; fatigue test; interventional cardiology; intravascular device test; pressure control; pulsatile fatigue; stent durability; stent fatigue; stent test; strain control; vascular stent

ANNEXES

(Mandatory Information)

A1. PHYSIOLOGICAL PRESSURE TEST METHOD FOR PULSATILE FATIGUE/DURABILITY TESTING OF VASCULAR STENTS

A1.1 Summary of Test Method

A1.1.1 With this technique, a fixed volume of fluid is injected into a fluid filled mock vessel that has been manufactured to provide a targeted physiological compliance. The injected volume is adjusted so that the measured cyclic pressure range is equivalent to targeted physiological pressures. The primary measurements made with this apparatus are the cyclic pressure, test frequency, cycle count, and temperature. (See general test parameters.)

A1.2 Significance and Use

A1.2.1 This test method is to determine the durability of a stent under pulsatile vascular conditions, to assess conformance to product specifications and guidance documents, and to support regulatory submissions, quality control, and manufacturing.

A1.2.2 The success of this test method depends on the use of a vessel that possesses physiologically relevant ID and diametric compliance at physiologically relevant frequencies as well as at higher testing frequencies.

A1.3 Apparatus

A1.3.1 *Loading*—Specimen is deployed into a mock vessel that is then mounted onto a fatigue/durability testing system that can deliver quantifiable pressures to the vessel.

A1.3.2 In this test method, a replication of the loading conditions that occur *in vivo* requires the choice of a vessel that has the ID and diametric compliance properties possessed by the target vessel. Once a stent is deployed into a native or mock vessel with these properties, a cyclic pressurization of that vessel will cause the vessel to expand. At the same time, the amount of compressive loading that the vessel is applying to the stent is reduced in proportion to the increase in internal pressure. This repeated pressurization is the mechanism by which the stents are cyclically loaded. It is important that pressure be regularly monitored throughout the testing. In order to account for viscoelastic behavior of the mock vessel, the compliance of the mock vessel is evaluated at 72 beats per minute, and at the testing frequency that is to be utilized for the durability testing. The maximum test frequency may be limited by the dynamic response of the vessel.

A1.4 Procedure

A1.4.1 Determine the ID and dynamic (1.2 Hz) compliance of the physiological mock vessel over the desired pressure range (80 to 160 mm Hg unless otherwise justified) at the frequency of test to be used as outlined in ISO 7198 (load-controlled testing). The mean ID shall be determined as well as the compliance. The mean ID is determined to ensure conformity with 5.3.1. If multiple vessels are used, ensure that the mock vessels are mounted under uniform tension. Rationale: The mock vessel ID may be reduced and the radial compliance may be increased if the mock vessel were to be mounted under tension on the test instrument (see 7.5).

A1.4.2 Deploy the stent in the mock vessel following instructions for use. Leave enough length of the mock vessel extending beyond each end of the test article such that the test article will be in the region where the required compliance is valid, unaffected by any end effects imposed by the fatigue/durability test system (see 7.7). Re-measure dynamic (1.2 Hz) compliance using mounting tension similar to that used for the non-stented dynamic compliance measurements. Verify that this composite (stent and vessel) compliance is maintained at the desired test frequency.

A1.4.3 Inspect the deployed stents in a systematic and objective manner, using appropriate instruments or techniques, and record the location and severity of any anomalies. Document the inspection locations for correlation to post test inspection (see A1.6.2).

A1.4.4 Install each mock vessel/stent assembly onto the fatigue/durability test system using tensioning similar to that used for the dynamic compliance measurements and fill the system with the test solution. Purge trapped air from the system. Activate the temperature control system and allow the test system to equilibrate at 37 ± 2°C (unless otherwise justified).

A1.4.5 Start the fatigue/durability test system and adjust the frequency to the desired rate and adjust the cyclic pressure range to justified physiological levels (80 to 160 mm Hg should be used unless otherwise justified). Determine the maximum test frequency that provides mock vessel distension uniformity comparable to that measured at the physiological rate (72 bpm or 1.2 Hz). Document non-uniformities in vessel distension at test frequency and provide rationale for acceptable use at that frequency.

A1.4.6 Zero the counter.

A1.4.7 Verify the pressures at justifiable time intervals.

A1.4.8 If desired, carry out periodic inspections of the instrument and stent. If the stent is removed from the mock vessel for inspection, care must be taken to remove and re-deploy it in a manner that does not destroy the integrity of the test. Periodic inspection, or lack of inspection, shall be at the discretion of the stent manufacturer and justified in the report.

A1.4.9 Periodically re-measure the dynamic compliance of the deployed stent/vessel systems in addition to the mock vessel mean ID at the test frequency. This may be important as it checks for any change in loading or experimental properties that might be occurring. Determine if the change is due to a

change in the test article or the mock vessel. If the change is in the mock vessel, re-deploy the stent to a new mock vessel and continue the test. If it is determined that the change in compliance is due to a change in the test article itself, continue the test without changing the mock vessel. Provide justification for measurements and any mock vessel changes.

A1.5 Test Termination

A1.5.1 Continue to test until the required number of cycles (at least 380 million cycles for a 10 year test) has been applied to each stent.

A1.6 Post Test Inspection

A1.6.1 Re-measure the dynamic compliance and the mean inner diameter of the deployed stent/vessel systems at the test frequency when the test is complete.

A1.6.2 Inspect all stents as required in the protocol.

A2. DIAMETER CONTROL TEST METHOD FOR PULSATILE FATIGUE/DURABILITY TESTING OF VASCULAR STENTS

A2.1 Summary of Test Method

A2.1.1 The purpose of this test method is to reproduce the desired minimum and maximum diameters, or equivalent change in diameter at a mean, that the stent would see *in vivo*. To reproduce these diameters, a volume of testing fluid is injected into a fluid filled mock vessel that may or may not have a compliance that is physiologically relevant. Thick walled (thicker than physiological tubing walls) mock vessels are commonly used in order to achieve the desired higher frequency levels. The injected volume is adjusted so that the minimum diameter and maximum diameter of the stent is equivalent to the minimum and maximum diameters that the stent would experience under physiological conditions. The desired primary measurements made with this test method are the OD (outer diameter) of the stent, test frequency, cycle count and temperature, if necessary. If direct measurement of the OD of the stent is not possible, an empirical method may be used to relate the deployed stent OD with mock vessel inner diameter (ID). Several methods for determining the relationship of the OD of the stented mock vessel to the ID are provided in X2.5. The relationship between the OD and ID of the mock vessel used for this purpose shall be justified.

A2.2 Significance and Use

A2.2.1 This test method is to determine the durability of a stent under pulsatile vascular conditions, to assess conformance to product specifications and guidance documents, and to support regulatory submissions, quality control, and manufacturing.

A2.2.2 The success of this test method depends upon the use of a diameter measurement system that ensures that the desired minimum and maximum diameters, or equivalently, the desired mean diameter and change in diameter, of the stents are being achieved at all testing frequencies.

A2.3 Apparatus

A2.3.1 *Diameter Measurement System*—The apparatus should include a diameter measuring system that measures the resulting cyclic change in diameter of the stents within the mock vessel. If direct measurement of the OD of the stent is not possible, an empirical method may be used to relate the deployed stent outer diameter (OD) with the measured mock vessel outer diameter (OD). This measurement may be made by measuring the outer diameter (OD) of the mock vessel and calculating the outer diameter (OD) of the stent using a relationship and method similar to those found in Appendix X1, or other justified relationship(s) and method(s).

A2.4 Procedure

A2.4.1 Determine the minimum and maximum diameter to simulate the physiologic loading conditions. This can be done using one of two methods:

A2.4.2 *Method 1—Determination of Desired Minimum and Maximum Diameters Using a Physiological (Thin Walled) Mock Vessel:*

A2.4.2.1 Create a mock vessel with physiological compliance behavior. The (thin walled) mock vessel shall be engineered to simulate the dynamic (1.2 Hz) compliance and appropriate ID, at physiologic pressures (unless otherwise justified) for the stent size (see X1.1).

A2.4.2.2 Measure the ID and the OD of the mock vessel statically to establish the basis for determining the mock vessel ID from OD measurements.

A2.4.2.3 Install the mock vessel onto the fatigue/durability test system. If multiple vessels are used, ensure that the mock vessels are mounted under uniform tension. Rationale: The mock vessel ID may be reduced and the compliance may be increased if the mock vessel were to be mounted under excess tension on the test system (see 7.5).

A2.4.2.4 Fill the fatigue/durability test system with the test solution. Purge trapped air from the system. Activate the temperature control system and allow the test system to equilibrate at the required test temperature, if appropriate.

A2.4.2.5 Run the test system at 1.2 Hz and adjust the pressure and bellows displacement to achieve the expected mean pressure plus/minus half the expected pressure differential for the intended use location (such as, 120 ± 40 mm Hg; that is, 80 to 160 mm Hg) (see X1.1). Determine and record the maximum and minimum ID of the mock vessel by direct measurement, or by using an appropriate equation (see X2.2

for example equations) for maximum and minimum OD measurements of the mock vessel.

A2.4.2.6 Deploy the stent into the mock vessel following instructions for use. Leave enough length of the mock vessel extending beyond each end of the test article unaffected by any end effects imposed by the fatigue/durability test system (see 7.7).

A2.4.2.7 Run the test system at 1.2 Hz and adjust the pressure and bellows displacement to achieve the expected mean pressure plus/minus half the expected pressure differential for the intended use location (such as, 120 ± 40 mm Hg; that is, 80 to 160 mm Hg) (see X1.1). Determine and record the maximum and minimum OD of the stent by direct measurement, or by using an appropriate equation (see X2.2 for example equations).

A2.4.3 *Method 2—Determine Desired Radial Distension Based on FEA:*

A2.4.3.1 Determine the predicted minimum and the maximum diameter of the stent using Finite Element Analysis techniques to determine loading and boundary conditions that the stent will experience.

A2.4.3.2 Determine the native vessel compliance based on clinical data or literature (see X1.1).

A2.4.3.3 Using the compliances determine the minimum and the maximum diameters the combined stent/vessel will experience.

A2.4.4 *Test Procedure:*

A2.4.4.1 Use thick walled mock vessels that have sufficient wall thickness to enable the minimum and maximum stent diameters to be reproduced at higher than physiological frequencies using pressure levels that may differ from physiological levels. The ID and OD of each thick walled mock vessel must be characterized if mock vessel ID is to be calculated based on OD measurements.

A2.4.4.2 Install the thick wall mock vessels onto the fatigue/durability test system. If multiple vessels are used, ensure that the mock vessels are mounted under uniform tension. Rationale: The mock vessel ID may be reduced and the compliance may be increased if the mock vessel were to be mounted under tension on the test instrument.

A2.4.4.3 Fill the fatigue/durability test system with the test solution. Purge all trapped air from the system. Activate the temperature control system and allow the test system to equilibrate at the required test temperature.

A2.4.4.4 It is recommended to re-measure the mock vessel OD at the locations where the stents will be deployed and document (aka: mapping the tubes).

A2.4.4.5 Deploy stents into the mock vessels following instructions for use. Leave enough length of the mock vessel extending beyond each end of the test article unaffected by any end effects imposed by the fatigue/durability test system (see X2.5, Stent Deployment).

A2.4.4.6 Inspect the deployed stents, in a systematic and objective manner, using appropriate instruments or techniques and record the location and severity of any anomalies. Document the inspection locations for correlation to post test inspection (see A2.6.1).

A2.4.4.7 Record proximal and distal locations of each installed stent in the mock vessel prior to beginning the test.

A2.4.4.8 Start the fatigue/durability test instrument and adjust the frequency to the desired rate. Adjust the volumetric displacement of the instrument so that the desired minimum diameter and maximum diameter of the stented vessel is achieved (at the same locations along the stent as determined in the experimental, or FEA method).

A2.4.4.9 Zero the counter.

A2.4.4.10 Periodically monitor the minimum and maximum OD of the mock artery over each stent (at the same longitudinal positions used previously) at justifiable intervals. Document the diameters as well as the location of the stent in the mock vessel. Adjust the system as necessary to maintain the desired diametric boundary conditions (desired minimum and maximum stent OD).

A2.4.4.11 If desired, carry out periodic inspections of the instrument and stents. If the stent is removed from the mock vessel for inspection, care must be taken to remove and replace it in a manner that does not destroy the integrity of the test. Periodic inspection or lack of inspection shall be at the discretion of the stent manufacturer and justified in the report.

A2.5 Test Termination

A2.5.1 Continue to test until the required number of cycles (at least 380 million cycles for a 10 year test) has been applied to each stent.

A2.6 Post Test Inspection

A2.6.1 Inspect all stents as required in the protocol.