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Standard Guide for Testing Absorbable Stents[1]

This standard is issued under the fixed designation F3036; 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 covers select physical and mechanical characterizations of vascular stents with one or more absorbable components. Such absorbable stents (also referred to as vascular scaffolds) are used to provide temporary luminal support of the coronary and peripheral vasculature following interventional revascularization procedures. This Guide covers devices that are fabricated from one or more degradable polymers and/or metals (from this point on referred to as "absorbable"). This Guide provides a framework for evaluating the change in select physical and mechanical characteristics of absorbable stents from manufacture through their intended degradation *in vivo*. Specific testing recommendations are limited to existing ASTM standards for stent evaluation.

1.2 Recommendations specific to non-absorbable stents with absorbable coatings are not within scope.

1.3 Recommendations specific to testing absorbable stent grafts are not provided here, however this standard has many elements applicable to testing absorbable stent grafts.

1.4 Clinical need dictates that absorbable stents initially possess the same general dimensions and mechanical function as their non-absorbable counterparts. Thus, utilization of already established mechanical stent evaluation methods is possible when absorbable test specimens are previously conditioned under physiologically relevant temperature and humidity. As a result, this standard addresses absorbable-specific testing issues related to the mechanical and physical evaluation of these devices. This standard is limited to providing absorbable-specific testing recommendations for evaluations where an ASTM method for durable (i.e., non-absorbable) stents is already available. Specifically, this standard provides testing recommendations for adapting the elastic recoil (ASTM F2079), securement/dislodgement (ASTM F2394), and three-point bending (ASTM F2606) tests to fully absorbable devices. This guide generally describes specimen conditioning, as appropriate, for absorbable devices, which can range from none to extensive – depending on the measured attribute and relevant clinical exposure conditions, including time in the in-use environment. There are additional stent evaluation methods that are not addressed explicitly in this guide, e.g., chronic durability, that may require absorbable-specific provisions. The user should justify the appropriate testing for the specific polymer and device.

1.4.1 While the primary purpose of this guide is to address absorbable stent-related issues specific to the tests described in Section 1.3, additional testing (e.g., radial strength) will likely also be needed. Thus, aspects of what is presented herein may be applicable to additional relevant device attributes, such as those described in ISO 25539-1 and/or 25539-2.

1.5 This Guide may not be appropriate for all absorbable devices, for example those that possess limited hydrolytic or corrosion susceptibility and degrade *in vivo* primarily through enzymatic action. The user is cautioned to consider the appropriateness of the standard in view of the particular absorbable device and its potential application.

1.6 This Guide does not address the methods necessary to characterize the chemical degradation of the absorbable stent (e.g., changes in mass, molecular weight, or degradants). However, this type of characterization does represent an important component of the degradation profile and mechanism of the device. These characterizations are addressed in ASTM F1635.

1.7 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.8 *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.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D618 Practice for Conditioning Plastics for Testing

E6 Terminology Relating to Methods of Mechanical Testing

[1] This test method 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.

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process
E1823 Terminology Relating to Fatigue and Fracture Testing
F1635 Test Method for *in vitro* Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants
F2079 Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents
F2394 Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System
F2477 Test Methods for *in vitro* Pulsatile Durability Testing of Vascular Stents
F2606 Guide for Three-Point Bending of Balloon Expandable Vascular Stents and Stent Systems
F2914 Guide for Identification of Shelf-life Test Attributes for Endovascular Devices

2.2 *Other Standards:*[3]
ISO 14630 Non-Active Surgical Implants—General Requirements
ISO 25539-1 Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses
ISO 25539-2 Cardiovascular implants—Endovascular devices—Part 2: Vascular stents
ISO 10993-1 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process
ISO 10993-9 Biological evaluation of medical devices—Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-13 Biological evaluation of medical devices—Part 13: Identification and quantification of degradation products from polymeric medical device
ISO 10993-15 Biological evaluation of medical devices—Part 15: Identification and quantification of degradation products from metals and alloys

3. Terminology

3.1 *Definitions:*

3.1.1 Unless otherwise defined in this standard, the terminology related to mechanical testing that is used in these test methods will be in accordance with the definitions of Terminologies ASTM E6 and ASTM E1823, and the respective standards described in the annexes of this document.

3.1.2 *absorbable, adj*—in the body, referring to an initially distinct foreign material or substance that either directly or through intended degradation can be excreted, metabolized or assimilated by cells and/or tissue.

3.1.3 *stent, vascular, n*—a structure implanted in the native or grafted vasculature that is intended to provide mechanical radial support to enhance vessel patency.

3.1.4 *conditioning, v*—preparation of the device prior to mechanical testing to include elements that *(1)* affect the attribute to be tested, and *(2)* are imposed on device per clinical and/or degradation timeline up to points of interest for the attribute.

4. Significance and Use

4.1 Absorbable cardiovascular stents provide temporary support to the vasculature and are intended to degrade and absorb over time after being implanted into the vasculature.

4.2 The test methods used to evaluate the mechanical performance of absorbable devices are similar to those used to evaluate permanent (non-absorbable) cardiovascular devices. The absorbable-specific pre-test conditioning requirements, handling requirements before and during the test, and time-dependent mechanical property evaluations for absorbable devices are addressed here.

4.3 As the absorbable implant degrades, the mechanical performance of the device also deteriorates. The key to achieving effective revascularization with absorbable devices is to provide an adequate level of luminal support for the time frame needed for vessel stabilization.

5. Materials and Manufacture

5.1 The manufacturer should ensure that materials used to manufacture absorbable implants are suitable for implanting into the body. General requirements regarding a material's suitability for use as an implant are described in ISO 14630. Methods and guidance for assessment of biocompatibility can be found in ISO 10993. There may be additional issues related to the biocompatibility of absorbable materials that are not covered in ISO 10993.

6. General Requirements and Performance Considerations

6.1 *Absorbable Stents*—The following considerations may be important when determining the suitability of a stent for a particular application. However, the test methods referenced as in the Annexes may not be appropriate for all types of implant applications. The user is cautioned to consider the appropriateness of the test methods in view of the devices being tested and their potential application.

6.1.1 *Performance Considerations:*

6.1.1.1 To better characterize the degradation and degradation products of the absorbable stent, significant effort should be undertaken toward developing an *in vitro* model for the anticipated *in vivo* degradation mechanism (e.g., corrosion, hydrolysis, etc.). Such a model would reflect the implant's composition and any related interaction(s) with the physiologically relevant aqueous solution, including – as appropriate – consideration of the influence of additives (e.g., antimicrobials), temperature, ionic composition and strength, pH, and fluid flow conditions. This *in vitro* model might also be used to assess subsequent changes to the absorbable stent in lieu of animal experimentation.

6.1.1.2 Composition/chemical properties in the finished, sterilized state and during degradation.

6.1.1.3 Mechanical behavior of the finished, sterilized device and during degradation. Mechanical evaluation should be completed for relevant device attributes including, but not

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

limited to bending (e.g., bending stiffness). Additional mechanical characteristics may need to be evaluated to determine the degree of vascular support and resistance to non-radial vessel deformation.

6.1.1.4 While chronic durability should be assessed for absorbable stents, this Guide does not specify methods to perform this characterization. The user should justify the appropriate durability testing for the specific absorbable stent, including structural integrity and the potential for device embolization.

6.1.2 *Aging and Shelf Life Requirements:*

6.1.2.1 The user should establish the labeled shelf-life of the absorbable device through appropriate real-time studies according to ASTM F2914. A justification for attributes covered in this guide not addressed as part of real-time studies should be provided. Accelerated testing may be performed with appropriate justification.

7. General Sampling, Conditioning, and Testing Considerations

7.1 *Apparatus, Equipment, and Materials*—The test equipment should be maintained to the necessary precision and accuracy, as appropriate for the specific device and functional output being tested.

7.1.1 *Specimen Container*—A glass or plastic container capable of holding the test specimen and the conditioning solution should be used. The container should be sealable to prevent solution loss due to evaporation, as appropriate. Multiple specimens may be stored in the same container, provided *(1)* suitable specimen separation is maintained to allow fluid access to each specimen surface *(2)* specimen-to-specimen contact is precluded, and *(3)* the environment is identical.

7.1.2 *Conditioning/Soaking Solution:*

7.1.2.1 For absorbable stents manufactured from hydrolytically degradable polymers, a physiologically relevant aqueous solution should be used. (For more detail see ASTM F1635 and References contained in Section X1.2)

7.1.2.2 For absorbable stents fabricated from degradable (corrodible) metals, a physiologically relevant aqueous solution with appropriate pH, buffer capacity, isotonicity, and ion concentration should be used (e.g., artificial plasma: ISO 10993-15). The user is cautioned that the ions present in the soaking solution (and in blood) may carry potential to chemically react with the released metallic ions.

7.1.2.3 If accelerated degradation is desired, changes in temperature, pH, or composition of solution may be used with appropriate justification.

7.1.3 *Constant Temperature Bath or Oven:*

7.1.3.1 An aqueous bath or oven capable of maintaining the specimens at a physiologic temperature (37 ± 2°C) for the specified testing periods should be used.

7.1.3.2 The fluid environment should be well-mixed during conditioning and mechanical testing.

7.1.4 *pH Meter:*

7.1.4.1 A pH metering device with appropriate accuracy and precision in the physiological range (pH 6 to pH 8) should be used.

7.2 *Specimen Acquisition & Evaluation Frequency:*

7.2.1 *Sampling*—If appropriate, representative random specimens should be taken from multiple batches/lots in accordance with Practice E122.

7.2.2 *Evaluation Frequency*—For a complete history of the behavior of a specimen during degradation and absorption, functional attributes of the device should be evaluated at appropriate time points determined by resolution required to confidently characterize the decline in mechanical properties of the device and the time frame over which the attribute are relevant.

7.2.2.1 Evaluation time points should be both clinically relevant and reflective of the expected changes resulting from exposure to the physiologically relevant aqueous solution (e.g., degradation).

7.2.2.2 The testing intervals should be documented in the test report.

7.3 *Conditioning*—All devices subjected to conditioning should be completely fabricated, and finished absorbable stents or stent systems should be sterilized as intended by the manufacturer. This section provides guidance for characterization of the performance of the stent over time, with sufficient resolution to adequately characterize the attribute.

7.3.1 Fig. 1 presents a timeline for the sterilized, finished, absorbable device in different environments and conditions; however, the durations of each phase will vary depending on the device material and design.

7.3.1.1 The conditioning performed prior to evaluation of a specific attribute should include all relevant exposures up to the final time point for the attribute (see 7.3.2). Relevant exposures may include humidity, flow, radial and non-radial cyclic deformation, all of which need to be conducted under relevant thermal conditions.

7.3.1.2 It may be necessary to measure additional functional attributes of the device as dictated by the indications for use and/or failure mode.

7.3.2 Upon introduction to the physiologically relevant aqueous solution, polymeric absorbable materials will uptake fluid prior to hydrolysis, which may affect some attributes. For example, stent radial strength may increase with fluid uptake prior to a significant change in molecular weight. The user should consider characterizing these dynamic attributes upon deployment of the device and during hydration, prior to a significant decline in molecular weight. Such attributes should also be monitored at multiple time points throughout degradation in order to characterize their change over time.

7.3.2.1 If the time frame for fluid uptake is very short, it may not be possible to measure some device functional attributes after stable hydration and before onset of degradation. In these instances, evaluation of device functional attributes at deployment as well as interim points at multiple time points during degradation may be adequate.

7.3.2.2 The time required for the specimen to reach a stable temperature and/or hydration state may extend longer than the time frame for a particular attribute to become clinically relevant. For example, stent securement is only relevant from insertion through deployment (or through withdrawal if assessing withdrawal repositioning, or aborted stenting). Similarly;

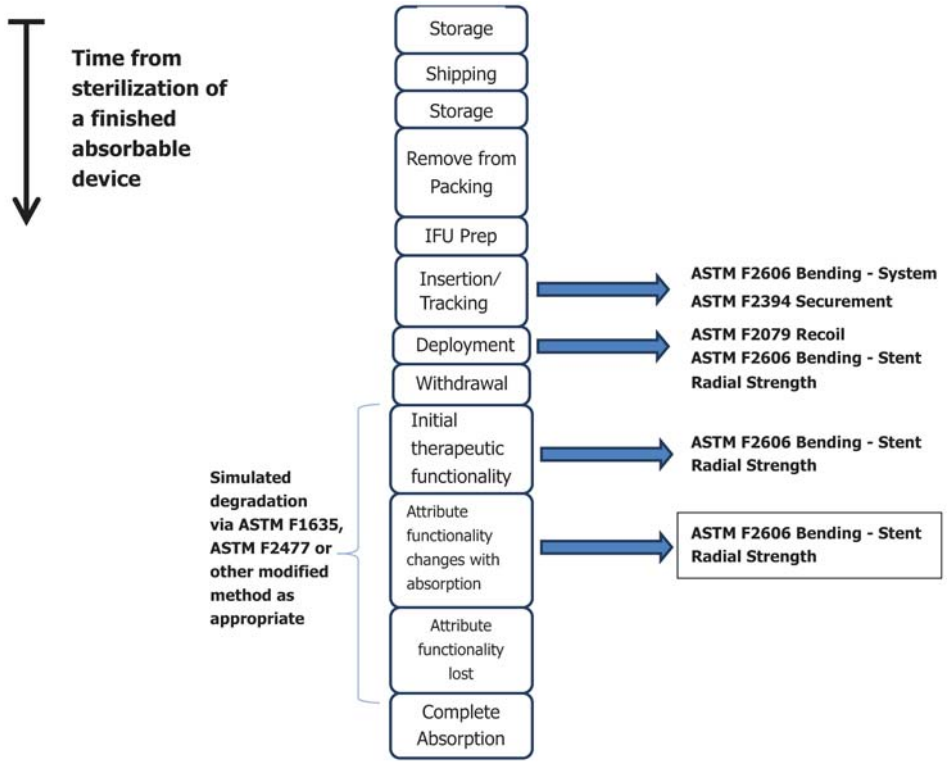

FIG. 1 Timeline representing the environments and degradation conditions to which sterilized, finished, absorbable devices are exposed throughout the device life; and the relevant time points at which example functional attributes may be evaluated. Additional time points of interest for a specific attribute may exist. Refer to Sections 7.3.2 through 7.3.3.5 for additional detail.

stent system bending is relevant from insertion through deployment. Also, recoil and radial strength become relevant upon stent deployment. In such instances, appropriate clinically relevant conditioning may not allow for the stent to reach a stable temperature and/or hydration state.

7.3.2.3 Degradable (corrodible) metals typically do not uptake fluid and therefore, evaluation of device attributes after hydration, prior to degradation, may not be relevant.

7.3.3 Relevant functional attributes of the device related to its therapeutic intent should be evaluated at multiple time points during degradation to evaluate the kinetics of their decline at various stages of chemical breakdown.

7.3.3.1 A generalized *in vitro* degradation test method for absorbable devices in the absence of mechanical loading or accelerated conditions can be found in ASTM F1635.

7.3.3.2 The specific time points chosen throughout degradation will vary for the device material, design, and potentially, the device's intended use.

7.3.3.3 An elevated solution temperature or change in solution composition enabling an accelerated degradation rate may be used with appropriate justification.

7.3.3.4 If the device is intended for use in a loaded physiological condition, it is important to consider characterizing the influence of static and/or fatigue loads during degradation on the mechanical properties of the test specimen. Applied load types and magnitudes that are representative of anticipated physiological conditions should be used or an alternative should be justified. For example, if the user is only considering radial loads, ASTM F2477 (Test Method for Radial Pulsatile Fatigue of Stents) may be adapted to allow for degradation monitoring.

7.3.3.5 If accelerated loading is applied, the degradation should be synchronized to the accelerated loading rate.

7.4 *Specimen Testing:*

7.4.1 *Care and Handling*—Care, handling, and positioning of the absorbable device specimen should be conducted in accordance with its Instructions for Use where available and appropriate.

7.4.2 *Testing while Specimen is Immersed*—A reasonable approximation of *in vivo* environmental conditions is to test specimens while fully immersed in a physiologically relevant aqueous solution at 37 ± 2°C.

7.4.3 *Timing*—Mechanical testing is to occur within an appropriate time after relevant conditioning, as determined by the dehydration behavior of the material being tested and the sensitivity of the attribute to temperature and hydration state. Once retrieved, excess conditioning medium may be removed and the specimen should then be promptly positioned in accordance with the specific test method.

7.4.4 *Ambient Testing*—Depending on the specimen and test method, testing while the specimen is immersed as described in Section 7.4.2 may be impractical to implement. In these cases, the device may be removed from the conditioning environment prior to testing. Any damage induced by removal of the specimen from the conditioning environment (e.g., removal

from a mock vessel) should be identified and assessed for the potential to impact the attribute under measurement. It is also recommended that the relationship between functional outputs in the tested hydration and temperature states and clinically relevant state be assessed. Testing of dried or drying specimens should be undertaken with caution due to the potential to affect the functional attributes and/or variability of the attribute under measurement.

7.4.5 *Reporting Requirements*—The selected specimen conditioning and testing parameters should be included in the report (see X1.4).

8. Keywords

8.1 absorbable; bend testing; conditioning; degradable; elastic recoil; fatigue; radial loading; securement; stent; stent graft; vascular scaffold

ANNEXES

(Mandatory Information)

A1. INTRODUCTION TO ANNEXES

A1.1 The provided annexes list specific provisions or variations to test methods that may be relevant to evaluation of absorbable cardiovascular stents. Recommendations specific to testing absorbable stent grafts are not addressed here, however these annexes have many elements applicable to testing stent grafts. Each listed annex is specific to a particular standard and provides a section-by-section listing of needed variations or new provisions necessary to properly evaluate an absorbable balloon-expandable stent or stent system. The provisions listed herein are specific to the testing of absorbables and carry precedent over language within the referenced standard.

A2. F2606-08 STANDARD GUIDE FOR THREE-POINT BENDING OF BALLOON-EXPANDABLE VASCULAR STENTS AND STENT SYSTEMS

A2.1 Scope

A2.1.1 There are no absorbable specific provisions.

A2.2 Terminology

A2.2.1 Unless stated otherwise, terms should be defined as presented within Section 3 of this absorbable cardiovascular standard.

A2.3 Significance and Use

A2.3.1 There are no absorbable specific provisions or variations.

A2.4 Summary of Guide

A2.4.1 Three-point bending evaluation of absorbable stent specimens is undertaken while completely immersed in a physiologically relevant aqueous-based solution or other appropriate medium maintained at 37 ± 2°C. As described in Section 7.3, the conditioning performed prior to evaluation of a three-point bending of the delivery system should include all relevant exposures from insertion through deployment, and three-point testing of the stent should include additional exposure as appropriate.

A2.4.2 Evaluation of absorbable stent systems (e.g., catheter mounted) may be performed in standardized room temperature conditions as described in Section 7.3, if the temperature and hydration are not expected to affect the test article, or the relationship between temperature, hydration and three-point bending performance is known.

A2.5 Apparatus

A2.5.1 *Test specimen*—The test specimen should be completely fabricated, and finished absorbable stents or stent systems should be sterilized as intended by the manufacturer.

A2.5.2 Evaluation of the bending properties of deployed (i.e., unmounted) absorbable stent specimens should occur while completely immersed in a fluid medium maintained at 37 ± 2°C. Therefore, the testing apparatus should include a fluid containment component or bath and fluid heating and recirculating instrumentation. If recirculation is not required (e.g., the fluid volume is low and the heating surface is large), then a justification may be provided. Details regarding appropriate physiologically relevant fluids are provided in Section 7.3.

A2.6 Test Specimens

A2.6.1 There are no absorbable specific provisions or variations.

A2.7 Procedure

A2.7.1 When testing while the specimen is immersed:

A2.7.1.1 Assure that the solution temperature at the point of testing complies with test requirements.

A2.7.1.2 Assure the test specimens are completely immersed in the solution throughout the test and compensate for potential buoyancy factors as appropriate.

A2.7.1.3 It may be necessary to ensure that the specimens have attained a stable temperature and/or hydration state, where applicable to the device material before testing.

A2.7.1.4 The rate of loading should be appropriate to the material being tested.

A2.8 Calculation and Interpretation of Data

A2.8.1 There are no absorbable specific provisions or variations.

A2.9 Report

A2.9.1 Attention is directed to adhere closely to the reporting provision contained in ASTM F2606 Section 9.1.9, regarding thermal sensitivity, and Section 9.1.10, regarding sensitivity to hydration. Reporting should include details regarding any specimen conditioning and the specific composition of the physiologically relevant immersion solution.

A2.9.2 Additional damage: Indicate if any damage to the test specimen occurred during the test (for example, strut fracture).

A3. F2079-09 STANDARD TEST METHOD FOR MEASURING INTRINSIC ELASTIC RECOIL OF BALLOON-EXPANDABLE STENTS

A3.1 Scope

A3.1.1 It is not the intention of this Annex or test method to define levels of performance, in that insufficient information is available to predict the consequences of any particular design.

A3.1.2 This Annex is intended for balloon-expandable absorbable stents.

A3.2 Terminology

A3.2.1 Unless stated otherwise, terms should be defined as presented within Section 3 of this absorbable stent standard.

A3.3 Significance and Use

A3.3.1 There are no absorbable specific provisions or variations.

A3.4 Summary of Test Method

A3.4.1 As stated in ASTM F2079, this test method provides recommendations for measuring the stent diameter while it is still mounted on the balloon and following deflation of the balloon such that it is no longer in contact with the stent. In addition, the diameter measurements should be acquired using non-contact methods. The absorbable stent should be fully immersed in a physiologically relevant aqueous solution maintained at 37 ± 2°C during expansion and subsequent deflation of the balloon and measurement of intrinsic elastic recoil.

A3.5 Apparatus

A3.5.1 Expansion of the absorbable stent specimen and subsequent deflation of the delivery balloon should be undertaken while completely immersed in a physiologically relevant aqueous solution maintained at 37 ± 2°C. Therefore, a fluid bath as well as a fluid heating and recirculation instrument are necessary. Details regarding appropriate physiologically relevant fluids are provided in Section 7.1. Additional specimen conditioning guidance may be found in Appendix X1.

A3.5.2 If possible, the calibrated optical system used for measuring diameter of the stent should allow for the stent to be fully immersed in physiologically relevant fluid at 37 ± 2°C. If this bath cannot be integrated with the optical system, the stent and its delivery system may be removed from the bath and immediately measured for its diameter.

A3.6 Sampling, Test Specimens, and Test Units

A3.6.1 *Test specimen*—The test specimen should be completely fabricated, and finished absorbable stents or stent systems should be sterilized as intended by the manufacturer.

A3.7 Procedure

A3.7.1 It may be necessary to expose the device to an appropriate medium such that temperature and/or hydration levels are clinically relevant before testing (see Section 7.3).

A3.7.2 When deploying the stent and deflating the balloon, assure the test specimens are completely immersed in the solution throughout the time period necessary to perform the deployment and deflation.

A3.7.3 When deploying the stent and deflating the balloon while the specimen is immersed, assure that the solution temperature at the point of testing complies with test requirements.

A3.7.4 Because recoil properties may exhibit some time dependency, the recoil measurements may be acquired on immersed stents immediately following balloon deployment and/or at some time point after deployment, but before significant degradation, consistent with the Instructions for Use and/or clinical practice, to ensure that the diameter has stabilized. The time points at which the stent diameter is measured with the balloon in the inflated and deflated states should be specified and justified.

A3.8 Calculation

A3.8.1 There are no absorbable stent specific provisions or variations.

A3.9 Report

A3.9.1 Attention is directed to adhere to the reporting provision contained in ASTM F2079 Section 9.1.8, regarding

temperature. Reporting should include details regarding specimen immersion, any conditioning, and the specific composition of the physiologically relevant immersion solution.

A3.10 Precision and Bias

A3.10.1 There are no absorbable stent specific provisions or variations.

A3.11 Keywords

A3.11.1 There are no absorbable stent specific provisions or variations.

A4. F2394-07 STANDARD GUIDE FOR MEASURING SECUREMENT OF BALLOON-EXPANDABLE VASCULAR STENT MOUNTED ON DELIVERY SYSTEM

A4.1 Scope

A4.1.1 There are no absorbable specific provisions or variations. It is not the intention of this Annex or test method to define levels of performance, in that insufficient information is available to predict the consequences of any particular design.

A4.1.2 This Annex is intended for balloon-expandable absorbable stents. This Annex does not provide for assessing securement of self-expanding stents.

A4.2 Terminology

A4.2.1 Unless stated otherwise, terms should be defined as presented within Section 3 of this absorbable stent standard.

A4.3 Significance and Use

A4.3.1 There are no absorbable specific provisions or variations.

A4.4 Clinical Scenarios

A4.4.1 There are no absorbable specific provisions or variations.

A4.5 Test Method Considerations

A4.5.1 *Test specimen*—The test specimen should be completely fabricated, and finished absorbable stents or stent systems should be sterilized as intended by the manufacturer.

A4.6 Apparatus and Procedure

A4.6.1 Relevant environmental conditions for evaluating securement of absorbable stents include dry conditions at room temperature or fully immersed conditions at physiologic temperature. These conditions will provide securement estimates of the device in its as manufactured state and a state relevant to its use *in vivo*.

A4.6.2 When testing while the specimen is immersed, assure the test specimens are completely immersed in the solution throughout the test.

A4.6.3 When testing while the specimen is immersed, assure that the solution temperature at the point of testing complies with test requirements.

A4.6.4 For testing while the specimen is immersed, the device may require a pre-soak period that corresponds to the expected clinical delivery time in order to ensure that the device remains secure under relevant hydration and temperature levels.

A4.6.5 Solution media used should be physiologically relevant and consistent with Section 7.1 of this absorbable standard.

A4.7 Test Report

A4.7.1 Attention is directed to adhere to the reporting provision contained in ASTM F2079 Section 9.1.8, regarding temperature. Reporting should include details regarding specimen immersion, any conditioning, and the specific composition of the physiologically relevant immersion solution.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 With the development of absorbable polymers, metals, and composites for use in implantable devices, there is a need to define standard testing methods that aid in characterizing material and mechanical properties with time in a simulated physiological environment. This specification is intended to provide useful and consistent information related to the terminology, performance, and application of test methods for absorbable devices.

X1.2 The described phosphate buffered saline (PBS) soaking solution is taken directly from Test Method F1635, Section X1.6. The addition of sodium azide at a concentration of 0.1 % is common. Other anti-microbials that are commonly used include penicillin (100 U/mL), streptomycin (100 µg/mL), and amphotericin (0.25 to 2.5 µg/mL). As noted previously, these materials may be hazardous, and all persons using them should review the material safety data sheet (MSDS) before handling and use all recommended safety precautions.

X1.3 The Committee recommends that, where practical, testing be performed on specimens that are immersed in a physiologically relevant aqueous solution at 37 ± 2 °C. Alternatively, testing can be performed on devices or device attributes not sensitive to temperature under wet conditions at room temperature (23°C). However, the user is cautioned that temperature changes and moisture evaporation (even under normal room temperature conditions) can impart significant changes in physical properties. Thus, in order to avoid erratic and/or erroneous results, the temperature and moisture content of the specimen should remain in a range over which the attribute remains stable throughout testing. The temperature and hydration test conditions should be reported.

X1.4 *Nomenclature*—Synthetic implants fabricated from hydrolysable alpha-hydroxy polyesters have been described as "absorbable" since the first polyglycolide-based sutures were commercialized in the United States in the 1970s. At that time, both poly(glycolide) (DEXON – Davis and Geck) and poly(glycolide-co-lactide) copolymer (VICRYL – Ethicon) based sutures were classified as "Absorbable Surgical Suture" by the United States Pharmacopeia (USP) and the United States Food and Drug Administration (US-FDA), a designation that remains to this day. In contrast with "Nonabsorbable Surgical Suture," synthetic glycolide-lactide and collagen-based sutures undergo hydrolytic- and/or enzymatic-driven chain scission, generating byproducts that are then *absorbed* by the body. Since designation, other terms such as "degradable" and "resorbable" have been used interchangeably to describe absorbable implants, with the prefix "bio-" often applied to all these terms. Based on historical usage and regulatory precedent, this document preferentially utilizes the term absorb/absorbable/absorption to describe implantable synthetic hydrolysable polymers and devices. The prefix "bio" is avoided since it is redundant in the context of implant applications. "Resorb" and its derivatives are avoided since they are accepted medical terms routinely utilized to describe natural resorption processes present in dynamic tissue, such as osteoclastic-driven bone remodeling. "Degrade" and its various derivatives are avoided when referring to either an implantable device or a raw material since common utilization is routinely applied broadly to include composting and other natural processes (including ultra-violet radiation) that cause materials to either intentionally or unintentionally break down into chemical and/or particulate matter. However, use of the term "degrade" and its derivatives is considered acceptable when referring to chain scission within the implantable device or polymer (e.g., "The absorbable implant degrades through hydrolysis," or, "During extrusion, absorbable polyglycolide is prone to thermal degradation.").

REFERENCES

(1) Agrawal, C. M., Athanasiou, K. A., Technique to control pH in vicinity of biodegrading PLA-PGA implants, *J Biomed Mater Res*., 1997 Summer; 38(2):105-14.