Designation: F3036 – 21

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. The annexes in this standard provide absorbable-specific testing recommendations for evaluations where an ASTM test method for durable (that is, non-absorbable) stents is already available. Specifically, this standard provides testing recommendations for adapting the elastic recoil (F2079), dimensional attributes (F2081), securement/dislodgement (F2394), pulsatile durability (F2477), FEA of stents (F2514), three-point bending (F2606), coating/acute particulate characterization (F2743), shelf life (F2914), axial bend torsional rigidity (F2942), radial loading (F3067), design verification sampling (F3172), fatigue to fracture (F3211), and fixation durability (F3374) 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. Additional stent evaluation methods that are not addressed explicitly in this guide may require absorbable-specific provisions. The user should justify the appropriate testing for the specific absorbable material 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 1.4, additional testing (for example, 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 (for example, 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 Test Method F1635, ISO 13781, or Guide F3268, as appropriate.

1.7 The provided supplemental information is to be considered as specific to absorbable constructs and applies only to the respective referenced cardiovascular-oriented ASTM documents.

1.8 Additional (especially non-mechanical) device attributes that are not addressed in this document or through the current cardiovascular-oriented ASTM standards may also be relevant to appropriate evaluation of absorbable stent constructs. See ISO/TS 17137 for additional guidance on such cardiovascular-specific absorbable device considerations.

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.30 on Cardiovascular Standards.

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

1.10 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.11 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E6 Terminology Relating to Methods of Mechanical Testing

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

F2081 Guide for Characterization and Presentation of the Dimensional Attributes of Vascular 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

F2514 Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading

F2606 Guide for Three-Point Bending of Balloon-Expandable Vascular Stents and Stent Systems

F2743 Guide for Coating Inspection and Acute Particulate Characterization of Coated Drug-Eluting Vascular Stent Systems

F2902 Guide for Assessment of Absorbable Polymeric Implants

F2914 Guide for Identification of Shelf-life Test Attributes for Endovascular Devices

F2942 Guide for ***in vitro*** Axial, Bending, and Torsional Durability Testing of Vascular Stents

F3067 Guide for Radial Loading of Balloon-Expandable and Self-Expanding Vascular Stents

F3172 Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices

F3211 Guide for Fatigue-to-Fracture (FtF) Methodology for Cardiovascular Medical Devices

F3268 Guide for ***in vitro*** Degradation Testing of Absorbable Metals

F3374 Guide for Active Fixation Durability of Endovascular Prostheses

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

ISO 13781 Implants for surgery—Homopolymers, copolymers and blends on poly(lactide)—In vitro degradation testing

ISO/TS 17137 Cardiovascular implants and extracorporeal systems—Cardiovascular absorbable implants

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 E6 and 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 *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.

3.1.4 *stent, vascular, n*—a 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 not covered by synthetic textile or tissue graft material.

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

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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

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 (for example, 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 (for example, anti-microbials), 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 (for example, 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 pre-conditioning (for example, aging to labeled shelf life) and 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 Guide F2914. Appropriate storage conditions (for example, refrigerated, room temperature, relative humidity) need to be defined and then modeled at the most challenging limit of the acceptable labeled range. 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. Additional guidance regarding product shelf life considerations can be found in Guide F2902 and in ISO/TS 17137, which also contains guidance regarding accelerated aging.

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 Test Method F1635 and X1.2.

7.1.2.2 For absorbable stents fabricated from degradable (via corrosion) metals, a physiologically relevant aqueous solution with appropriate pH, buffer capacity, isotonicity, and ion concentration should be used; for more detail see Guide F3268.

7.1.2.3 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. pH should be controlled to ±0.2. If it is not possible to hold this pH range, the impact of the wider pH range on the degradation of the test sample shall be understood and indicated in the final report.

7.1.2.4 A buffer should be considered as critical for pH control, but can be undertaken at reduced levels with more stringent or continuous pH monitoring and compensation.

7.1.2.5 Non-phosphate buffers may be necessary with the selected buffer likely different for absorbable polymeric and metallic test specimens, where the utilized buffer will be degradation mechanism dependent.

7.1.2.6 Limited excursions outside of the specified pH range are tolerable provided the time-weighted average (TWA) pH after buffer replenishment is maintained within this range (see TWA discussion and related appendix within Test Method F1635).

7.1.2.7 Use of microbicide should be undertaken only after consideration of potential for impact on device degradation.

7.1.2.8 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 °C, with appropriate tolerances per Test Method F1635, ISO 13781, or Guide F3268, as appropriate) for the specified testing periods should be used. If the range in the referenced standard is not achievable in a particular experimental setup, the temperature shall be maintained within the minimum practical limits to maintain experimental consistency and reproducibility. Such a universally recognized *in vivo* temperature is considered to broadly represent the physiological condition and thereby provide the most broadly applicable scientific value. However, testing at other temperatures may also be included to determine differences in reaction mechanisms and rates. An additional alternate evaluation temperature may be especially useful if the temperature at the intended implant application and/or the temperature in a particular animal model differs significantly from 37 °C. Thus, the effect of the actually achieved temperature ranges outside those provided in the referenced standard on the degradation of the test sample shall be understood and indicated in the final report.

7.1.3.2 The fluid environment should be well mixed during conditioning and mechanical testing. It is critical for pH to be controlled during device degradation. If needed, the fluid environment can be replaced during mechanical testing to address the impact of degradation products.

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 and 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 attributes 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 (for example, 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

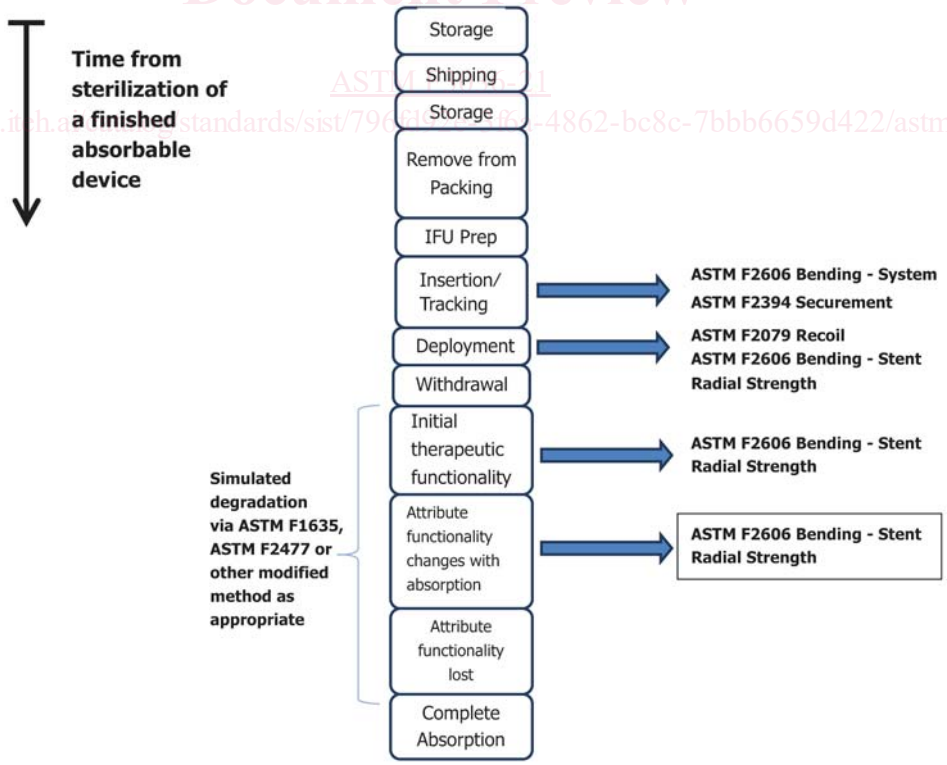

FIG. 1 Timeline representing the environments and degradation conditions to which sterilized, finished, absorbable devices are exposed throughout the device life, and the relevant time points at which example functional attributes may be evaluated. Additional time points of interest for a specific attribute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

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.

NOTE 1—Localized changes are common when evaluating absorbable stents, especially where stress is concentrated. However, this aspect and how it may affect mechanical attribute characterization upon degradation is not directly addressed. For example, radial strength addresses the therapeutic aspect from the perspective of the whole device but is not sensitive to localized changes. High-resolution imaging of any morphological changes or localized changes in surface area of degradation may address this to some extent.

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, 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 (via corrosion) 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 Test Method F1635, ISO 13781, or Guide F3268, as appropriate.

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, Test Methods F2477 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 °C, with tolerances per Test Method F1635, ISO 13781, or Guide F3268, as appropriate. If it is not possible for the apparatus to hold this temperature range, the impact of the actually achieved temperature range on the degradation of the test sample shall be understood and indicated in the final report.

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 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 (for example, 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*—A description of the selected specimen conditioning and testing parameters should be

included as separate sections within the report for the respective attribute's test method.

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 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 (2021) STANDARD GUIDE FOR THREE-POINT BENDING OF BALLOON-EXPANDABLE VASCULAR STENTS AND STENT SYSTEMS

A2.1 Unless stated otherwise, terms should be defined as presented within Section 3 of this absorbable cardiovascular standard. The test specimen should be completely fabricated, and finished absorbable stents or stent systems should be sterilized as intended by the manufacturer. The relevant sampling, conditioning, and testing considerations shall consider the information presented within Section 7. Additional specimen conditioning guidance may be found in Appendix X1. It may be necessary to ensure that the test specimen has attained a stable temperature and/or hydration state, where applicable to the device material, before testing. The rate of loading should be appropriate to the material being tested. If the test specimen is immersed a justification may be provided if recirculation is not required.

A2.2 Attention is directed to adhere closely to the reporting provision contained in Guide F2606 subsection 9.1.9 regarding thermal sensitivity, and subsection 9.1.10 regarding sensitivity to hydration. Reporting should also include details regarding any specimen conditioning and the specific composition of the physiologically relevant immersion solution. Note test results at different degradation time points and any additional damage to the test specimen (for example, strut fracture).

A3. F2079–09 (2017) STANDARD TEST METHOD FOR MEASURING INTRINSIC ELASTIC RECOIL OF BALLOON-EXPANDABLE STENTS

A3.1 Unless stated otherwise, terms should be defined as presented within Section 3 of this absorbable cardiovascular standard. The balloon-expandable test specimen should be completely fabricated, and finished absorbable stents or stent systems should be sterilized as intended by the manufacturer. The relevant sampling, conditioning, and testing considerations shall consider the information presented within Section 7. Additional specimen conditioning guidance may be found in Appendix X1. It may be necessary to ensure that the test specimen has attained a stable temperature and/or hydration state, where applicable to the device material, before testing.

A3.2 The absorbable stent should be fully immersed in a physiologically relevant aqueous solution during expansion and subsequent deflation of the balloon and measurement of intrinsic elastic recoil. If possible, the calibrated optical system

used for measuring diameter of the stent should allow for the stent to be fully immersed during measuring. 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. If the test specimen is immersed a justification may be provided if recirculation is not required. 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.

A3.3 Attention is directed to adhere to the reporting provision contained in Test Method F2079 subsection 9.1.8 regarding temperature, including range. Reporting should also include details regarding specimen immersion, any conditioning, and the specific composition of the physiologically relevant immersion solution.

A4. F2081–06 (2017) STANDARD GUIDE FOR CHARACTERIZATION AND PRESENTATION OF THE DIMENSIONAL ATTRIBUTES OF VASCULAR STENTS

A4.1 Unless stated otherwise, terms should be defined as presented within Section 3 of this absorbable cardiovascular standard. The test specimen should be completely fabricated, and finished absorbable stents or stent systems and should be sterilized as intended by the manufacturer. The relevant sampling, conditioning, and testing considerations shall consider the information presented within Section 7. Additional specimen conditioning guidance may be found in Appendix X1. It may be necessary to ensure that the test specimen has attained a stable temperature and/or hydration state, where applicable to the device material, before testing. If the test specimen is immersed, a justification may be provided if recirculation is not required.

A4.2 Consideration should be given to potential changes in stent dimensional attributes post implantation (for example, swelling due to hydration) but prior to significant degradation. Clinically significant changes in inner diameter and/or stent length shall be characterized and understood.

A4.3 The absorbable stent should be prepared and deployed unconstrained per IFU in a physiologically relevant aqueous solution. Dimensional measurements should be taken post deployment and at subsequent time points, (for example, 24 h), until dimensional stability is reached (<10 % change from previous measurement).

A4.4 It is recommended to determine the limit of expansion prior to strut fracture. While immersed in a physiologically relevant aqueous solution, the stent should be expanded with increasing balloon sizes until strut fracture is observed. The internal diameter at fracture may be estimated from the balloon inflation pressure compliance chart.

NOTE A4.1—As an alternative to conducting the expansion test while immersed in a physiologically relevant aqueous solution, the device can be preconditioned (tracking through a torturous path model without withdrawal of the delivery system and dilation to RBP) prior to the test, simulating the mechanical loading and effect of the solution during implantation of the device. The stent expanded to RBP can then immediately be tested in air (still soaked and wet), if an actual measurement of the diameter at fracture is conducted, instead of an estimation based on pressure compliance charts.

A5. F2394–07 (2017) STANDARD GUIDE FOR MEASURING SECUREMENT OF BALLOON-EXPANDABLE VASCULAR STENT MOUNTED ON DELIVERY SYSTEM

A5.1 Unless stated otherwise, terms should be defined as presented within Section 3 of this absorbable cardiovascular standard. The balloon-expandable test specimen should be completely fabricated, and finished absorbable stents or stent systems should be sterilized as intended by the manufacturer. The relevant sampling, conditioning, and testing considerations shall consider the information presented within Section 7. Additional specimen conditioning guidance may be found in Appendix X1. It may be necessary to ensure that the test specimen has attained a stable temperature and/or hydration state, where applicable to the device material, before testing.