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Standard Guide for Assessment of Absorbable Polymeric Implants[1]

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1. Scope

1.1 This guide describes general guidelines for the chemical, physical, mechanical, biocompatibility, and preclinical assessments of implantable synthetic polymeric absorbable devices. This guide also describes evaluation methods that are potentially useful and should be considered when assessing absorbable implants or implant components.

1.2 The described evaluations may assist a manufacturer in establishing the safety and effectiveness of an absorbable implant device. This listing of assessment methods may also be utilized to assist in establishing substantial equivalence to an existing commercially marketed device. However, these polymeric material-oriented guidelines do not necessarily reflect the total needs for any particular implant application (for example, orthopedic, cardiovascular), which may require additional and potentially essential application-specific evaluations.

1.3 This guide is intended to cover all forms of absorbable polymeric components and devices, including solid (for example, injection-molded) and porous (for example, fibrous) forms. This guide is also intended to cover devices fabricated from amorphous and/or semi-crystalline absorbable polymer systems.

1.4 This guide has been generated with principal emphasis on the evaluation of devices formed from synthetic polymers that degrade *in vivo* primarily through hydrolysis (for example, α-hydroxy-polyesters). Evaluation methods suggested herein may or may not be applicable to implants formed from materials that, upon implantation, are substantially degraded through other mechanisms (for example, enzymatically induced degradation).

1.5 This guide references and generally describes various means to assess absorbable materials, components, and devices. The user needs to refer to specific test methods for additional details. Additionally, some of the recommended test methods may require modification to address the properties of a particular device, construct, or application.

1.6 Adherence to all aspects of these guidelines is not mandatory, in that assessments and tests listed within this guide are not necessarily relevant for all absorbable implant systems and applications.

1.7 Absorbable polymers used as a matrix to control the *in vivo* release of bioactive agents (drugs, antimicrobials, and so forth) may be evaluated according to many of the methods described herein. However, additional test methods not covered by this guide will likely be needed to evaluate a bioactive agent's composition, loading, release kinetics, safety, and efficacy.

1.8 Composites of absorbable polymers with ceramics and/or metals may be evaluated according to many of the methods described herein. However, additional test methods not covered by this guide will likely be needed to evaluate the composite's other component(s).

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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D570 Test Method for Water Absorption of Plastics
D638 Test Method for Tensile Properties of Plastics
D695 Test Method for Compressive Properties of Rigid Plastics
D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement
D1042 Test Method for Linear Dimensional Changes of Plastics Caused by Exposure to Heat and Moisture

[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 F04.11 on Polymeric Materials.

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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.

D2990 Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics
D2991 Test Method for Stress-Relaxation of Plastics (Withdrawn 1990)[3]
D3079 Test Method for Water Vapor Transmission of Flexible Heat-Sealed Packages for Dry Products
D3418 Test Method for Transition Temperatures and Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry
D4404 Test Method for Determination of Pore Volume and Pore Volume Distribution of Soil and Rock by Mercury Intrusion Porosimetry
D5296 Test Method for Molecular Weight Averages and Molecular Weight Distribution of Polystyrene by High Performance Size-Exclusion Chromatography
E96/E96M Test Methods for Water Vapor Transmission of Materials
E128 Test Method for Maximum Pore Diameter and Permeability of Rigid Porous Filters for Laboratory Use
E398 Test Method for Water Vapor Transmission Rate of Sheet Materials Using Dynamic Relative Humidity Measurement
E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System
E793 Test Method for Enthalpies of Fusion and Crystallization by Differential Scanning Calorimetry
E794 Test Method for Melting And Crystallization Temperatures By Thermal Analysis
E1356 Test Method for Assignment of the Glass Transition Temperatures by Differential Scanning Calorimetry
E1441 Guide for Computed Tomography (CT) Imaging
E1570 Practice for Computed Tomographic (CT) Examination
E2207 Practice for Strain-Controlled Axial-Torsional Fatigue Testing with Thin-Walled Tubular Specimens
F99 Guide for Writing a Specification for Flexible Barrier Rollstock Materials
F316 Test Methods for Pore Size Characteristics of Membrane Filters by Bubble Point and Mean Flow Pore Test
F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
F1249 Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor
F1635 Test Method for *in vitro* Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants
F1925 Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants
F1980 Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
F1983 Practice for Assessment of Selected Tissue Effects of Absorbable Biomaterials for Implant Applications
F2097 Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products
F2210 Guide for Processing Cells, Tissues, and Organs for Use in Tissue Engineered Medical Products (Withdrawn 2015)[3]
F2313 Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide
F2450 Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue-Engineered Medical Products
F2477 Test Methods for *in vitro* Pulsatile Durability Testing of Vascular Stents
F2502 Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants
F2559 Guide for Writing a Specification for Sterilizable Peel Pouches
F2579 Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants
F2791 Guide for Assessment of Surface Texture of Non-Porous Biomaterials in Two Dimensions

2.2 *ISO Standards:*[4]
ISO 10993 Biological Evaluation of Medical Devices
ISO 11135 Sterilization of Health Care Products—Ethylene Oxide
ISO 11137 Sterilization of Health Care Products—Radiation
ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes
ISO 13781 Poly(L-lactide) Resins and Fabricated Forms for Surgical Implants—In Vitro Degradation Testing
ISO 15814 Implants for Surgery—Copolymers and Blends Based on Polylactide—In Vitro Degradation Testing
ISO/TS 12417 Cardiovascular Implants and Extracorporeal Systems—Vascular Device-Drug Combination Products
ISO 9000 Quality Management Systems—Fundamentals and Vocabulary
ISO 9001 Quality Systems Management

2.3 *AAMI Standards:*[5]
AAMI STBK9–1 Sterilization—Part 1: Sterilization in Health Care Facilities
AAMI STBK9–2 Sterilization—Part 2: Sterilization Equipment
AAMI STBK9–3 Sterilization—Part 3: Industrial Process
AAMI TIR17 Compatibility of Materials Subject to Sterilization

2.4 *U. S. Code of Federal Regulations:*[6]
21 CFR Part 58 Title 21 Food And Drug Administration, Part 58—Good Laboratory Practice for Nonclinical Laboratory Studies
21 CFR Part 820 Title 21 Food And Drug Administration, Part 820—Quality System Regulation

[3] The last approved version of this historical standard is referenced on www.astm.org.

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

[5] Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, http://www.aami.org.

[6] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

2.5 *U. S. Pharmacopeia (USP) Standards:*[7]
<231> Heavy Metals—Method II
<724> Drug Release
<905> Uniformity of Dosage Units
<1207> Sterile Product Packaging—Integrity Evaluation
<1208> Sterility Testing—Validation of Isolator Systems
<1209> Sterilization—Chemical and Physiochemical Indicators and Integrators
<1211> Sterilization and Sterility Assurance of Compendial Articles

2.6 *Other Documents:*[8]
ICH Q3C International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Quality Guideline: Impurities: Residual Solvents

3. Terminology

3.1 *Definitions:*

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

NOTE 1—See Appendix X4 for a discussion regarding the usage of absorbable and other related terms.

3.1.2 *bioactive agent, n*—any molecular component in, on, or with the interstices of a device that is intended to elicit a desired tissue or cell response.

3.1.2.1 *Discussion*—Growth factors, antibiotics, and antimicrobials are typical examples of bioactive agents. Device structural components or degradation byproducts that evoke limited localized bioactivity are not included.

3.1.3 *plasticizer, n*—substance incorporated into a material to increase its workability, flexibility, or distensibility.

3.1.4 *porogen, n*—one or more added materials that, upon removal, produce voids that result in generation of a porous structure.

3.1.4.1 *Discussion*—The need for inclusion of a porogen is process dependent, with many porous structures able to be generated without the utilization of porogens. A porogen can be a gas, liquid, or solid and can be either intentionally or unintentionally added.

4. Significance and Use

4.1 This guide is aimed at providing guidance for assessments and evaluations to aid in preclinical research and development of various absorbable components and devices.

4.2 This guide includes brief descriptions of various intended uses, processing conditions, assessments, and both qualitative and quantitative analyses for raw materials to finished product components.

4.3 The user is encouraged to utilize appropriate ASTM and other standards to conduct the physical, chemical, mechanical, biocompatibility, and preclinical tests on absorbable materials, device components, or devices prior to assessment in an *in vivo* model.

4.4 Whenever an absorbable material is mixed or coated with other substances (bioactive, polymeric, or otherwise), the physical and degradation properties of the resulting composite may differ significantly from the base polymer. Thus, unless prior experience can justify otherwise, performance characterizations described herein should be conducted on the composite construct rather than on individual components.

4.5 Assessments of absorbable materials should be performed in accordance with the provisions of the FDA Good Laboratories Practices Regulations 21 CFR 58, where feasible.

4.6 Studies to support regulatory approval for clinical or commercial use, or both, should conform to appropriate nationally adopted directives or guidelines, or both, for the development of medical devices [for example, CE approval; US-FDA Investigational Device Exemption (IDE), Pre- Market Approval (PMA), or 510K submission].

4.7 Assessments based upon data from physical, chemical, mechanical, biocompatibility, and preclinical testing models are highly valuable but carry inherent limitations. Thus, the clinical relevance of each assessment needs to be carefully considered and the user is cautioned that pre-clinical evaluations may not be predictive of human clinical performance.

5. Fabrication and Processing Related Features and Considerations

5.1 *Thermal Processing*—Synthetic absorbable implants are routinely fabricated through thermal means, with typical examples including extrusion and injection molding. Extrusion is typically used to manufacture fibrous forms (for example, woven or knitted meshes, monofilament or braided sutures, fibrous nonwovens), as well as films and tubes. Injection molding typically includes screws, tacks, barbs, pins, and bone anchors.

5.1.1 *Thermal Degradation Control*—The act of thermal processing can potentially degrade absorbable polymers. In addition, any presence of moisture will introduce an additional degradation mechanism, which will occur rapidly at elevated processing temperatures. Consequently, the impact of actual processing conditions—including temperature, moisture, and their variations—on the resulting product should be both understood and appropriately controlled.

5.2 *Solvent Casting*—Synthetic absorbable implants can be fabricated through dissolution in a solvent followed by casting into a desired form. This process is typically utilized in the formation of films, but other forms are possible.

5.2.1 *Compositional Purity*—The purity of the solvent(s) utilized in the casting process must be known and of a grade suitable for the intended application. The overall system (that is, incoming raw materials and all device fabrication processes) needs to maintain a level of particle control appropriate for the intended application. It is important to note that the act of solvating a hydrolysable polymer inherently increases its chain

[7] Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.

[8] Available from International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), ICH Secretariat, c/o IFPMA, 15 ch. Louis-Dunant, P.O. Box 195, 1211 Geneva 20, Switzerland, http://www.ich.org.

motion, thereby increasing its potential for reactivity. If any chemically reactive moiety (such as water) is present in the solvent, degradation can increase significantly from the polymer's solid state condition. Consequently, the impact of actual processing conditions (for example, solution temperature, moisture content) on the resulting product should be both understood and controlled.

5.2.2 *Chemical Compatibility*—All components of a solvent casting system need to possess a level of compatibility suitable for the intended application. Examples of incompatibility include, but are not limited to, reactivity (unintended generation of differing chemical moieties within the solution) and phase separation (unintended formation of colloids/precipitates/particles that may be detrimental to overall biocompatibility and/or desired *in vivo* performance).

5.2.3 *Solvent Removal*—The solvent casting process inherently includes a drying step to remove the major portion of the solvent. Any remaining residual solvent will effectively temporarily plastisize the device, potentially affecting its initial physical properties. In addition, residual solvent may pose biocompatibility-related issues, details of which are addressed in Section 8.

5.2.4 *Dimensional Control*—As with any forming process, casting dimensions (including thickness) shall be controlled within limits determined to be suitable for the intended application.

5.3 *Coating*—Polymers with hydrolysable segments can be applied to a device using various methods ranging from dip-coating (aqueous or organic solvent) to vapor deposition.

5.3.1 *Physical Deposition Control*—Coating characteristics—including, but not limited to, density, thickness, and/or bioactive agent loading—shall be controlled within limits determined to be suitable for the intended application.

5.3.2 *Compositional Purity*—The purity of the coating itself and any solvent(s) utilized in the coating process shall be known and of a grade suitable for the intended application. Any aqueous-based solvent systems shall utilize water that meets USP Sterile Water for Injection requirements. Non-aqueous solvent systems need to maintain a level of particle control appropriate for the intended application. Additionally, International Conference on Harmonisation (ICH) based residual solvent limits—as described in Section 8 and in synthetic absorbable resin Specifications F1925, F2579, and F2313—need to be met. Devices are to be characterized by analytic detection limits sufficient to assure that total solvent residuals are maintained below ICH guidelines.

5.4 *Additives*—In the context of this guide, an additive is any substance that is intentionally added to the implant, regardless as to whether or not it is removed during subsequent processing. As a result, additives needing consideration can range broadly from processing aids (for example, mold release agents) to fillers to pharmaceuticals. Since *in vivo* release is categorically inherent to absorbability, a thorough understanding of any additive's biological/toxicological properties is essential to implant design. Also worthy of consideration is the impact expected additive concentration(s) may impart on manufacturing processes and/or the physical properties of the polymeric device itself.

5.4.1 *Plasticizers*—In the context of this guide, plasticization can be imparted by anything added to a macromolecular device or component that swells and/or solvates its polymeric structure to effectively lower its glass transition temperature (Tg). Almost any low molecular weight molecule able to penetrate the polymeric structure—including solvents, water, and bioactive agents—carries potential to impart a plasticization effect. Thus, plasticizer should be perceived as a descriptive term that is not limited solely to the class of chemicals commonly added to modify/affect the mechanical properties of the polymer and/or device.

5.4.1.1 Any material used to plasticize absorbable polymers will, upon polymer absorption, inherently be released into the body. As a result, any plasticizer should be fully understood as to its systemic toxicity (for example, excretion, concentration in organs, and so forth). If adequate toxicological information is unavailable for the utilized placticizer(s), such data must be generated. Additionally, the purity of the raw material plasticizer must be known and of a grade suitable for the intended application.

5.4.1.2 The chemical composition of the plasticizer raw material shall be determined by means of an assay of the basic composition and a quantification of any expected other components (due to raw material sources and/or processing methods; for example, reactive chemical byproducts, trace metals/catalysts). Quantification of each expected other component is to be undertaken at an analytic level that brings assurance that tissue response in the final product will be suitable for the intended application. Low or non-toxic materials may need no-to-minimal monitoring, depending on extraction efficiency and expected residual levels within the formed device. Higher toxicity materials will require elevated awareness and monitoring, dependent on extraction efficiency expected residual levels within the formed device.

5.4.1.3 The plasticizer content in the finished as-formed device must also be known, along with quantification of any expected other components possessing toxicity and/or quantities that may impact tissue response and/or display either local or systemic toxicity.

5.4.2 *Porogens*—Porogens are one or more added materials that, upon their removal, produce voids that result in a porous structure. A porogen can be a gas, liquid, or solid and can be either intentionally or unintentionally added. The need for inclusion of a porogen is process-dependent, with many porous structures able to be generated without the utilization of porogens. Any porogen needs to deliver the desired pore characteristics, which typically includes porosity, presence of open/closed cells, pore size, and so forth. Characterization of a porogen raw material should, at minimum, include:

5.4.2.1 *Dimensions*—Provide some relevant measure of the porogen's size profile.

5.4.2.2 *Chemical Composition*—Assay the basic composition of the porogen and quantify any expected other components (due to raw material sources and/or processing methods; for example, reactive chemical byproducts, trace metals/catalysts). Quantification of each expected other component is

to be undertaken at an analytic level that assures that the tissue response in the final porous product will be suitable for the intended application. Low or non-toxic materials may need no-to-minimal monitoring, depending on extraction efficiency and expected residual levels within the formed porous device. Higher toxicity materials will require elevated awareness and monitoring, the extent of which will depend on extraction efficiency and expected residual levels within the formed porous device.

5.4.2.3 *Characterization of Formed Porous Device*—The pore characteristics of the formed device should be assessed by appropriate means as summarized in Guide F2450. Additionally, any remaining residual porogen(s) or other components that display either local or systemic toxicity or have the potential to adversely impact tissue response or device performance should be quantified.

5.4.3 *Bioactive Agents*—Bioactive agents are typically considered to be pharmaceuticals, growth factors, antibiotics, or antimicrobials. Additionally, cells or specific cell surface/growth factor antigens may be components of the device. If a bioactive substance is to be released from a device or a device component, the release profile should be characterized.

5.4.3.1 *Controlled Release*—Any controlled release of a bioactive agent or substance from an absorbable device (be it from the bulk or a coating, or both) needs to be sufficiently understood and characterized to assure that the effective dosage into the surrounding tissue is both safe (that is, below toxic levels) and accomplishes the design goal.

NOTE 2—See X1.1 for more information on appropriately characterizing the controlled release of bioactive agents, drugs/pharmaceuticals, antimicrobials, or cells, or combination thereof.

5.5 *Post-formation Thermal Processing*—Fabricated forms typically undergo at least one or more thermal processes, which may include thermally induced annealing, crosslinking, solvent extraction, and so forth. Any thermal processing of the fabricated form (including cooling/quenching processes) should be documented and the mechanical, physical, and chemical effects assessed.

5.6 *Sterilization Processing*—A summary of sterilization methods and standards is presented later in 7.2. However, it is important to emphasize that sterilization is a manufacturing process that can have significant impact on an absorbable implant system's material or (if present) bioactive agent properties. Thus, evaluations considered to be representative of actual performance *in vivo* and/or finished product shall be conducted on devices or test specimens that have been sterilized by means that approximate the intended commercial method.

6. Device Characterizations/Assessments

NOTE 3—Sterilization of absorbable polymeric materials should be expected to cause changes in molar mass or structure, or both. This can affect the initial mechanical and physical properties of a material or device, as well as its subsequent rate of degradation. Therefore, if a test is intended to be representative of actual performance *in vivo* and/or finished product, assess the test absorbable polymeric material in a form that is representative of a product produced under standard manufacturing conditions and ready for sale.

6.1 *Compositional Properties:*

6.1.1 *Raw Material Characterization*—It is recommended that the required characteristics of all incoming raw material be specified, including absorbable resin. Factors that should be considered for inclusion within specifications for hydrolysable polyesters can be found in Specifications F1925, F2313, and F2579.

6.1.2 *Chemical Properties Characterization (Fabricated Device)*—It is recommended that the chemical properties of a fabricated absorbable device be specified. Factors that should be considered for inclusion within the specification can be found in Specifications F1925, F2313, and F2579. Additional items for consideration can be found in Table 1—Sections A and B of this guide.

6.1.3 *Physical Description Properties Characterization*—It is recommended that the physical properties of a fabricated absorbable device be specified. Factors that should be considered for inclusion within the specification can be found in Table 1—Sections C, D, and E.

6.1.4 *Thermal Properties Characterization*—It is recommended that the thermal properties of a fabricated absorbable device be specified. Factors that should be considered for inclusion within the specification can be found in Table 1—Section F.

6.2 *Mechanical/Performance Properties*—The objective of any mechanical characterization is to adopt relevant evaluation methods that approximate the expected clinical loading of the device (for example, don't rely solely on tensile testing when clinical loading is in shear). Besides understanding and modeling normal service conditions, mechanical characterizations should assess the worst case clinical failure mode and then evaluate device performance under similar conditions. Worst case failure may be the result of numerous combined factors, which can include materials composition, physiological fluids and temperatures, effects of clinical placement, and *in vivo* loading conditions. However, the user is cautioned that such pre-clinical testing does not, in itself, assure suitability to a particular application and may not be predictive of human clinical performance. Mechanical properties that should be considered for inclusion within a specification can be found in Table 2—Sections A to F.

6.2.1 *Initial Characteristics/Properties*—Characterize the relevant initial (that is, as-manufactured) mechanical properties of the device. The initial dimensional and net mechanical characteristics of the device will need to reflect the intended application and the resulting design. An example of mechanical characterizations appropriate for absorbable implants designed toward a specific function can be found in Specification F2502. However, each different absorbable application or design approach will likely require appropriate variations in the applied assessment method(s).

6.2.2 *Hydrolytic Degradation Properties (Degradation Profiling/Modeling)*—Characterize the loss of relevant mechanical properties of the device over time under conditions that are representative of expected *in vivo* service conditions. Once conditioned for a clinically relevant time interval, evaluations may include destructive mechanical testing or testing until failure (in the case of static or cyclic loading evaluations). Depending on the indicated use of a device, clinical relevance

TABLE 1 Chemical and Physical Properties

Property, Behavior, or Characteristics	Applicable Issues/Design Considerations	Potentially Relevant Analyses, Characterizations, and Test Methods
A—Chemical Composition	**Main Ingredients**: Polymers (incl copolymer ratio), Chain extenders, Cross-linking agents, Coating composition, Plasticizer(s)/processing aids **Purity/Trace Elements:** Catalysts Low Mw components (water solvent, monomers, oligomers) **Stereoregularity and Optical Purity**	NMR GC HPLC Residual Ignition AA ICP IR GPC Karl-Fischer Titration Polarimeter (optical rotation
B—Molecular Structure	**Polymer Blending** **Crosslinking** **Copolymer block/branch length** **Copolymer conversion efficiency** **Mn, Mw, Polydispersity, MWD**	NMR GPC IR Solubility Swelling Viscosity ASTM D5296
C—Morphology (Supermolecular Structure)	**% Crystallinity** **Phases** (Types, amount, and orientation)	X-ray diffraction DSC DTA Optical Microscopy Birefringence X-ray diffraction Draw ratio
D—Composite Structure	**Laminate Structure:** Ply thickness and orientation Ply orientation and stacking sequence (incl symmetry) **Reinforcement**: Location within part 3D orientation Volume or weight fraction Contacts/cross-overs, homogeneity Cross-section shape Fiber—twist and denier Weave—types, ends/mm **Coatings**—number and thickness of each layer **Voids:** Mean Vol % Interconnections Depth and Profile	Scanning Electron Microscopy (SEM) Optical Microscopy Micro-CT Porosimetry
E—Physical Properties	**Water Absorption** **Dimensional Changes** **Density** (mass and volume) (smallest and largest device sizes) **Porosity Distribution** **Surface Area:** (smallest and largest device sizes)—determined by overall external dimensions, not intended to include internal surfaces with microporous structures **Surface Characteristics**—(Texture, patterns, roughness, and so forth)	ASTM D570 ASTM D1042 ASTM D792 ASTM F2450 Porosimetry (ASTM D4404) Porometry (ASTM E128, F316 ASTM F2791
F—Thermal Properties	**Glass Transition Temperature** **Crystallization Temperature** **Melting Temperature**	ASTM D3418 ASTM E793 ASTM E794 ASTM E1356

may indicate the need for one or more of the following conditioning methods.

NOTE 4—Hydrolytic environments that are intended to mimic *in vivo* conditions typically include buffered saline-based water baths. In such baths, attention toward buffer capacity and careful maintenance of pH is essential for proper hydrolytic evaluation of a hydrolysable device.

NOTE 5—Since loss of mechanical properties within an absorbable polymeric device is typically the result of chain scission, concurrent monitoring of molar mass should be considered since measurable loss can be expected prior to any detectable degradation of mechanical properties.

6.2.2.1 *Mechanically Unloaded Hydrolytic Evaluation*—Conditioning of a hydrolysable device under mechanically unchallenged hydrolytic conditions at 37°C in water or buffered saline is described in Test Method F1635. Additional more specific polymer-related guidance may be found in ISO 13781 and ISO 15814. While testing of unloaded specimens is a common means to obtain a first approximation of the degradation profile of an absorbable material or device, it does not necessarily represent actual *in vivo* service conditions, which