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.

Designation: F2902 – 16$^{\varepsilon 1}$

Standard Guide for Assessment of Absorbable Polymeric Implants[1]

This standard is issued under the fixed designation F2902; 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.

ε[1] NOTE—Editorial corrections were made throughout in May 2017.

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, sutures, and dermal fillers), 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.*

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]

D570 Test Method for Water Absorption of Plastics

[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.

Current edition approved Dec. 1, 2016. Published January 2017. Originally approved in 2012. Last previous edition approved in 2012 as F2902 - 12. DOI: 10.1520/F2902-16E01.

[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.

Copyright © ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959. United States