



Designation: F1635 – 16

Standard Test Method for *in vitro* Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants¹

This standard is issued under the fixed designation F1635; 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 test method covers *in vitro* degradation of hydrolytically degradable polymers (HDP) intended for use in surgical implants.

1.2 The requirements of this test method apply to HDPs in various forms:

1.2.1 Virgin polymer resins, or

1.2.2 Any form fabricated from virgin polymer such as a semi-finished component of a finished product, a finished product, which may include packaged and sterilized implants, or a specially fabricated test specimen.

1.3 This test method provides guidance for mechanical loading or fluid flow, or both, when relevant to the device being evaluated. The specifics of loading type, magnitude, and frequency for a given application are beyond the scope of this test method.

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

1.5 *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

D638 Test Method for Tensile Properties of Plastics

D671 Test Method for Flexural Fatigue of Plastics by

Constant-Amplitude-of-Force (Withdrawn 2002)³

D695 Test Method for Compressive Properties of Rigid Plastics

D747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam

D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials

D882 Test Method for Tensile Properties of Thin Plastic Sheet

D1708 Test Method for Tensile Properties of Plastics by Use of Microtensile Specimens

D1822 Test Method for Tensile-Impact Energy to Break Plastics and Electrical Insulating Materials

D2857 Practice for Dilute Solution Viscosity of Polymers

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 *ISO Standards:*⁴

ISO 31-8 Physical Chemistry and Molecular Physics - Part 8: Quantities and Units

ISO 10993-1 Biological Evaluation of Medical Devices—Part 1 Evaluation and Testing

ISO 10993-9 Biological Evaluation of Medical Devices—Part 9 Framework for Identification and Quantification of Potential Degradation Products

ISO 13781 Poly(L-lactide) resins and fabricated forms for surgical implants – In vitro degradation testing

2.3 *NIST Standard:*⁵

NIST Special Publication SP811 Guide for the Use of the International System of Units (SI)

3. Terminology

3.1 *Definitions:*

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 F04.15 on Material Test Methods.

Current edition approved Dec. 1, 2016. Published January 2017. Originally approved in 1995. Last previous edition approved in 2011 as F1635 – 11. DOI: 10.1520/F1635-16.

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 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 National Institute of Standards and Technology (NIST), 100 Bureau Dr., Stop 1070, Gaithersburg, MD 20899-1070, at <http://physics.nist.gov/cuu/Units/bibliography.html>.