



Designation: F 1635 – 95

Standard Test Method for In Vitro Degradation Testing of Poly (L-lactic Acid) Resin and Fabricated Form for Surgical Implants¹

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1. Scope

1.1 This test method covers poly(L-lactic acid) resin intended for use in surgical implants.

1.2 The requirements of this test method apply to poly(L-lactic acid) in various forms:

1.2.1 Virgin polymer, 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.

2. Referenced Documents

2.1 *ASTM Standards:*

D 638 Test Method for Tensile Properties of Plastics²

D 671 Test Method for Flexural Fatigue of Plastics by Constant-Amplitude-of-Force²

D 695 Test Method for Compressive Properties of Rigid Plastics²

D 747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam²

D 790 Test Method for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials²

D 882 Test Method for Tensile Properties of Thin Plastic Sheetings²

D 1708 Test Method for Tensile Properties of Plastics by Use of Microtensile Specimens²

D 1822 Test Method for Tensile-Impact Energy to Break Plastics and Electrical Insulating Materials²

D 2857 Test Method for Dilute Solution Viscosity of Polymers³

F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices⁴

3. Summary of Test Method

3.1 Samples of poly(L-lactic acid) resin, semi-finished components, finished surgical implants, or specially designed test

specimens fabricated from poly(L-lactic acid) resin are placed in buffered saline solution at physiologic temperatures. Samples are periodically removed and tested for various material or mechanical properties at specified intervals (typically 1, 3, 6, 12, 26, 52 and 104 weeks).

4. Significance and Use

4.1 This test method is intended to help assess the biodegradation rates and changes in material or structural properties, or both, of poly(L-lactic acid) materials used in surgical implants.

4.2 This test method may not be appropriate for all types of implant applications. The user is cautioned to consider the appropriateness of the test method in view of the materials being tested and their potential application.

4.3 The application of mechanical loading or other forms of energy to the specimens during aging may significantly alter (that is, increase) the rate at which properties change. This needs to be considered when comparing in vitro behavior with that expected/observed at an in vivo site.

5. Apparatus

5.1 *Physiologic Soaking Solution*—A phosphate-buffered saline (PBS) solution shall be used. The pH of the solution shall be maintained at 7.4 ± 0.2 (see X1.3). The ionic concentration should be in the physiological range (for example, a solution that contains 0.1 M phosphate buffer and 0.1 M NaCl would be appropriate). The solution:specimen mass ratio shall be as high as practical. Although there is some experience with ratios as low as 20:1, the experimenter is cautioned that at lower ratios (that is, less buffering capacity) the solution pH may change more quickly. In accordance with 9.1.3 and X1.4, aging/testing is to be terminated once solution temperature or pH are allowed to drift outside of the specified ranges. Higher solution:specimen ratios (that is, 100:1) will facilitate maintenance of stable aging conditions.

5.1.1 Over the course of the study it may be possible to adjust solution pH and ionic concentration through the addition of individual solution constituents; however, it is preferable to exchange the test solution completely when it nears the limits of acceptability. Refer to X1.5 for additional information.

5.1.2 Other physiologic solutions, such as bovine serum, may be substituted provided the solution is properly buffered. An anti-microbial additive should be used to inhibit the growth

¹ This test method is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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² *Annual Book of ASTM Standards*, Vol 08.01.

³ *Annual Book of ASTM Standards*, Vol 08.02.

⁴ *Annual Book of ASTM Standards*, Vol 13.01.