



## Standard Specification for Virgin Poly(L-Lactic Acid) Resin for Surgical Implants<sup>1</sup>

This standard is issued under the fixed designation F 1925; 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.

<sup>ε1</sup> NOTE—Figure 2 was editorially added in July 2001 because it had been inadvertently left out of the previous edition.

### 1. Scope

1.1 This specification covers virgin poly(L-lactic acid) resin (or abbreviated as PLLA resin) intended for use in surgical implants. This specification does not cover stereoisomeric compositions based on various D, L, or DL copolymer ratios.

1.2 This specification addresses material characteristics of virgin poly(L-lactic acid) resin and does not apply to packaged and sterilized finished implants fabricated from this material.

1.3 As with any material, some characteristics may be altered by processing techniques (such as molding, extrusion, machining, assembly, sterilization, and so forth) required for the production of a specific part or device. Therefore, properties of fabricated forms of this resin should be evaluated using those test methods which are appropriate to assure safety and efficacy.

1.4 The values stated in SI units are to be regarded as the 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:

D 1505 Test Method for Density of Plastics by the Density-Gradient Technique<sup>2</sup>

D 1898 Practice for Sampling of Plastics<sup>3</sup>

D 2857 Practice for Dilute Solution Viscosity of Polymers<sup>3</sup>

D 3536 Test Method for Molecular Weight Averages and Molecular Weight Distribution by Liquid Exclusion Chromatography (Gel Permeation Chromatography - GPC)<sup>4</sup>

D 3593 Test Method for Molecular Weight Averages and Molecular Weight Distribution of Certain Polymers by Liquid Size-Exclusion Chromatography (Gel Permeation Chromatography - GPC) Using Universal Calibration<sup>4</sup>

D 3892 Practice for Packaging of Plastics<sup>4</sup>

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices<sup>5</sup>

#### 2.2 ISO Standard:

ISO/DIS 10993-9, Biological Evaluation of Medical Devices, Part 9 Degradation of Materials Related to Biological Testing, Annex A<sup>6</sup>

### 3. Terminology

#### 3.1 Definitions of Terms Specific to This Standard:

3.1.1 *generic property*—that property which is determined solely by the chemical composition and structure of the virgin polymer

3.1.2 *virgin polymer*—the form of poly(L-lactic acid) as obtained from the manufacturer and before fabrication into a medical device.

### 4. Virgin Poly(L-Lactic Acid) Resin Requirements

#### 4.1 Generic Properties:

4.1.1 The virgin polymer shall be a homopolymer of L-lactide with a density between 1.20 and 1.28 g/cm<sup>3</sup> (see 6.5 for evaluation method).

4.1.2 The molecular mass of the virgin polymer shall be indicated by relative solution viscosity in accordance with 6.2. In addition to solution viscosity (but not in place of), weight average molecular mass and molecular mass distributions may be determined by gel permeation chromatography (GPC) according to Test Methods D 3536 or D 3593.

4.1.3 The virgin polymer shall be identified as a polylactide by infrared or <sup>1</sup>H-NMR spectroscopy.

4.1.3.1 The virgin polymer shall yield an infrared spectrum which exhibits major absorption bands only at the wavelengths that appear in a suitable reference spectrum. A typical infrared transmission spectrum is shown in Fig. 1.

4.1.3.2 Additional absorption bands may be indicative of known, or unknown, impurities including residual solvents and catalysts (refer to residual solvent limits specified in Table 1).

4.1.3.3 An infrared spectrum cannot distinguish between the different available stereoisomeric polylactic acids. It is used

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<sup>2</sup> Annual Book of ASTM Standards, Vol 08.01.

<sup>3</sup> Annual Book of ASTM Standards, Vol 08.02.

<sup>4</sup> Annual Book of ASTM Standards, Vol 08.03.

<sup>5</sup> Annual Book of ASTM Standards, Vol 13.01.

<sup>6</sup> Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.