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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0661-2017

Replacing YY/T 0661-2008

**Standard specification for semi-crystalline poly(lactide)
polymer and copolymer resin for surgical implants**

外科植入物 半结晶型聚丙交酯聚合物和共聚物树脂

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Table of Contents

Foreword

1 Scope

2 Normative references

3 Terms and definitions

Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009. This standard replaces YY/T 0661-2008 "surgical implant poly (L-lactic acid) resin standard", and YY/T 0661-2008 In addition, editorial changes in addition to the main technical changes are as follows:

- Increased the scope of the standard (see Chapter 1);
- Added and modified certain physical and chemical performance requirements and the corresponding test methods (see Chapter 5, Chapter 6, Chapter 7);
- Increased size, quality and tolerance (see Chapter 8);
- Increasing the sample preparation (see Chapter 9);
- Increased proof (see Chapter 10);
- Increased naming (see Appendix A) and biocompatibility (see Appendix C). This standard uses redrafted Law reference ASTM F1925-09 "surgical implants semi-crystalline polylactide polymers and copolymers Resin "preparation. Please note that some of this document may be patentable. The issuing agencies of this document do not bear the responsibility of identifying these patents. This standard proposed by the State Food and Drug Administration. This standard by the National Surgical Implants and Orthopedic Instruments Standardization Technical Committee (SAC/TC110) centralized. This standard was drafted unit. Tianjin Medical Device Quality Supervision and Inspection Center, Le Pu (Beijing) Medical Devices Co., Ltd., Jiangsu 100 Easy Medical Technology Co., Ltd. The main drafters of this standard. Li Yuan, Zhu Jin, Zheng Jun translation, Fang Yuan, Ding Jianzhong, Zou Rongrong. This standard replaces YY/T 0661-2008. YY/T 0661-2008 the previous version of the release.
- YY/T 0661-2008. Surgical implant semi-crystalline polylactide Polymer and copolymer resins

1 Scope

YY/T 0661 is the material specification for semi-crystalline polylactide polymer and copolymer resin used in surgical implants, the raw material behind resorbable screws, pins, plates and sutures. It sets what the resin has to be before it becomes a device: identity, molecular weight, residual monomer and the characteristics that govern how the finished implant will degrade in the body. With a resorbable implant the material specification carries more weight than usual, because the resorption profile the surgeon relies on is fixed by the polymer long before the part is machined or moulded. The version in circulation carries amendment 1 of 2025. For a manufacturer of resorbable orthopaedic or craniomaxillofacial implants, or a resin supplier serving them, this is the incoming material specification for the Chinese market.

1.1 This standard applies to surgical implants with a native semi-crystalline poly (L-lactide) or poly (D-lactide) homopolymer resin, also applies to L-lactide and other bio-absorbable monomer copolymerized semi-crystalline resin. These monomers include but are not limited to glycolide, D-lactide and DL-lactide. Poly (L-lactide) or poly (D-lactide) homopolymers and copolymers in this standard contain lactide fragments long enough, So after annealing will cause its potential crystallization. This polymer typically has a mole fraction of L-lactide equal to or greater than 50%. This standard It is especially suitable for the production of isotactic lactide-based block copolymers or composites of D-lactide and L-lactide with a total molar difference of more than 1.5% Synthesized polymer or copolymer. This standard includes fully soluble in methylene chloride or chloroform at 30 ° C native semi-crystalline Type polylactic acid based resin.

Note. Refer to Appendix A for the nomenclature of polymers.

1.2 This standard does not apply to glycolide molar fraction of greater than or equal to 70% (mass fraction of 65.3%) of lactide - glycolide copolymerization Does not apply to lactide glycolide copolymers that have a glycolide segment of sufficient size to provide a potential glycolide-based crystal, The material needs to be completely dissolved at room temperature using a fluorinated solvent (see ASTM F2313); it also does not apply to amorphous polymers or to total Copolymers of D-lactide and L-lactide complexes with a difference in molar fraction of more than 1.5% (see YY/T 0510).

1.3 This standard, the semi-crystalline resin is annealed by differential scanning calorimetry to determine the glass transition temperature above the heat of crystallization to define of. While fragments of other copolymerization segments may also crystallize upon annealing (eg, glycolide), other than the crystalline structure formed from lactide The specific characterization of the crystal structure is outside the scope of this standard.

1.4 This standard specifies the material properties of primary semi-crystalline polylactide-based resins for surgical implants that are not suitable for use in the manufacture of these materials Packaged sterilized finished implant. Any of the materials,

processing techniques used to manufacture parts or equipment (such as molding, extrusion, machining, Assembly, sterilization, etc.) can change its performance. Therefore, the resin processed products, the performance standards involved in this should be used to ensure its safety and Effective test method for evaluation.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version applies to this article Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 1033.2 Determination of density of plastics, non-foamed plastics - Part 2. Density gradient column method

GB/T 1632.5 Plastics - Determination of the viscosity of dilute polymer solutions using a capillary viscometer - Part 5. Thermoplastic homopolymerization and copolymerization Polyester (TP)

GB/T 6040 General rules of infrared spectroscopy

GB/T 6425 thermal analysis terms

GB 11998 plastic glass transition temperature measurement method (thermal mechanical analysis)

GB/T 19466.3 Plastics - Differential Scanning Calorimetry (DSC) - Part 3. Determination of melting and crystallization temperature and enthalpy

GB/T 21864 Polystyrene average molecular weight and molecular weight distribution of the standard test methods High-performance size exclusion chromatography

YY/T 0510 surgical implants with amorphous polylactide resin and lactide - glycolide copolymer resin