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YY/T 0606.5—2007

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组织工程医疗产品 第 5 部分：基质及支架的性能和测试

Tissue engineered medical Products—Part 5:
Characterization and testing of substrates and scaffolds

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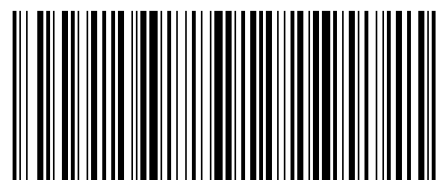
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- and Solutions for Biomedical Applications.
- [42] ASTM F641;1998 Standard Specification for Implantable Epoxy Electronic Encapsulants.
- [43] ASTM F665;1998 Standard Classification for Vinyl Chloride Plastics Used in Biomedical Application.
- [44] ASTM F702;1998 Standard Specification for Polysulfone Resin for Medical Applications.
- [45] ASTM F755;1999 Standard Specification for Selection of Porous Polyethylene for Use in Surgical Implants.
- [46] ASTM F997;1998 Standard Specification for Polycarbonate Resin for Medical Applications.
- [47] ASTM F1088;2004 Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation.
- [48] ASTM F1249;2001 Standard Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor.
- [49] ASTM F1251;1989 Standard Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices.
- [50] ASTM F1925;1999 Standard Specification for Virgin Poly(L-Lactic Acid) Resin for Surgical Implants.
- [51] ASTM F1579;2002 Standard Specification for Polyaryletherketone (PAEK) Polymers for Surgical Implant Applications.
- [52] ASTM F1581;1999 Standard Specification for Composition of Anorganic Bone for Surgical Implants.
- [53] ASTM F1634;1995 Standard Practice for In-Vitro Environmental Conditioning of Polymer Matrix Composite Materials and Implant Devices.
- [54] ASTM F1855;2000 Standard Specification for Polyoxymethylene (Acetal) for Medical Applications.
- [55] ASTM F1876;1998 Standard Specification for Polyetherketoneetherketoneketone (PE-KEKK) Resins for Surgical Implant Applications.
- [56] ASTM F1884;2004 Standard Test Method for Determining Residual Solvents in Packaging Materials.
- [57] ASTM F1926;2003 Standard Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Coatings.
- [58] ASTM F1980;2002 Standard Guide for Accelerated Aging of Sterile Medical Device Packages.
- [59] ASTM F2025;2000 Standard Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment.
- [60] ASTM F2212;2002 Standard Guide for Characterization of Type I Collagen as Starting Materials for Surgical implants and Substrates for Tissue Engineered Medical Product (TEMPs).
- [61] ASTM G120;2001 Standard Practice for Determination of Soluble Residual Contamination in by Soxhlet Extraction.

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- [1] Omstead DR, Baird LG., Christenson L, Moulin GD, Tubo R., et al, "Voluntary Guidance for the development of tissue - engineered products," Tissue Engineering, Vol 4, No3, 1998, pp. 239-266.
- [2] Von Recum, AF, Editor, "Handbook of Biomaterials Evaluation Scientific, Technical, and clinical testing of implant materials " Macmillan Publishing Co., New York, NY, USA, Second Edition, 1986.
- [3] Shoichet MS and Hubbell JA, Editors, "Polymers for Tissue Engineering," VSP, Utrecht, The Netherlands, 1998.
- [4] Lanza RP, Langer R and Chick WL, Editors, " Principles of Tissue Engineering", Academic Press Inc., R. G. Landes Company, Austin, Texas, USA, Second edition, 2000.
- [5] Ratner BD and Porter SC, "Surfaces in Biology and Biomaterials: Description and Characterization" in Interfacial Phenomena and Bioproducts, J. L. Brash and P. W. Wojciechowski, Eds. Marcel Dekker, Inc., New York, pp. 57-84, 1996, pp. 57-84.
- [6] Ratner BD and Castner DG, "Surface Analysis for Biomaterials and Biological Systems," in Surfaces, Vacuum and Their Applications I. Hernandez-Calderon and R. Asomoza, Editors, AIP Press, Woodbury, 1996, pp. 524-529.
- [7] Crank J and Park GS, Editors, " Diffusion in Polymers," Academic Press, New York, NY, USA, 1968.
- [8] Burg KJL and Shalaby SW, "Radiation Sterilization of Medical and Pharmaceutical devices" in Radiation Effects of Polymers: Chemical & technological Aspects, ACS Washington DC, 240-245, 1996.
- [9] Williams DF, "The Williams Dictionary of Biomaterials", Liverpool University Press, Liverpool, UK, 1999.
- [10] ASTM D747; 2002 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam.
- [11] ASTM D790; 2003 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.
- [12] ASTM D792; 2000 Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement.
- [13] ASTM D1042; 2001 Test Method for Linear Dimensional Changes of Plastics Under Accelerated Service Conditions.
- [14] ASTM D1388; 1996 Standard Test Method for Stiffness of Fabrics.
- [15] ASTM D1623; 2003 Standard Test Method for Tensile And Tensile Adhesion Properties Of Rigid Cellular Plastics.
- [16] ASTM D2857; 1995 Standard Practice for Dilute Solution Viscosity of Polymers.
- [17] ASTM D2990; 2001 Standard Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics.
- [18] ASTM D3016; 1997 Standard Practice for Use of Liquid Exclusion Chromatography Terms and Relationships.
- [19] ASTM D3039/D3039M; 2000 Standard Test Method for Tensile Properties of Polymer Ma-

前 言

YY/T 0606《组织工程医疗产品》分为：

- 第 1 部分：通用要求；
- 第 2 部分：术语学；
- 第 3 部分：通用分类；
- 第 4 部分：皮肤替代品(物)的术语和分类；
- 第 5 部分：基质及支架的性能和测试；
- 第 6 部分：I 型胶原蛋白；
- 第 7 部分：壳聚糖；
- 第 8 部分：海藻酸钠；
- 第 9 部分：透明质酸钠；
- 第 10 部分：修复或再生关节软骨的植入物体内评价；
- 第 12 部分：细胞、组织、器官的加工处理指南；
- 第 13 部分：产品保存；
- 第 16 部分：活细胞或组织的海藻酸盐凝胶固定或微囊化指南。

本部分为 YY/T 0606 的第 5 部分。

本部分的附录 A、附录 B、附录 C 是资料性附录。

本部分由国家食品药品监督管理局提出。

本部分由中国药品生物制品检定所归口。

本部分由中国药品生物制品检定所医疗器械检验中心起草。

本部分主要起草人：陈亮、奚廷斐、王春仁、范成相。