



Standard Criteria for Implantable Thermoset Epoxy Plastics¹

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1. Scope

1.1 These criteria cover thermoset plastics based on diglycidyl ethers of bisphenol A (DGEBA) and appropriate curing agents or catalysts as opposed to thermoplastics based on epoxy structures.

1.2 These criteria are generic and are intended to provide definitions and a standard description of epoxy plastics used in implantable devices. It is also intended to serve as a standard guide for the preparation of more specific documents with values and limits covering specific end uses.

1.3 Compliance with these criteria shall not be construed as an endorsement of implantability. The biocompatibility of epoxy plastics as a class has not been established. Epoxy plastic is a generic term relating to the class of polymers formed from epoxy resins, certain curing agents or catalysts, and various additives. Since many compositions and formulations fall under this class, it is essential that the formulator or fabricator ensure biocompatibility of the specific composition or formulation in its intended end use. Since these criteria provide guidance for the preparation of more specific documents covering specific end uses, these documents will provide bases for standardized evaluation of biocompatibility appropriate for a specific end use.

1.4 Each of the properties listed shall be considered in selecting materials for specific end uses. A list of selected properties with limiting values assigned is suggested for separate product specifications.

1.5 All of the properties and test methods listed may not be pertinent in any specific situation, nor may all of the tests outlined be required.

1.6 These criteria are limited to functionally or fully cured epoxy plastics. Uncured or incompletely cured formulations are specifically excluded.

1.7 The epoxy plastics covered by this standard are those to be evaluated for use in implantable biomedical devices. The term implantable is herein considered to include devices used in vivo for time periods in excess of 30 days.

1.8 *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 appro-*

priate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

2.1 ASTM Standards:

- D 149 Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies²
- D 150 Test Methods for A-C Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical Insulating Materials²
- D 257 Test Methods for D-C Resistance or Conductance of Insulating Materials²
- D 570 Test Method for Water Absorption of Plastics³
- D 621 Test Methods for Deformation of Plastics Under Load³
- D 638 Test Method for Tensile Properties of Plastics³
- D 785 Test Method for Rockwell Hardness of Plastics and Electrical Insulating Materials³
- D 792 Test Methods for Specific Gravity (Relative Density) and Density of Plastics by Displacement³
- D 883 Terminology Relating to Plastics³
- D 952 Test Method for Bond or Cohesive Strength of Sheet Plastics and Electrical Insulating Materials³
- D 1042 Test Method for Linear Dimensional Changes of Plastics³
- D 1434 Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting⁴
- D 1763 Specification for Epoxy Resins³
- D 2393 Test Method for Viscosity of Epoxy Resins and Related Components⁵
- D 2471 Test Method for Gel Time and Peak Exothermic Temperature of Reacting Thermosetting Resins⁵
- D 2562 Practice for Classifying Visual Defects in Parts Molded from Reinforced Thermosetting Plastics⁵
- D 2566 Test Method for Linear Shrinkage of Cured Thermosetting Casting Resins During Cure⁵
- D 2734 Test Method for Void Content of Reinforced Plastics⁵
- D 2990 Test Method for Tensile, Compressive, and Flexural Creep and Creep Rupture of Plastics⁵

¹ These criteria are under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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² *Annual Book of ASTM Standards*, Vol 10.01.

³ *Annual Book of ASTM Standards*, Vol 08.01.

⁴ *Annual Book of ASTM Standards*, Vol 15.09.

⁵ *Annual Book of ASTM Standards*, Vol 08.02.