



Standard Criteria for Implantable Thermoset Epoxy Plastics¹

This standard is issued under the fixed designation F 602; 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.

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 appropriate 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 ac Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical Insulating Materials²
- D 257 Test Methods for dc Resistance or Conductance of Insulating Materials²
- D 570 Test Method for Water Absorption of Plastics³
- D 621 Test Methods for Deformation of Plastics Under Load⁴
- 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 Density and Specific Gravity (Relative 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 Plastics Under Accelerated Service Conditions³
- D 1434 Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheet⁵
- D 1763 Specification for Epoxy Resins³
- D 2393 Test Method for Viscosity of Epoxy Resins and Related Components⁶
- D 2471 Test Method for Gel Time and Peak Exothermic Temperature of Reacting Thermosetting Resins⁷
- D 2562 Practice for Classifying Visual Defects in Parts

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

Current edition approved Apr. 10, 2003. Published May 2003. Originally approved in 1978. Last previous edition approved in 1998 as F 602 – 98a.

² Annual Book of ASTM Standards, Vol 10.01.

³ Annual Book of ASTM Standards, Vol 08.01.

⁴ Discontinued; See 1994 Annual Book of ASTM Standards, Vol 08.01.

⁵ Annual Book of ASTM Standards, Vol 15.09.

⁶ Discontinued; See 1995 Annual Book of ASTM Standards, Vol 08.02.

⁷ Annual Book of ASTM Standards, Vol 08.02.