



Standard Specification for Acrylic Molding Resins for Medical Implant Applications¹

This standard is issued under the fixed designation F3087; 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 This specification covers acrylic resins supplied in virgin form (typically pellets, powder, or granules) for medical implant applications. The co-polymers are limited to random co-polymers. This specification provides requirements and associated test methods for this thermoplastic when it is intended for use in manufacturing implantable medical devices or components of medical devices.

1.1.1 While a variety of co-monomers may be used, the composition of the resin shall contain poly(methyl methacrylate) (PMMA) as its primary ingredient. Classification **D788** defines an acrylic molding compound as “having at least 70% of the polymer polymerized from methyl methacrylate.” The terms PMMA and acrylic as used herein refer generically to both the homopolymer and to co-polymers as defined above.

1.2 As with any material, some characteristics may be altered by the processing techniques (such as molding, extrusion, machining, 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 test methods that are appropriate to ensure safety and efficacy as agreed upon between the supplier, purchaser, and regulating bodies.

1.3 This specification allows for designation of acrylic resins for all medical implant applications. The actual extent of performance and suitability for a specific application shall be evaluated by the medical device manufacturer and regulating bodies.

1.4 The properties included in this specification are those applicable for both unfilled acrylic polymers and for formulated resins containing barium sulfate. Indicated properties (Table 1 and Table X3.1) are for unfilled injection molded forms. Forms containing fillers other than barium sulfate, colorants, polymer blends that contain PMMA, or reclaimed materials are not covered by this specification.

1.5 Compliance with this specification does not obviate the need for functional testing of any device fabricated from the resin to demonstrate effectiveness in its intended application.

1.6 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.7 *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:²

- D638** Test Method for Tensile Properties of Plastics
- D695** Test Method for Compressive Properties of Rigid Plastics
- D788** Classification System for Poly(Methyl Methacrylate) (PMMA) Molding and Extrusion Compounds
- D792** Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement
- D1238** Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer
- D1898** Practice for Sampling of Plastics (Withdrawn 1998)³
- F451** Specification for Acrylic Bone Cement
- F748** Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 ISO Standards⁴

- ISO 10993-1** Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 17025** General Requirements for the Competence of Testing and Calibration Laboratories

¹ This test method is under the jurisdiction of ASTM Committee **F04** on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee **F04.11** on Polymeric Materials.

Current edition approved July 15, 2015. Published July 2015. DOI: 10.1520/F3087-15.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ The last approved version of this historical standard is referenced on www.astm.org.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.