Designation: F3087 – 15

Standard Specification for Acrylic Molding Resins for Medical Implant Applications[1]

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 Standards*[4]

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.

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[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.

2.3 *Other Reference:*

Klaus-Dieter Kuhn, "Up-to-Date Comparison of Physical and Chemical Properties of Commercial Materials," *Bone Cements*, Springer, 2000.

3. Terminology

3.1 *Definitions:*

3.1.1 *formulated resin, n*—materials, parts, or devices fabricated from virgin polymer resin in such a way as to contain intentional or unintentional adjuvant substances.

3.1.2 *poly(methyl methacrylate) (PMMA), n*—homopolymer of methyl methacrylate (MMA), or random copolymer of MMA with other vinyl monomers in which MMA constitutes the majority of the final content.

3.1.3 *virgin polymer, n*—the initially delivered form of the polymer as synthesized from its monomers prior to any processing or fabrication into a medical device. The resin is typically provided in the form of pellets, granules, or powder and is the material from which fibers, tubes, rods, slabs, sheets, films, or specific parts and devices are fabricated.

4. Significance and Use

4.1 This specification identifies the composition and recommends test methods to establish a reasonable level of confidence concerning the performance of acrylic resins for use in medical implant devices. The required properties are intended to provide a means of ensuring consistent performance. Additional testing should be considered in selecting a material in accordance with specific end-use requirements.

4.2 Acrylic resins may be considered for use in implantable medical devices as well as in non-implant medical applications, but this standard specifically covers resins used for implants. Resins meeting the requirements of this specification may be suitable for non-implant applications, but other acrylic resins that do not conform to this standard may also be suitable for use in non-implant medical applications.

4.3 Acrylic resins intended for use in implant applications are manufactured with more rigorous use of manufacturing or testing controls, or both, to ensure consistency of properties, cleanliness, and biocompatibility. This is further elaborated in 5.1.

5. Classification

5.1 Acrylic resins meeting the requirements of this specification may be considered for use for either prolonged or permanent medical implant applications. Resins classified for permanent implant applications may require additional testing beyond that required for prolonged use as agreed upon between the device manufacturer and regulating bodies. Use of resins for implant applications also implies a higher degree of manufacturing control. Implant grade resins shall be in compliance with the relevant aspects of Good Manufacturing Practices (GMPs), use of process validation, enhanced controls, and testing in a laboratory meeting the requirements of ISO 17025. Acrylic resins classified for implantable devices shall be evaluated for biological response in accordance with ISO 10993-1 or Practice F748, Section 10, or both.

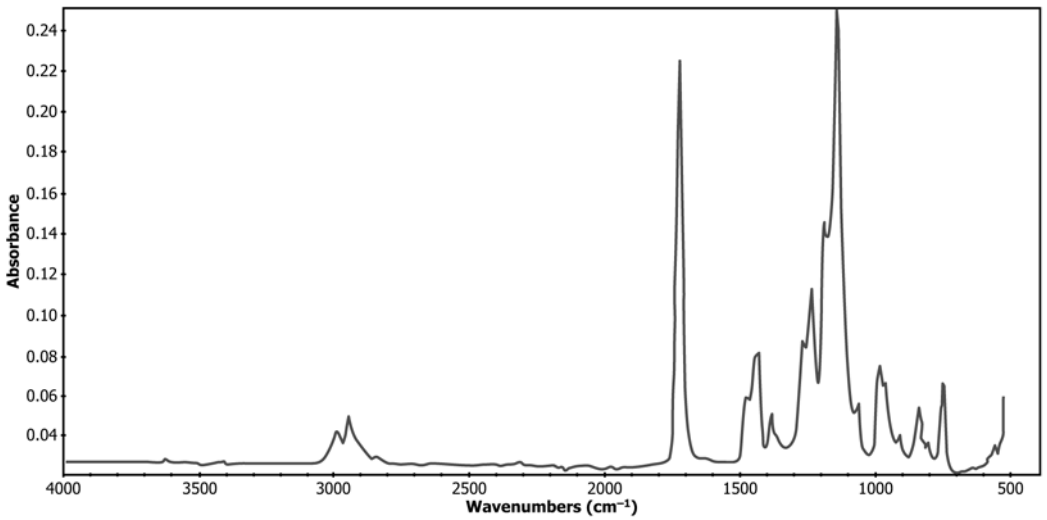
NOTE 1—Implant uses are medical applications implanted in the human body and devices that are in contact with bodily fluids or tissues for greater than 24 h; that is, prolonged (24 h to 30 days) or permanent (> 30 days) exposure. Non-implant uses are medical applications in which the device is in contact with bodily fluids or tissues for 24 h or less (that is, limited exposure).

5.2 The class and grade of unfilled acrylic plastic shall be designated in accordance with Classification D788.

6. Chemical Composition

6.1 The acrylic resin shall be a homopolymer of MMA or a random co-polymer of MMA and other vinyl monomers where MMA constitutes the majority of the composition. No additives other than radiopaque fillers or stabilizers shall be used.

6.2 The acrylic resin shall yield an infrared transmittance spectrum that exhibits major transmittance bands at the same



NOTE 1—Spectrum courtesy of Wright Medical Technology, Memphis, TN. Nicolet Magna IR spectrometer, Attenuated Total Reflectance mode.

FIG. 1 Poly(Methyl Methacrylate) Homopolymer Infrared Spectrum