



Standard Specification for Acrylic Bone Cement¹

This standard is issued under the fixed designation F451; 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 self-curing resins used primarily for the fixation of internal orthopedic prostheses. The mixture may be used in either the predough or dough stage in accordance with the manufacturer's recommendations.

1.2 Units of premeasured powder and liquid are supplied in a form suitable for mixing. The mixture then sets in place.

1.3 While a variety of copolymers and comonomers may be incorporated, the composition of the set cement shall contain poly(methacrylic acid esters) as its main ingredient.

1.4 This specification covers compositional, physical performance, and biocompatibility as well as packaging requirements. The biocompatibility of acrylic bone cement as it has been traditionally formulated and used has been reported in the literature (1, 2).²

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

1.6 *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:*³

D638 Test Method for Tensile Properties of Plastics

D695 Test Method for Compressive Properties of Rigid Plastics

D1193 Specification for Reagent Water

¹ This specification 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 Oct. 1, 2016. Published December 2016. Originally approved in 1976. Last previous edition approved in 2008 as F451 – 08. DOI: 10.1520/F0451-16.

² The boldface numbers in parentheses refer to the list of references at the end of this standard.

³ 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.

D3835 Test Method for Determination of Properties of Polymeric Materials by Means of a Capillary Rheometer
F619 Practice for Extraction of Medical Plastics
F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
F749 Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit
F756 Practice for Assessment of Hemolytic Properties of Materials
F763 Practice for Short-Term Screening of Implant Materials
F813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices
F895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity
F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Insertion into Bone

2.2 *ANSI/ADA Standard:*

No. 15 Specification for Acrylic Resin Teeth⁴

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *doughing time*—the time after commencement of mixing at which the mixture ceases to adhere to a standard probe (see 7.5).

3.1.2 *exothermic or maximum temperature*—the maximum temperature of the mixture due to self-curing in a standard mold (see 7.6).

3.1.3 *extrusion*—the rate of flow of the material through a standard orifice under load (see 7.8.1).

3.1.4 *intrusion*—the distance of flow of the mixture into a standard mold under load (see 7.8.3).

3.1.5 *setting time*—the time after commencement of mixing at which the temperature of the curing mass equals the average of the maximum and ambient temperatures (see 7.7).

3.1.6 *unit*—one package or vial of premeasured powder component and one package or vial of premeasured liquid component.

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