Designation: F1855 – 00 (Reapproved 2019)

# Standard Specification for Polyoxymethylene (Acetal) for Medical Applications[1]

This standard is issued under the fixed designation F1855; 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 polyoxymethylene (acetal) resin for medical applications. This specification provides requirements and associated test methods for a form of this thermoplastic which is intended for use in manufacturing medical devices, instrumentation or components thereof.

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 a specific application. Therefore properties of fabricated forms of this resin should be evaluated using appropriate test methods to assure safety and efficacy.

1.3 Although this resin has been used for specific implant applications in the United States, the use of this resin in medical devices should be restricted to non-implant applications until biocompatibility evaluations appropriate for the intended applications are successfully completed.

1.4 The biocompatibility of plastic compounds made up of polyoxymethylene (acetal) resin containing colorants, fillers, processing aids, or other additives as well as polymer blends which contain polyacetal should not be assumed on the basis of resin biocompatibility alone. Their biocompatibility must be established by testing the final (end-use) compositions using evaluation methods appropriate for the intended applications. It should be noted that the types, test levels, and biological effects of extractives yielded by the additives contained in a compound or blend may also have to be evaluated for some end-use applications.

1.5 The values stated in inch-pound 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

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.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

## 2. Referenced Documents

2.1 *ASTM Standards:*[2]

D570 Test Method for Water Absorption of Plastics

D638 Test Method for Tensile Properties of Plastics

D695 Test Method for Compressive Properties of Rigid Plastics

D732 Test Method for Shear Strength of Plastics by Punch Tool

D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement

D883 Terminology Relating to Plastics

D1600 Terminology for Abbreviated Terms Relating to Plastics

D1822 Test Method for Tensile-Impact Energy to Break Plastics and Electrical Insulating Materials

D4181 Classification for Acetal (POM) Molding and Extrusion Materials (Withdrawn 2005)[3]

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

## 3. Chemical Composition

3.1 The chemical composition of the material shall conform to Classification D4181. The FTIR spectrum of the material must be consistent with a reference or standard piece of the appropriate grade of the polymer. It may be helpful for the

[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 Dec. 1, 2019. Published December 2019. Originally approved in 1998. Last previous edition approved in 2011 as F1855–00(2011). DOI: 10.1520/F1855-00R19.

[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.