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

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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 will 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 and 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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D4181 Classification for Acetal (POM) Molding and Extrusion Materials (Withdrawn 2005)[3]

D883 Terminology Relating to Plastics

D1600 Terminology for Abbreviated Terms Relating to Plastics

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 Specification 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 reader to review Terminology D883 and Terminology D1600 for clarification of terminology.

3.2 Class 1, Grade 1 of polyoxymethylene of Group 1, 2, or 3 (as described in Specification D4181), is recommended for use in medical applications, however other grades of this polymer may be found to be acceptable through appropriate testing.

4. Physical Properties

4.1 The mechanical properties of the material shall conform to those listed in Specification D4181 for the appropriate grade and class of polymer being evaluated. Table 1 provides typical values for both physical and mechanical properties of medical grade polyoxymethylene (acetal) for medical applications.

5. Inspection and Certification

5.1 The following information shall be reported in the material certification: Grade and color identification (that is, color number).

NOTE 1—Some coloring agents have the potential to elicit an adverse biological response, therefore any grades containing pigments, dyes, or

[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.

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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.