Designation: F 1855 – 9800

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 there of.

1.2 As will any material, some characteristics may be altered by the processing techniques (such as molding, extrusion, machining, sterilization, etc.) 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 ~~510(k) cleared by the U.S. Food and Drug Administration~~ 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 *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:*

D 4181 Specification for Acetal (POM) Molding and Extrusion Materials[2]

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[1] This specification is under the jurisdiction of ASTM Committee ~~F-4~~ F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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D 883 Terminology Relating to Plastics[3]
D 1600 Terminology for Abbreviated Terms Relating to Plastics
F 748 Practices for Selecting Generic Biological Test Methods for Materials and Devices[4]

3. Chemical Composition

3.1 The chemical composition of the material shall conform to Specification D 4181. 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 standards D 883 and D 1600 for clarification of terminology.

3.2 Class 1, Grade 1 of polyoxymethylene of Group 1, 2, or 3 (as described in ASTM D 4181), 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 D 4181 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 additives should be separately evaluated for biocompatibility as appropriate for the particular application.

6. Biocompatibility

6.1 Biocompatibility of acetal resins and implant devices made using these materials shall be determined in accordance with Practice F 748, unless otherwise agreed upon by packager and consumer, and regulating bodies.**(1-5)**[5] Any potential filler colorants, processing aids, or sterilization processes, or all of these, anticipated for the end product should be incorporated in these tests.

7. Keywords

7.1 acetal; copolymer; homopolymer; polyoxymethylene; thermoplastic resin

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[2] *Annual Book of ASTM Standards*, Vol 08.02.
[3] *Annual Book of ASTM Standards*, Vol 08.01.
[4] *Annual Book of ASTM Standards*, Vol ~~03.03.~~ 13.01.
[5] The boldface numbers given in parentheses refer to a list of references at the end of the text.

TABLE 1 Physical and Mechanical Properties of Medical Grade Polyoxymethylene (Acetal) for Medical Applications

	Temperature	Units	ASTM Test Method	Results
Physical:				
Specific Gravity	73°	gms/cc	D 792	1.41
Water Absorption	73°	%	D 570	0.22
Equilibrium	73°	%	D 570	0.8
Mechanical:				
Tensile Yeild Strength	73°	10^3 psi	D 638	8.8
Tensile Elongation Break	73°	%	D 638	75
Tensile Modulus	73°	10^3 psi	D 638	380–390
Tensile Impact Strength		ft-lb/in.	D 1822	90
Compressive Strength				
1% deflection		10^3psi	D 695	4.5
10% deflection		10^3psi	D 695	16.0
Sheer Strength	73°	10^3psi	D 732	7.7

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The intent of this specification is to guide the user in selection of an appropriate grade of polyoxymethylene when considering the use of this polymer in a medically related application. This specification does not attempt to cover all tests that may be applicable to the specific application, but is meant to aid the user in the selection process.

References

(**1**) Autian, J., Toxicological Evaluation of Biomaterials: "Primary Acute Toxicity Screening Program," *Journal of Artificial Organs,* Vol 1, No. 1, 1977.
(**2**) Autian, J. "The New Field of Plastic Toxicological Methods and Results," *CRC Critics Review in Toxicology,* 1973.
(**3**) Homsy, C.A., Ansevin, K.D., O'Brannon, W., Thompson, S.H., Hodge, R., and Estrella, M.E., "Rapid in Vitro Screening of Polymers for Biocompatibility," *Journal of Macromolecular Science, Chemistry,* Vol A4, No. 3, May 1970, pp 615-634.
(**4**) *Biological Evaluation of Medical Devices-Part 1: Guidance on Selection of Tests,"* American National Standard, ANSI/AAMI 10993-1: 1994.
(**5**) Alpert, Susan, "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' ", *General Program Memorandum #95-1,* May 1, 1995. Online: http://www.fda.gov/cdrh/g951.html