



Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments¹

This standard is issued under the fixed designation F 1839; 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 rigid unicellular polyurethane foam for use as a standard material for performing mechanical tests utilizing orthopaedic devices or instruments. The specification is applicable to sheets or blocks of foam, or foam that is made by the user using a two-part liquid mixture.

1.2 This specification covers polyurethane foam material that is used in the laboratory for mechanical testing, as described in 1.1. These materials are not intended for implantation into the human body.

1.3 The foam described herein possesses mechanical properties which are on the order of those reported for human cancellous bone. See Appendix X1 Rationale for further information regarding the appropriateness of using the specified foam as a model for human cancellous bone.

1.4 This specification covers compositional requirements, physical requirements, mechanical requirements, and test methods for rigid polyurethane foam in the solid final form.

1.5 This specification provides qualification criteria for vendor or end-user processes and acceptance criteria for individual material lots.

1.6 This specification provides mechanical properties of five different grades of foam in the solid final form.² A foam that does not meet the specified mechanical properties shall be identified as an ungraded foam.

1.7 Unless otherwise indicated, the values stated in SI units are to be regarded as standard. The values in parentheses are given for information only.

1.8 The following precautionary statement pertains to the test method portion only, Section 8, of this specification: *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:

C 273 Test Method for Shear Test in Flatwise Plane of Flat Sandwich Constructions or Sandwich Cores³

D 1621 Test Method for Compressive Properties of Rigid Cellular Plastics⁴

D 1622 Test Method for Apparent Density of Rigid Cellular Plastics⁴

E 4 Practices for Load Verification of Testing Machines⁵

F 117 Test Method for Driving Torque of Medical Bone Screws⁶

F 1691 Test Method for Determining the Axial Pullout of Medical Bone Screws⁶

2.2 ISO Standards:

5835-1 Implants for Surgery - Metal Bone Screws with Hexagonal Driver Connection, Spherical Under Surface of Head, Asymmetrical Thread - Dimensions⁷

3. Terminology

3.1 Definitions:

3.1.1 *final form*—the condition of the foam product when used by the end-user to perform tests of orthopaedic devices or instruments. The condition of the foam product of which all physical and mechanical tests required by this specification are performed.

3.1.1.1 *solid*—the foam is in a uniform solid form, such as a slab, plate or block.

3.1.2 *foam rise direction*—the nominal direction that the foam rises during the polymerization (“foaming”) process, either at the suppliers production facilities for the solid supplied foam, or at the end-users facilities for foam produced from the liquid supplied form. The foam rise direction shall be marked on the foam block or indicated in the shipping documentation for foam that is supplied in the Solid form.

3.1.3 *grades*—The grade designation refers to the nominal density of the foam, in its Solid Final form, expressed in units of kg/m³ (lbm/ft³). Five grades of foam have been defined in this specification. Their nominal densities are given below:

¹ This test method is under the jurisdiction of ASTM Committee F-04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

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² General Plastics Manufacturing Company, 4910 Burlington Way, Tacoma Washington, 98409, producers of Last-a-Foam® polyurethane foam, has been found to be a satisfactory supplier of this material. Other manufacturers of rigid polyurethane foam may also be available.

³ Annual Book of ASTM Standards, Vol 15.03.

⁴ Annual Book of ASTM Standards, Vol 08.01.

⁵ Annual Book of ASTM Standards, Vol 03.01.

⁶ Annual Book of ASTM Standards, Vol 13.01.

⁷ Available from American National Standards Institute, 11 W. 42nd St., New York, NY 10036.