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Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments[1]

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.

ε^1 NOTE—Units information was editorially corrected in August 2009.

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. A foam that does not meet the specified mechanical properties shall be identified as an ungraded foam.

~~1.7Unless otherwise indicated, the values stated in SI units are to be regarded as standard. The values in parentheses are mathematical conversions to inch-pound units that are provided for information only and are not considered standard.~~

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

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:*[2]

C 273 Test Method for Shear Properties of Sandwich Core Materials
D 1621 Test Method for Compressive Properties Of Rigid Cellular Plastics
D 1622 Test Method for Apparent Density of Rigid Cellular Plastics
E 4 Practices for Force Verification of Testing Machines
F 543 Specification and Test Methods for Metallic Medical Bone Screws

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.

3.1.1.1 *Discussion*—This is the condition of the foam product of which all physical and mechanical tests required by this specification are performed.

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

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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.

3.1.2 *foam rise direction*—the nominal direction that the foam rises during the polymerization ("foaming") process, either at the supplier's production facilities for the solid supplied foam, or at the end-user's 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/m^3 ~~(lbm/ft^3)~~.. Ten grades of foam have been defined in this specification. Their nominal densities are:

~~Grade 5:~~	~~80.1 kg/m^3 (5.0 lbm/ft^3)~~
Grade 5:	80.1 kg/m^3
~~Grade 10:~~	~~160.2 kg/m^3 (10.0 lbm/ft^3)~~
Grade 10:	160.2 kg/m^3
~~Grade 12:~~	~~192.2 kg/m^3 (12.0 lbm/ft^3)~~
Grade 12:	192.2 kg/m^3
~~Grade 15:~~	~~240.3 kg/m^3 (15.0 lbm/ft^3)~~
Grade 15:	240.3 kg/m^3
~~Grade 20:~~	~~320.4 kg/m^3 (20.0 lbm/ft^3)~~
Grade 20:	320.4 kg/m^3
~~Grade 25:~~	~~400.5 kg/m^3 (25.0 lbm/ft^3)~~
Grade 25:	400.5 kg/m^3
~~Grade 30:~~	~~480.5 kg/m^3 (30.0 lbm/ft^3)~~
Grade 30:	480.5 kg/m^3
~~Grade 35:~~	~~560.6 kg/m^3 (35.0 lbm/ft^3)~~
Grade 35:	560.6 kg/m^3
~~Grade 40:~~	~~640.7 kg/m^3 (40.0 lbm/ft^3)~~
Grade 40:	640.7 kg/m^3
~~Grade 50:~~	~~800.9 kg/m^3 (50.0 lbm/ft^3)~~
Grade 50:	800.9 kg/m^3

Foam that does not fit into one of these ten grades because it does not meet one or more of the physical requirements of Section 4 is termed ungraded.

3.1.3.1 *Discussion*—Grade 5 designates the nominal value of 5 lbm/ft^3.

3.1.4 *supplied form*—the condition of the foam product when received from the supplier by the end user.

3.1.4.1 *Discussion*—The supplied form may be a solid or a liquid. The foam may be in a uniform solid form such as a slab, plate, or block or a liquid in which two liquid components (base and activator) can be mixed by the end user to produce a rigid, unicellular foam slab.

4. Physical and Mechanical Requirements

4.1 *Composition*—The material shall be supplied either in solid or liquid form. The solid or combined liquid parts shall produce a foam consisting of polyether polyurethane.

4.2 *Appearance*:

4.2.1 *Solid Supplied Form*—The solid foam slab shall be free of obvious extraneous matter, and appear to the unaided eye to be uniform throughout the slab in color and porosity.

4.2.2 *Liquid Supplied Form*—The two liquid components shall appear to the unaided eye throughout their volumes to be uniform and free from obvious extraneous matter or particulate debris.

4.2.3 *Solid Final Form*—The solid foam slab shall be free of obvious extraneous matter, and appear to the unaided eye to be uniform throughout the slab in color and porosity.

4.3 *Void Content*—The material in the solid final form shall meet the requirements of Table 1 for voids, cracks and nonuniform areas, when examined using the procedures described in 8.1. All specimens shall meet this requirement.

4.4 *Density*—The material in the solid final form shall have a density within the ranges specified in Table 2, according to the foam's grade specification. The density shall be determined using the method described in 8.2. All specimens shall meet this requirement.

4.5 *Dimensional Stability*—The material in the solid final form shall have an average percentage thickness change less than 5.0 %, when tested according to the method described in 8.3.

4.6 *Compressive Strength*—The material in the solid final form shall meet the compressive strength requirements given in Table 3, when tested according to the method described in 8.4. All specimens shall meet this requirement.

4.7 *Compressive Modulus*—The material in the solid final form shall meet the compressive modulus requirements given in Table 4, when tested according to the method described in 8.4. All specimens shall meet this requirement.

4.8 *Shear Strength*—The material in the solid final form shall meet the shear strength requirements given in Table 5, when tested according to the method described in 8.5. All specimens shall meet this requirement.

4.9 *Shear Modulus*—The material in the solid final form shall meet the shear modulus requirements given in Table 6, when tested according to the method described in 8.5. All specimens shall meet this requirement.

4.10 *Screw Pullout*—The material in the solid final form shall meet the screw pullout requirements given in Table 7, when tested according to the method described in 8.6. All specimens shall meet this requirement.

5. Significance and Use

5.1 This specification describes the compositional requirements, physical requirements, mechanical requirements, and test

TABLE 1 Requirements for Voids, Cracks, and Nonuniform Areas

Defects	Requirements
Voids	
~~Void depth (measured perpendicular to slab's transverse plane)~~	~~Void depth shall be less than 50 % of the slab thickness, and less than 6.35 mm (0.250 in.)~~
Void depth (measured perpendicular to slab's transverse plane)	Void depth shall be less than 50 % of the slab thickness, and less than 6.35 mm
Void diameter (measured parallel to slab's transverse plane)	
~~Larger than 6.35 mm (0.250 in.)~~	~~None allowed in any grade~~
Larger than 6.35 mm	None allowed in any grade
~~Between 3.18 mm (0.125 in.) and 6.35 mm (0.250 in.)~~	~~No more than 10 allowed per 230 cm^2 (36 in.^{2}) surface area for Grades 5 and 10. No more than 1 allowed for Grades 12, 15, 20, 25, 30, and 35. None allowed for Grades 40 and 50.~~
Between 3.18 mm and 6.35 mm	No more than 10 allowed per 230 cm^2 surface area for Grades 5 and 10. No more than 1 allowed for Grades 12, 15, 20, 25, 30, and 35. None allowed for Grades 40 and 50.
~~Between 1.57 mm (0.062 in.) and 3.18 mm (0.125 in.)~~	~~No more than 20 allowed per 230 cm^2 (36 in.^{2}) surface area for Grades 5 and 10. No more than 6 allowed for Grades 12, 15, 20, 25, 30, and 35. No more than 3 allowed for Grades 40 and 50.~~
Between 1.57 mm and 3.18 mm	No more than 20 allowed per 230 cm^2 surface area for Grades 5 and 10. No more than 6 allowed for Grades 12, 15, 20, 25, 30, and 35. No more than 3 allowed for Grades 40 and 50.
Cracks	None allowed
Non-uniform areas	Concentrated areas of poor construction, irregular cells, and hard and soft spots shall not exceed 10 % of the visible surface area

TABLE 2 Grade Designation and Density

Grade	Minimum Density, kg/m^3 ~~(lbm/ft^3)~~	Maximum Density, kg/m^3 ~~(lbm/ft^3)~~
~~5~~	~~72.10 (4.5)~~	~~88.10 (5.5)~~
5	72.10	88.10
~~10~~	~~144.0 (9.0)~~	~~176.0 (11.0)~~
10	144.0	176.0
~~12~~	~~173.0 (11.0)~~	~~211.5 (13.0)~~
12	173.0	211.5
~~15~~	~~216.0 (13.5)~~	~~264.5 (16.5)~~
15	216.0	264.5
~~20~~	~~288.5 (18.0)~~	~~352.5 (22.0)~~
20	288.5	352.5
~~25~~	~~360.5 (22.5)~~	~~440.5 (27.5)~~
25	360.5	440.5
~~30~~	~~432.5 (27.0)~~	~~528.5 (33.0)~~
30	432.5	528.5
~~35~~	~~504.5 (31.5)~~	~~617.0 (38.5)~~
35	504.5	617.0
~~40~~	~~576.5 (36.0)~~	~~705.0 (44.0)~~
40	576.5	705.0
~~50~~	~~721.0 (45.0)~~	~~881.0 (55.0)~~
50	721.0	881.0

TABLE 3 Requirements for Compressive Strength

Grade	Minimum Compressive Strength, MPa (psi)		Maximum Compressive Strength, MPa (psi)
5	0.4495	(65.20)	0.7800(113.0)
5	0.4495	0)	0.7800
10	1.745	(253.0)	2.820(409.0)
10	1.745	2.0)	2.820
12	2.485	(360.5)	3.970(576.0)
12	2.485	3.5)	3.970
15	3.820	(554.0)	6.050(877.5)
15	3.820	(554.0)	6.050
20	6.630	(961.5)	10.45(1515)
20	6.630	1.5)	10.45
25	10.15	(1470)	16.00(2320)
25	10.15	1470)	16.00
30	14.30	(2075)	22.70(3290)
30	14.30	2075)	2.70
35	19.15	(2775)	30.55(4430)
35	19.15	(2775)	30.55
40	24.60	(3570)	39.55(5735)
40	24.60	3570)	39.55
50	37.35	(5415)	61.05(8855)
50	37.35	(5415)	61.05

TABLE 4 Requirements for Compressive Modulus

Grade	Minimum Compressive Modulus, MPa (psi)		Maximum Compressive Modulus, MPa (psi)
5	12.30	(1780)	20.35(2950)
5	12.30	(1780)	20.35
10	45.75	(6640)	71.70(10 400)
10	45.75	(6640)	71.70
12	64.50	(9350)	100.5(14 575)
12	64.50	(9350)	100.5
15	98.00	(14 200)	151.0(21 900)
15	98.00	14 200)	151.0
20	167.5	(24 295)	257.5(37 345)
20	167.5	25)	257.5
25	253.5	(36 770)	390.0(56 565)
25	253.5	36 770)	390.0
30	355.5	(51 560)	548.5(79 555)
30	355.5	51 560)	548.5
35	472.0	(68 460)	732.0(106 170)
35	472.0	(68 460)	732.0
40	603.0	(87 460)	941.0(136 480)
40	603.0	(87 460)	941.0
50	907.5	(131 620)	1435(208 130)
50	907.5	131 620)	1435

methods for rigid unicellular polyurethane foam for use in testing orthopaedic devices or instruments.

5.2 This foam described in this specification is not intended to replicate the mechanical properties of human or animal bone. The requirements of this specification are intended to provide a consistent and uniform material with properties on the order of human cancellous bone to use as a test medium when testing various orthopaedic devices, such as bone screws.

6. Apparatus

6.1 *Analytical Balance or Scale*—capable of weighing foam specimens to the nearest mg.

6.2 *Micrometer Dial Gage or Caliper*—capable of measuring dimensions of the foam specimens to ±0.1 %.

6.3 *Conditioning Oven*—Forced-air circulating oven capable of maintaining 121 ± 2.8°C (250 ± 5°F) for 24 h.

6.4 *Desiccator*—containing desiccant with high affinity for water vapor (anhydrous calcium chloride or equivalent).

6.5 *Vacuum Apparatus*—capable of applying a vacuum pressure of 508 mm (20 in.) of mercury to foam specimen for dimensional stability test.

6.6 *Testing Machine and Load Cell*—conforming to Practices E 4 and capable of applying tensile and compressive loads at a constant displacement rate.

7. Sampling and Test Specimens

7.1 The number of test specimens and the specimen sizes required for physical characterization and mechanical testing are