



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

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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.*

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.

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:

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.

Grade 10:	160.2 kg/m ³ (10.0 lbm/ft ³)
Grade 12:	192.2 kg/m ³ (12.0 lbm/ft ³)
Grade 15:	240.3 kg/m ³ (15.0 lbm/ft ³)
Grade 20:	320.4 kg/m ³ (20.0 lbm/ft ³)
Grade 40:	640.7 kg/m ³ (40.0 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 *solid*—the foam is in a uniform solid form, such as a slab, plate or block.

3.1.4.2 *liquid*—two liquid components (base and activator) that can be mixed by the end-user to produce a rigid, unicellular foam slab.

3.1.5 *ungraded*—foam which does not fit into one of the five grades specified in 3.1, due to the foam not meeting one or more of the physical or mechanical requirements of Section 4.

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 its volume 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.

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 inch)
Void Diameter (measured parallel to slab's transverse plane.)	
Larger than 6.35 mm (0.250 inch)	None allowed in any grade
Between 3.18 mm (0.125 inch) and 6.35 mm (0.250 inch)	No more than 1 allowed per 230 cm ² (36 in ²) surface area for grades 10, 12 and 15. None allowed in grades 20 and 40.
Between 1.57 mm (0.062 inch) and 3.18 mm (0.125 inch)	No more than 6 allowed per 230 cm ² (36 in ²) surface area for grades 10, 12 and 15. No more than 3 allowed in grades 20 and 40.
Cracks	
	None allowed
Nonuniform areas	
	Concentrated areas of poor construction, irregular cells, and hard and soft spots shall not exceed 10 % of the visible surface area

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 of change less than 1.0 %, 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. The values in Table 3 are stated at ± 16.0 kg/m³ (± 1.0 lbm/ft³) around each grade's nominal density.

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. The values in Table 4 are stated at ± 16.0 kg/m³ (± 1.0 lbm/ft³) around each grade's nominal density.

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. The values in Table 5 are stated at ± 16.0 kg/m³ (± 1.0 lbm/ft³) around each grade's nominal density.

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. The values in Table 6 are stated at ± 16.0 kg/m³ (± 1.0 lbm/ft³) around each grade's nominal density.

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 standard describes the compositional requirements, physical requirements, mechanical requirements, and test methods for rigid unicellular polyurethane foam for use in testing orthopaedic devices or instruments.

5.2 This foam described in this standard is not intended to replicate the mechanical properties of human or animal bone. The requirements of this standard 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

TABLE 2 Grade Designation and Density

Grade	Minimum Density kg/m ³ (lbm/ft ³)	Maximum Density kg/m ³ (lbm/ft ³)
10	144.2 (9.0)	176.2 (11.0)
12	176.2 (11.0)	208.2 (13.0)
15	224.3 (14.0)	256.3 (16.0)
20	304.4 (19.0)	336.4 (21.0)
40	624.7 (39.0)	656.8 (41.0)

TABLE 3 Requirements for Compressive Strength

Grade	Minimum Compressive Strength, kPa (psi)		Maximum Compressive Strength, kPa (psi)	
10	2095	(304)	2895	(420)
12	2895	(420)	3790	(550)
15	4280	(620)	5315	(770)
20	7000	(1015)	8245	(1195)
40	22 410	(3250)	24 300	(3525)

TABLE 4 Requirements for Compressive Modulus

Grade	Minimum Compressive Modulus, kPa (psi)		Maximum Compressive Modulus, kPa (psi)	
10	56 300	(8165)	76 700	(11 125)
12	76 700	(11 125)	99 200	(14 390)
15	111 200	(16 130)	136 650	(19 820)
20	178 100	(25 830)	207 800	(30 140)
40	539 600	(78 260)	582 800	(84 530)

TABLE 5 Requirements for Shear Strength

Grade	Minimum Shear Strength, kPa (psi)		Maximum Shear Strength, kPa (psi)	
10	1650	(240)	2170	(315)
12	2170	(315)	2725	(395)
15	3000	(435)	3620	(525)
20	4590	(665)	5275	(765)
40	12 340	(1790)	13 240	(1920)

TABLE 6 Requirements for Shear Modulus

Grade	Minimum Shear Modulus, kPa (psi)		Maximum Shear Modulus, kPa (psi)	
10	20 820	(3020)	27 680	(4015)
12	27 680	(4015)	35 100	(5090)
15	39 000	(5655)	47 130	(6835)
20	60 160	(8725)	69 400	(10 060)
40	167 170	(24 245)	179 470	(26 030)

TABLE 7 Requirements for Screw Pullout

Grade	Minimum Pullout, N (lb)		Maximum Pullout, N (lb)	
10	335	(75)	415	(95)
12	400	(90)	545	(125)
15	485	(110)	675	(150)
20	670	(150)	800	(180)
40	2455	(550)	2755	(620)

specimens to the nearest $\pm 0.1\%$.

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

6.3 *Conditioning Oven*—Forced-air circulating oven capable of maintaining $121 \pm 2.8^\circ\text{C}$ ($250 \pm 5^\circ\text{F}$) for 24 h.

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

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

6.6 A 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 described in 8.1-8.6. Test specimens are required for each grade and formulation.

7.2 Test specimens shall be solid foam blocks. The short-transverse direction of the specimens shall coincide with the foam rise direction of the original foam bun.

8. Procedure

8.1 Determination of Void Content:

8.1.1 Use the foam block specimens described and specified in 8.2-8.6.

8.1.2 Examine all of the surfaces and edges of test specimens for voids and nonuniform areas with the unaided eye. Measure the dimensions of the void or nonuniform areas using an instrument capable of measuring ± 0.025 mm (0.001 inch).

8.2 Determination of Foam Density:

8.2.1 Prepare three specimens, 25.4 by 25.4 by 25.4 mm (1 by 1 by 1 in.) from solid foam.

8.2.2 Determine the apparent density of the three foam specimens, in kg/m^3 (lbm/ft^3), in accordance with Test Method D 1622.

8.2.3 Calculate the average apparent density of the three foam specimens.

8.3 Determination of Dimensional Stability:

8.3.1 Prepare three specimens, 25.4 by 25.4 by 12.7 mm (1 by 1 by 0.5 in.) from solid foam.

8.3.2 Condition the specimen for 24 h at $21 \pm 2.8^\circ\text{C}$ ($70 \pm 5^\circ\text{F}$) and $50 \pm 10\%$ relative humidity. Measure the specimen thickness near the center of the length to ± 0.025 mm (0.001 in.) and mark the location of the measurement.

8.3.3 Place the specimen on a 6.35 mm (0.25 in.) thick aluminum plate and apply a minimum vacuum pressure of 508 mm (20 in.) of mercury under a vacuum bag or diaphragm. Place this assembly in a circulating forced-air oven for 2 h minimum at $121 \pm 2.8^\circ\text{C}$ ($250 \pm 5^\circ\text{F}$). Remove the assembly and allow to cool to 49°C (120°F) or less while maintaining the vacuum.

8.3.4 Recondition and remeasure the thickness at the marked location in accordance with 8.3.2. Calculate the percent thickness change.

8.3.5 Calculate the average percent thickness change of the three specimens.

8.4 Determination of Compressive Strength and Modulus:

8.4.1 Prepare five specimens, 50.8 by 50.8 by 25.4 mm (2 by 2 by 1 in.), from solid foam, with the thickness of the specimen parallel to the foam rise direction. Measure the dimensions within ± 0.025 mm (± 0.001 in.). The specimens shall be conditioned at $24 \pm 2.8^\circ\text{C}$ ($75 \pm 5^\circ\text{F}$) for 3 h prior to testing.

8.4.2 Test in accordance with Test Method D 1621 at $24 \pm 2.8^\circ\text{C}$ ($75 \pm 5^\circ\text{F}$). The specimens shall be oriented such that the axis of the compressive load is applied parallel to the foam rise direction.

8.4.3 Determine the compressive strength using Procedure A of Test Method D 1621 and the maximum compressive modulus for each specimen.

8.4.4 Calculate the average compressive strength and modulus of the five specimens.

8.5 Determination of Shear Strength and Modulus:

8.5.1 Prepare five specimens, 76.2 by 25.4 by 6.35 mm (3