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

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, health, and*

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 F04.21 on Osteosynthesis.

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environmental practices and determine the applicability of regulatory limitations prior to use.

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*²

[C273 Test Method for Shear Properties of Sandwich Core Materials](#)

[D1621 Test Method for Compressive Properties of Rigid Cellular Plastics](#)

[D1622 Test Method for Apparent Density of Rigid Cellular Plastics](#)

[E4 Practices for Force Verification of Testing Machines](#)

[F543 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. In the final form the foam is in a uniform solid 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 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.

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.

3.1.3 *grades*—the grade designation refers to the nominal density of the foam, in its solid final form, expressed in units of kg/m³. Ten grades of foam have been defined in this specification. Their nominal densities are:

Grade 5:	80.1 kg/m ³
Grade 10:	160.2 kg/m ³
Grade 12:	192.2 kg/m ³
Grade 15:	240.3 kg/m ³
Grade 20:	320.4 kg/m ³
Grade 25:	400.5 kg/m ³
Grade 30:	480.5 kg/m ³
Grade 35:	560.6 kg/m ³
Grade 40:	640.7 kg/m 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/ft³.

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 supplied form 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 final form 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.

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
Void diameter (measured parallel to slab’s transverse plane)	
Larger than 6.35 mm	None allowed in any grade
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 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
Nonuniform 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	Maximum Density, kg/m ³
5	72.10	88.10
10	144.0	176.0
12	173.0	211.5
15	216.0	264.5
20	288.5	352.5
25	360.5	440.5
30	432.5	528.5
35	504.5	617.0
40	576.5	705.0
50	721.0	881.0

TABLE 3 Requirements for Compressive Strength

Grade	Minimum Compressive Strength, MPa	Maximum Compressive Strength, MPa
5	0.4495	0.7800
10	1.745	2.820
12	2.485	3.970
15	3.820	6.050
20	6.630	10.45
25	10.15	16.00
30	14.30	22.70
35	19.15	30.55
40	24.60	39.55
50	37.35	61.05

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,

TABLE 4 Requirements for Compressive Modulus

Grade	Minimum Compressive Modulus, MPa	Maximum Compressive Modulus, MPa
5	12.30	20.35
10	45.75	71.70
12	64.50	100.5
15	98.00	151.0
20	167.5	257.5
25	253.5	390.0
30	355.5	548.5
35	472.0	732.0
40	603.0	941.0
50	907.5	1435

TABLE 5 Requirements for Shear Strength

Grade	Minimum Shear Strength, MPa	Maximum Shear Strength, MPa
5	0.420	0.805
10	1.225	2.010
12	1.610	2.580
15	2.235	3.510
20	3.395	5.275
25	4.665	7.275
30	6.025	9.495
35	7.460	11.95
40	8.960	14.55
50	12.10	20.40

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

TABLE 6 Requirements for Shear Modulus

Grade	Minimum Shear Modulus, MPa	Maximum Shear Modulus, MPa
5	5.460	9.000
10	15.15	22.75
12	19.70	29.20
15	27.10	39.70
20	40.75	59.25
25	55.70	81.15
30	71.70	105.0
35	88.65	131.0
40	106.5	159.0
50	144.0	220.0

TABLE 7 Requirements for Screw Pullout

Grade	Minimum Pullout, N	Maximum Pullout, N
5	56.00	176.0
10	220.0	453.0
12	309.5	592.5
15	464.5	831.0
20	770.0	1310
25	1125	1890
30	1520	2570
35	1950	3355
40	2400	4245
50	3380	6350

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 $\pm 0.1\%$.

6.3 *Conditioning Oven*—Forced-air circulating oven capable of maintaining $121 \pm 2.8^\circ\text{C}$ 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 E4 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.

8.2 Determination of Foam Density:

8.2.1 Prepare three specimens, 25.4 by 25.4 by 25.4 mm from solid foam.

8.2.2 Determine the apparent density of the three foam specimens, in kg/m^3 , in accordance with Test Method **D1622**.

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 from solid foam.

8.3.2 Condition the specimen for 24 h at 21 ± 2.8 °C and 50 ± 10 % relative humidity. Measure the specimen thickness near the center of the length to ± 0.025 mm and mark the location of the measurement.

8.3.3 Place the specimen on a 6.35-mm thick aluminum plate and apply a minimum vacuum pressure of 508 mm of mercury under a vacuum bag or diaphragm. Place this assembly in a circulating forced-air oven for not less than 2 h at 121 ± 2.8 °C. Remove the assembly and allow to cool to 49 °C 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, from solid foam, with the thickness of the specimen parallel to the foam rise direction. Measure the dimensions within ± 0.025 mm. The specimens shall be conditioned at 24 ± 2.8 °C for 3 h prior to testing.

8.4.2 Test in accordance with Test Method **D1621** at 24 ± 2.8 °C. 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 **D1621** 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, from solid foam, with the thickness of the specimen parallel to the foam rise direction. Measure the dimensions within ± 0.025 mm. The specimens shall be conditioned at 24 ± 2.8 °C for 3 h before testing.

8.5.2 Bond the edges of the foam specimen directly to the shear plates with an appropriate adhesive, such as an epoxy, so that the foam rise direction is perpendicular to the plane of maximum shear stress.

8.5.3 Test in accordance with Test Method **C273**.

8.5.4 Determine the shear strength and shear modulus for each specimen.

8.5.5 Calculate the average shear strength and modulus of the five specimens.

8.6 *Determination of Screw Pullout Strength:*

8.6.1 Prepare five specimens, 50.8 by 50.8 by 25.4 mm, from solid foam, with the thickness of the specimen parallel to the foam rise direction.

8.6.2 Obtain five steel screws or threaded tools that meet the thread requirements given in Specification **F543**, Annex A5. Grades 5, 10, 12, 15, 20, and 25 shall use screws or threaded tools with the thread form of HB 6.5 screws (see Table A5.4 of Specification **F543**, Annex A5), while Grades 30, 35, 40, and 50 shall utilize screws or threaded tools with the thread form of HA 4.5 screws (see Table A5.2 of Specification **F543**, Annex A5).

8.6.3 Drill a 3.2-mm hole in the center of each foam specimen, parallel to the thickness direction. The hole shall be positioned a minimum of 10 mm from any void or nonuniform area. Tap the hole to a minimum depth of 25.4 mm using a tap that corresponds to HB 6.5 or HA 4.5, as appropriate.

8.6.4 Insert the screw or threaded tool into each foam specimen to a depth of 20 mm.

8.6.5 Test in accordance with Specification **F543**, Annex A3.

8.6.6 Determine the maximum force, in Newtons, required to remove the screw or threaded tool from the foam specimen.

8.6.7 Calculate the average pullout force for the five specimens.

9. Report

9.1 Include the following information in the test report of the mechanical properties of the foam:

9.1.1 The lot number, specified grade (if applicable), manufacturer, and date of manufacture of the solid form or two-part liquid mixture.

9.1.2 For foams supplied in the liquid form, the report shall include the following:

9.1.2.1 Mixing ratio of the two liquid parts (expressed as a ratio of the base and activator based on either weight or volume).

9.1.2.2 Mixing and casting technique (for example, rate of stirring, pressurization, and so forth).

9.1.2.3 Ambient temperature and humidity during mixing and casting.

9.1.2.4 Any other parameters that may affect the quality of the polyurethane foam in the solid final form.

9.1.3 Any test results that did not meet the requirements of Section 4.

9.1.4 The average and standard deviation of the foam density as determined in **8.2**.

9.1.5 The average and standard deviation of the percent thickness change as determined in **8.3**.

9.1.6 The average and standard deviation of the compressive strength and modulus as determined in **8.4**.

9.1.7 The average and standard deviation of the shear strength and modulus as determined in **8.5**.

9.1.8 The average and standard deviation of the screw or threaded tool pullout force as determined in **8.6**.

10. Qualification and Acceptance Criteria

10.1 *Qualification Criteria:*

10.1.1 *Solid Supplied Form*—A supplier of foam in the solid form shall demonstrate that its production process (for a lot of material in a particular grade) results in foam that meets all of the physical and mechanical requirements of Section 4, by providing a report described in Section 9. Once the supplier has