



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 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 Properties of Sandwich Core Materials²
- D 1621 Test Method for Compressive Properties of Rigid Cellular Plastics³
- D 1622 Test Method for Apparent Density of Rigid Cellular Plastics³
- E 4 Practices for Force Verification of Testing Machines⁴
- F 543 Specification and Test Methods for Metallic Medical Bone Screws⁵

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:

| | |
|-----------|-----------------------------------------------------|
| 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.

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² *Annual Book of ASTM Standards*, Vol 15.03.

³ *Annual Book of ASTM Standards*, Vol 08.01.

⁴ *Annual Book of ASTM Standards*, Vol 03.01.

⁵ *Annual Book of ASTM Standards*, Vol 13.01.

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 that does not fit into one of the five grades specified in 3.1 because of 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.

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.

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 diameter (measured parallel to slab's transverse plane) | |
| Larger than 6.35 mm (0.250 in.) | None allowed in any grade |
| Between 3.18 mm (0.125 in.) and 6.35 mm (0.250 in.) | 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 in.) and 3.18 mm (0.125 in.) | 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 |

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) |

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 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 in.).

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 by 1 by 0.25 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 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 C 273.

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 (2 by 2 by 1 in.), 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 F 543, Annex 4. Grades 10, 12, and 15 shall use screws or threaded tools with the thread form of HB 6.5 screws (see Table A4.4 of Specification F 543, Annex 4), while Grades 20 and 40 shall utilize screws or threaded tools with the thread form of HA 4.5 screws (see Table A4.2 of Specification F 543, Annex 4).

8.6.3 Drill a 3.2-mm (0.126-in.) hole in the center of each foam specimen, parallel to the thickness direction. The hole shall be positioned a minimum of 10 mm (0.394 in.) from any void or nonuniform area. Tap the hole to a minimum depth of 25.4 mm (1 in.) 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 (0.787 in.).

8.6.5 Test in accordance with Specification F 543, 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 foam or two-part liquid mixture.

9.1.2 For liquid supplied foams 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 supplied 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 demonstrated this, the supplier is qualified for that particular grade. Provided there are no changes made to the production process for the qualified grade, subsequent lots of material of the qualified grade are only required to meet the acceptance criteria described in 10.2.

10.1.2 *Liquid Supplied Form*—The end user of the foam provided in the liquid supplied form shall demonstrate that the solid final form produced meet all of the physical and mechanical requirements of Section 4, by providing a report described in Section 9. Once the end user has demonstrated this, the user is qualified for that particular grade. Provided there are no changes made to the production process for the qualified grade (mixing ratio, humidity, temperature, mixing and pouring technique, and so forth) subsequent lots of material of the qualified grade are only required to meet the acceptance criteria described in 10.2.

10.2 *Acceptance Criteria*—Provided the grade of foam is qualified according to the criteria described in 10.1, a lot of foam material is accepted as meeting the requirements of this standard provided the requirements of 10.2.2 and 10.2.3 are met, and reported in a manner consistent with 9.1.1-9.1.4 and 9.1.8.

10.2.1 *Test Specimens*—Five specimens, 50.8 by 50.8 by 25.4 mm (2 by 2 by 1 in.), as specified in 4.10, shall be used for the acceptance examination and testing.

10.2.2 Physical Requirements:

10.2.2.1 *Composition*—See 4.1,

10.2.2.2 *Appearance*—See 4.2.3,

10.2.2.3 *Void Content*—See 4.3, and

10.2.2.4 *Density*—See 4.4.

10.2.3 *Screw Pullout*—See 4.10.

11. Storage

11.1 The solid foam should be stored in a cool dry place between uses, and protected from exposure to light, especially direct sunlight. Exposure to ultraviolet light for an extended period of time may degrade the outer surface of the foam.

11.2 The supplier is responsible for storage of the solid foam until the time of delivery. Therefore, the supplier is responsible for ensuring that the requirements of this specification are met at time of delivery for any foam that had previously met the acceptance criteria of 10.2.

11.3 The end user is responsible for storage of the solid foam after delivery and until the time of use. Therefore, the end user is responsible for ensuring that the requirements of this specification are met at time of use for any foam which had previously met the acceptance criteria of 10.2.

12. Precision and Bias

12.1 No information is presented about either the precision or bias of this test method for evaluating appearance or void content since these test results are nonquantitative.

12.2 The precision and bias of this test method for measuring Density are essentially as specified in Test Method D 1622.

12.3 Data establishing the precision and accuracy to be expected from this test method for determining dimensional stability have not yet been obtained.

12.4 The precision and bias of this test method for measuring compressive strength and compressive modulus are essentially as specified in Test Method D 1621.

12.5 The precision and bias of this test method for measuring shear strength and shear modulus are essentially as specified in Test Method C 273.

12.6 The precision and bias of this test method for measuring Screw Pullout are essentially as specified in Specification F 543, Annex A3.

13. Keywords

13.1 bone; cellular plastic; medical devices; polyurethane; rigid foam

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 This specification provides compositional, physical, and mechanical requirements for rigid polyurethane foam. These requirements ensure a consistent and uniform material that may be used as a test medium when testing various medical devices. These rigid polyurethane foam materials are not intended for implantation into the human body.

X1.2 Researchers have found that certain densities of rigid polyurethane foam exhibit similar closed-cell structure as human cancellous bone, and possess mechanical properties that are also in the range of those of human cancellous bone **(1-4)**⁶. The uniformity and consistent properties of rigid polyurethane foam make it an ideal material for comparative testing of bone screws and other medical devices and instruments **(5-7)**. General Plastics Manufacturing Company, 4910 Burlington Way, Tacoma, WA 98409, is a producer of Last-a Foam polyurethane foam that previously met the requirements of this standard. At the time of this revision, the firm could not guarantee to meet the physical requirements for any individual sample of the material. Other manufacturers of rigid polyurethane foam may exist that can meet the requirements of this standard.

X1.3 The original purpose of this standard was to provide a consistent and uniform material for incorporation into the revision of Specification F 543, Annex A 2 for use as a standard medium for testing the driving torque of medical bone screws. Future applications may include: standard material for pullout tests of medical bone screws, standard material for measuring cutting diameter of intramedullary reamers, and standard material for measuring the cutting performance of medical drills.

X1.4 The mechanical properties of the foam that may be important for standardization or for comparison to human cancellous bone will likely depend on the particular test method that is being developed. It is suggested that a test method that references this specification foam material should also address the relative importance of the different mechanical properties of the foam and suggest foam grades which may provide similar performance as human cancellous bone.

X1.5 This specification provides five grades (densities) of rigid polyurethane foam to provide a range of mechanical properties. It also provides that the foam may be supplied either in a solid form, or as a two-part liquid that is mixed together by the end user to produce a solid foam.

⁶ The boldface numbers given in parentheses refer to a list of references at the end of the text.

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