



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

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.

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 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/m³. Ten grades of foam have been defined in this specification. Their nominal densities are:

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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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.