



Standard Test Method for Strength Properties of Tissue Adhesives in Lap-Shear by Tension Loading¹

This standard is issued under the fixed designation F 2255; 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.

1. Scope

1.1 This test method is intended to provide a means for comparison of the adhesive strengths of tissue adhesives intended for use as surgical adhesives or sealants, or both, on soft tissue. With the appropriate choice of substrate, it may also be used for purposes of quality control in the manufacture of tissue adhesive based medical devices.

1.2 The values stated in SI units are to be regarded as the standard.

1.3 *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:

D 907 Terminology of Adhesives²

D 1002 Test Method for Apparent Shear Strength of Single-Lap-Joint Adhesively Bonded Metal Specimens by Tension Loading (Metal-to-Metal)²

E 4 Practices for Force Verification of Testing Machines³

2.2 American Association of Tissue Banks Standards:⁴

Standards for Tissue Banking

3. Terminology

3.1 **Definitions**—Many terms in this test method are defined in Terminology D 907.

3.2 Definitions:

3.2.1 **tissue adhesive**—for the purposes of this test method, tissue adhesive is defined as a compound or system intended for use in closing wounds (surgical or traumatic) or for sealing against leakage of body fluids.

3.2.2 **tissue sealant**—a surface coating with adequate adhesive strength to prevent leakage of body fluids.

4. Significance and Use

4.1 Materials and devices that function at least in part by adhering to living tissues are finding increasing use in surgical procedures either as adjuncts to sutures and staples, or as frank replacements for those devices in a wide variety of medical procedures. While the nature and magnitude of the forces involved varies greatly with indication and with patient specific circumstances, all uses involve to some extent the ability of the material to resist imposed mechanical forces. Therefore, the mechanical properties of the materials, and in particular the adhesive properties, are important parameters in evaluating their fitness for use. In addition, the mechanical properties of a given adhesive composition can provide a useful means of determining product consistency for quality control, or as a means for determining the effects of various surface treatments on the substrate prior to use of the device.

4.2 The complexity and variety of individual applications for tissue adhesive devices, even within a single indicated use (surgical procedure) is such that the results of a single-lap-shear test are not suitable for determining allowable design stresses without thorough analysis and understanding of the application and adhesive behaviors.

4.3 This test method may be used for comparing adhesives or bonding processes for susceptibility to fatigue and environmental changes, but such comparisons must be made with great caution since different adhesives may respond differently to varying conditions.

5. Apparatus

5.1 **Testing Machine**, of the constant-rate-of-crosshead-movement type and comprising essentially the following:

5.1.1 **Fixed Member**, a fixed or essentially stationary member carrying one grip.

5.1.2 **Movable Member**, a movable member carrying a second grip.

5.1.3 **Grips**, for holding the test specimen between the fixed member and the movable member of the testing machine can be either the fixed or self-aligning type.

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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² *Annual Book of ASTM Standards*, Vol 15.06.

³ *Annual Book of ASTM Standards*, Vol 03.01.

⁴ Available from the American Association of Tissue Banks (AATB), 1350 Beverly Rd., Suite 220-A, McLean, VA 22101.