



Designation: F2258 – 05

Standard Test Method for Strength Properties of Tissue Adhesives in Tension¹

This standard is issued under the fixed designation F2258; 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:*²

D907 Terminology of Adhesives

E4 Practices for Force Verification of Testing Machines

2.2 *American Association of Tissue Banks Standards:*³

Standards for Tissue Banking

3. Terminology

3.1 *Definitions*—Many terms in this test method are defined in Terminology D907.

3.2 *Definitions:*

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

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 The utility, range, and efficacy of adhesives in clinical medicine are well documented in the literature. Whether being used as an adhesive, hemostatic, sealant, or carrier for drugs or growth factors, or both, the scope of adhesive use in clinical medicine continues to expand. There are several factors which are vital to the success and efficacy of a medical tissue adhesive including, (1) adequate tissue bonding strength, (2) tissue compatibility, (3) acceptable biodegradable properties when the adhesive is used internally, (4) availability, (5) ease of application, and (6) cost.

4.2 Medical adhesives are currently used for a variety of applications and tissue types. Applications range from fixation of external tissues to internal application for use with either similar or dissimilar opposing surfaces. While the biological or chemical makeup, or both, of the adhesive may define its characteristics, additional mechanical factors including adhesive volume or method of application, or both, may also contribute significantly toward the performance of the adhesive. In an effort to fairly and adequately quantify adhesive bonding strength for medical adhesives, it is important to develop a consistent, reproducible testing standard for evaluative and comparative purposes. Due to the fact that the adhesives will be used on or in living tissues, a readily available biological testing surface is preferred.

4.3 The data generated from a standardized testing method on biologic tissue may vary from that found *in vivo*, however, testing results should offer valuable information on the potential bonding capacity and for the preparation of subsequent *in vivo* experiments.

4.4 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 tensile test are not suitable for determining allowable design stresses without thorough analysis and understanding of the application and adhesive behaviors.

4.5 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.

5.1.3.1 *Fixed Grips* are rigidly attached to the fixed and movable members of the testing machine. When this type of grip is used, extreme care should be taken to ensure that the test specimen is inserted and clamped so that the long axis of the test specimen coincides with the direction of pull through the centerline of the grip assembly.

5.1.3.2 *Self-aligning Grips* are attached to the fixed and movable members of the testing machine in such a manner that they will move freely into alignment as soon as any load is applied so that the long axis of the test specimen will coincide with the direction of the applied pull through the center line of the grip assembly. The specimens should be aligned as perfectly as possible with the direction of pull so that no rotary motion that may induce slippage or damage to the sample will occur in the grips; there is a limit to the amount of misalignment self-aligning grips will accommodate.

5.1.4 *Drive Mechanism*, for imparting to the movable member a uniform, controlled velocity with respect to the stationary member, with this velocity to be regulated as specified in 9.3.

5.1.5 *Load Indicator*, a suitable load-indicating mechanism capable of showing the total tensile load carried by the test specimen when held by the grips. This mechanism shall be essentially free of inertia lag at the specified rate of testing and shall indicate the load with an accuracy of $\pm 1\%$ of the indicated value, or better. The accuracy of the testing machine shall be verified in accordance with Practices E4.

5.2 *Temperature-controlling Equipment*, capable of maintaining the test temperature to $\pm 2^\circ\text{C}$. If ambient laboratory conditions are employed, the same degree of control is required. A water bath or environmental chamber capable of maintaining 37°C is required for testing on tissue substrates.

6. Test Substrate

6.1 For comparative testing, either fresh or frozen split thickness porcine skin graft may be used.

6.1.1 Frozen split thickness porcine skin that has been aseptically prepared is available commercially and is preferred

due to ease of use and the potential for more consistent properties. It should be thawed according to the manufacturer's instructions prior to use. Unused graft may be kept at 2 to 8°C for up to two weeks after thawing.

6.1.2 If fresh skin is chosen, it should be prepared according to the method in Appendix X1.

6.2 Application Specific Testing:

6.2.1 The strength of any adhesive is highly dependent on the test substrate, or adherend. For a specific application, the preferred substrate is freshly harvested tissue from the target organ of a domestic food animal. Tissue from bovine, porcine, or ovine origin is preferred due to wide availability and the fact that relatively large samples of tissue can be harvested from a single source. Ideally, the tissue should be used within 24 h of harvest, and should be kept between 5 and 10°C prior to testing if it cannot be used immediately after harvesting. Storage and handling of tissue samples should be carried out according to the guidelines set forth in Standards for Tissue Banking by the American Association of Tissue Banks. The specimens should be brought to the test temperature or other prescribed temperature (such as body temperature) prior to application of the adhesive.

6.2.2 Fixed tissue should not be used since it has been demonstrated that fixatives cause large alterations in the mechanical properties of the tissue and it is probable that the adhesive strength would be affected as well.

6.2.3 If the target organ is of a size or geometry, or both, that does not allow fabrication of test samples as shown in Fig. 1, a tissue of similar origin but larger size should be used. For example, if the intended indication is for anastomosis of small blood vessels, a larger vessel should be substituted.

6.2.4 The thickness of the tissue sample should be minimized and should not exceed 5 mm. Thicker samples will lead to distortion of the substrate and mixed loading (shear and tension). It is also important that the thickness be as uniform as possible.

6.3 Substrates for Quality Control Testing:

6.3.1 For testing that is undertaken as part of a quality control process in the manufacturing of a tissue adhesive

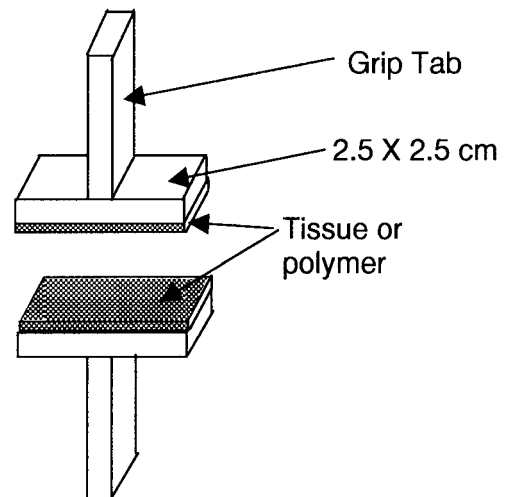


FIG. 1 Test Fixtures