Designation: F2255 – 05 (Reapproved 2015)

Standard Test Method for Strength Properties of Tissue Adhesives in Lap-Shear by Tension Loading[1]

This standard is issued under the fixed designation F2255; 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 standard. No other units of measurement are included in this 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:*

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.

[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.

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 ±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 ±2°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 device, the use of freshly harvested tissue is highly inconvenient and may also lead to unacceptable variation in the test results, especially if the failure occurs in the adherend (substrate failure). Since the purpose of quality control testing is to demonstrate consistency in the device, substitution of a model substrate is preferred so long as it is demonstrated that the adhesive does bond to the adherand. For devices that require contact with tissues to cure, Mediskin XenoGraft should be used for quality control testing as well as comparative testing.

7. Test Specimen

7.1 *Specimens with Soft-tissue Substrates* shall conform to the form shown in Fig. 1. The length of the tissue substrate (*L*) attached to each specimen holder should be at least 1.5 times the length of the overlap area in order to ensure that the failure occurs at the overlap bond and doesn't pull the tissue substrate off of the specimen holder. For very strong adhesives, *L* may need to be 2 to 3 times the overlap length. The tissue can be bonded to the specimen holder with any suitable adhesive. Gel-type cyanoacrylate adhesives have been found to be convenient for this purpose since they adhere well to moist tissues and cure quickly.

7.2 *Specimens with Polymer or Metal Substrates* shall conform to the form and dimensions shown in Fig. 2.

7.3 *Number of Test Specimens*—Test at least 10 specimens of each type. Discard results if failure occurs between the test fixture and the tissue sample and test additional samples to obtain a total of 10 valid tests. Tissue substrates tend to give higher variances and may require more samples to attain a reasonable estimate of the mean strength.

8. Sample Preparation

8.1 *Tissue Preparation:*

8.1.1 Tissue substrate materials should be kept moist at all times with phosphate buffered saline (PBS).

8.1.2 The substrate will be cut to the dimensions shown in Fig. 1 using a template and a fresh scalpel blade or a cutter

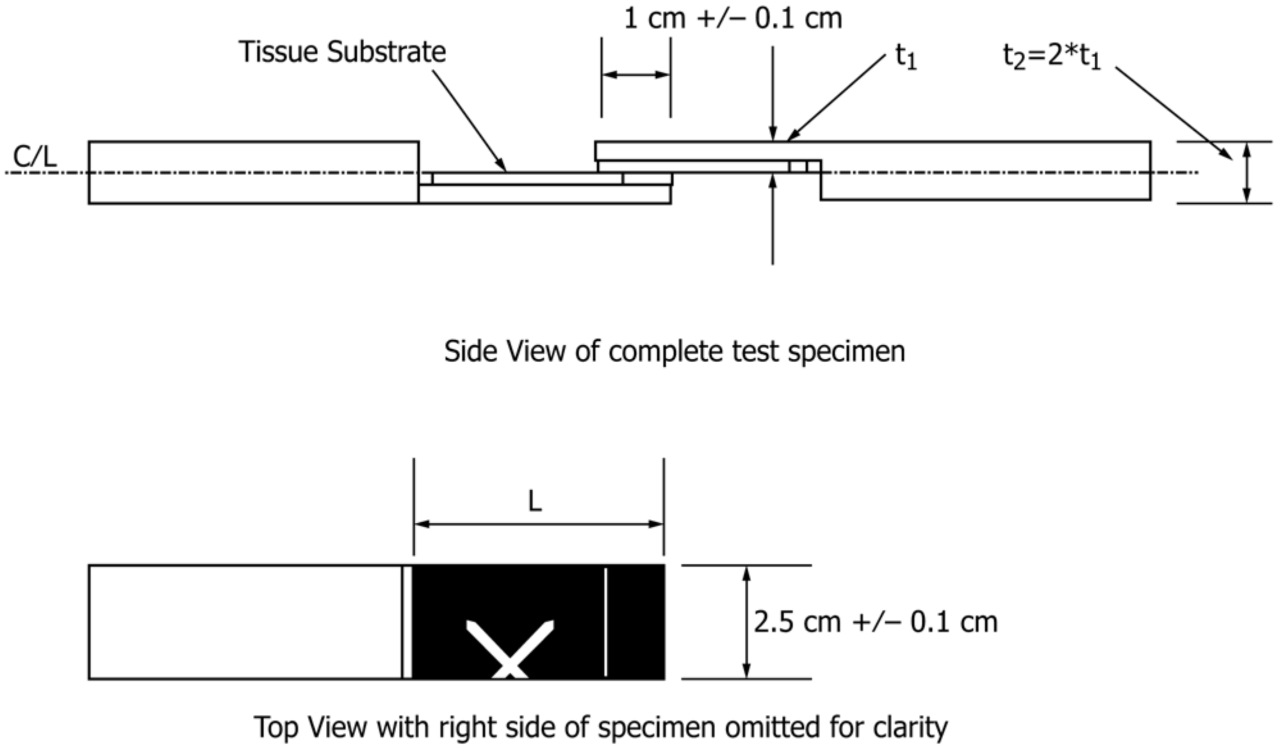

FIG. 1 Soft Tissue Fixture

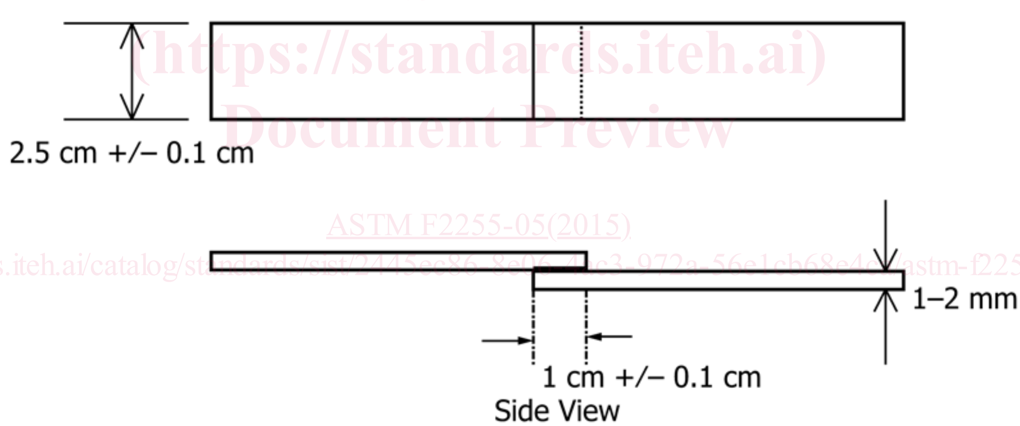

FIG. 2 Metal/Polymer Substrate Specimen

fabricated to the required dimensions. Alternatively, a slightly oversized piece of tissue can be glued to the test fixture, and trimmed to size using the fixture as a template.

8.1.3 The back-side of the tissue sample will be glued to the test fixture using a suitable adhesive. Gel-type cyanoacrylate adhesives have been found to be useful for this purpose since they set quickly and adhere to most materials. Care must be taken to ensure that the substrate is aligned square with the sides of the test fixtures and does not extend past the end of the fixture.

8.1.4 Wrap the tissue with gauze soaked in PBS, place the fixtures in a plastic bag, and place them in a water bath or environmental chamber at 37°C.

8.2 *Preparation of the Adhesive Bond:*

8.2.1 Prepare the test adhesive according to the manufacturer's directions or by other prescribed procedure.

8.2.2 Remove the test fixtures from the plastic bag and pat the surface of the tissue dry with fresh gauze.

8.2.3 Apply sufficient adhesive to uniformly coat the overlap area without significant overflow. Excess adhesive could run over the edge of the substrate, causing artificially high test values. The amount required will have to be determined experimentally. For adhesives that are delivered with a spray device, controlling the amount and distribution of the material will be difficult. It may be necessary to use a template to prevent overspray. Alternatively, petroleum jelly may applied to the portion of the tissue outside of the overlap area to prevent bonding.