Designation: F 2256 – 03

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

This standard is issued under the fixed designation F 2256; 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 Adhesives[2]

D 1876 Test Method for Peel Resistance of Adhesives (T-Peel Test)[2]

E 4 Practices for Force Verification of Testing Machines[3]

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 *flexible*—as used in this test method, indicates that the adherends shall have such dimensions and physical properties as to permit bending them through any angle up to 90° without breaking or cracking.

3.2.2 *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.

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

3.2.4 *T-peel strength*—the average load per unit width of bond line required to produce progressive separation of two bonded flexible adherends, under conditions designated in this method.

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 T-Peel 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.

[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.

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 ±1 % of the indicated value, or better. The accuracy of the testing machine shall be verified in accordance with Practices E 4.

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: Mediskin Xenograft[5] (Cat #102) should be used. It is a split thickness porcine skin graft material. The graft must be thawed according to manufacturer's instructions prior to use. Unused graft may be kept at 2 to 8°C for up to two weeks after thawing.

6.2 *Application Specific Testing*—Due to the size of the T-Peel test specimens, many tissues will not be suitable for this test.

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 (see 6.2).

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

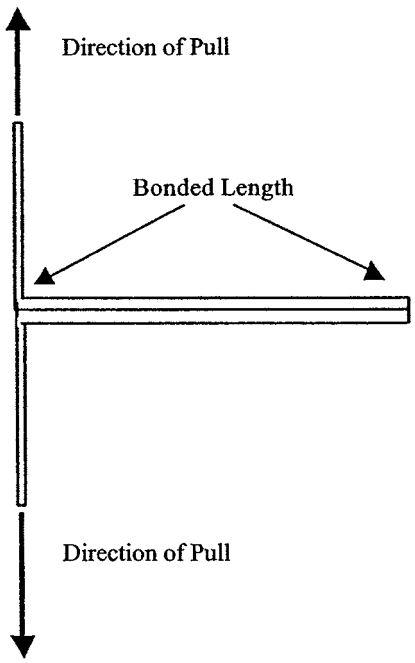

FIG. 1 T-Peel Sample Configuration (Side View)

[5] The sole source of supply of the substrate known to the committee at this time is Brennen Medical, Inc., 1290 Hammond Rd., Saint Paul, MN 55110-5867. If you are aware of alternative suppliers, please provide this information to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee,[1] which you may attend.