Designation: F2392 – 04

Standard Test Method for Burst Strength of Surgical Sealants[1]

This standard is issued under the fixed designation F2392; 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 provides a means for comparison of the burst or rupture strength of sealants on soft tissue. This test method can be used as a clinically relevant model for quality assurance, development, and comparative testing of different adhesives or adherends.

1.2 This test method measures only burst strength or "cohesive strength" of an adhesive/adherend system, and not the adhesive strength.

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

2.2 *American Association for Tissue Banks (AATB) Standard:*

Standards for Tissue Banking [3]

3. Terminology

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

3.2 *Definitions:*

3.2.1 *adhesive failure*—failure of the sealant/substrate interface during burst testing.

3.2.2 *burst strength*—the average pressure required to cause failure of the sealant, either by cohesive or adhesive mechanisms.

3.2.3 *cohesive failure*—failure of the sealant during burst testing.

3.2.4 *cohesive strength*—the internal strength of the sealant, sometimes referred to as the adhesive bulk strength.

3.2.5 *substrate failure*—failure of the substrate during burst testing.

3.2.6 *tissue sealant*—a surface coating 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 and cohesive properties, are important parameters in evaluating their fitness for use. In addition, the mechanical properties of a given sealant 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 sealant, even within a single indicated use (surgical procedure), is such that the results of a burst test are not suitable for determining allowable design stresses without thorough analysis and understanding of the application and sealant behaviors.

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

4.4 As the true sealant strength is strongly dependent on the strength of the sealant/substrate interface, the selection of a proper test substrate is critical. Care must be taken when extrapolating *in vitro* test results to *in vivo* expectations. *In vitro* sealant optimization may not translate to expected *in vivo* performance due to differences in substrate surface, strength, and elasticity.

[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 American Association for Tissue Banks (AATB), 1320 Old Chain Bridge Rd., Suite 450, McLean, VA 22101.

5. Apparatus

5.1 *Testing Machine*—A testing machine for determining the sealant strength and system failure mechanism and comprising essentially the following:

5.1.1 *Test Fixture*—A stationary fixture containing the test substrate and applied sealant. Fluid flows into the fixture at a fixed rate, allowing for the pressurization of the sealed substrate.

5.1.2 *Positive Displacement Fluid Pump*—A pump providing a constant flow of fluid to the test fixture. The pump must be capable of constant flow at pressures of interest. Syringe pumps are particularly well suited for this type of testing since they do not cause pulsatile flow. Peristaltic pumps have also been used successfully since the pump tubing tends to dampen pulsations.

NOTE 1—Saline is the typical fluid of choice. When air is used, a reduction in pressurization rate is expected due to gas compressibility.

5.1.3 *Pressure gage*—Consisting of a gage and method of capturing peak pressures. System sampling rate should be adequate to capture peak burst pressures. Sensitivity and precision should result in less than 1 % error. The burst test

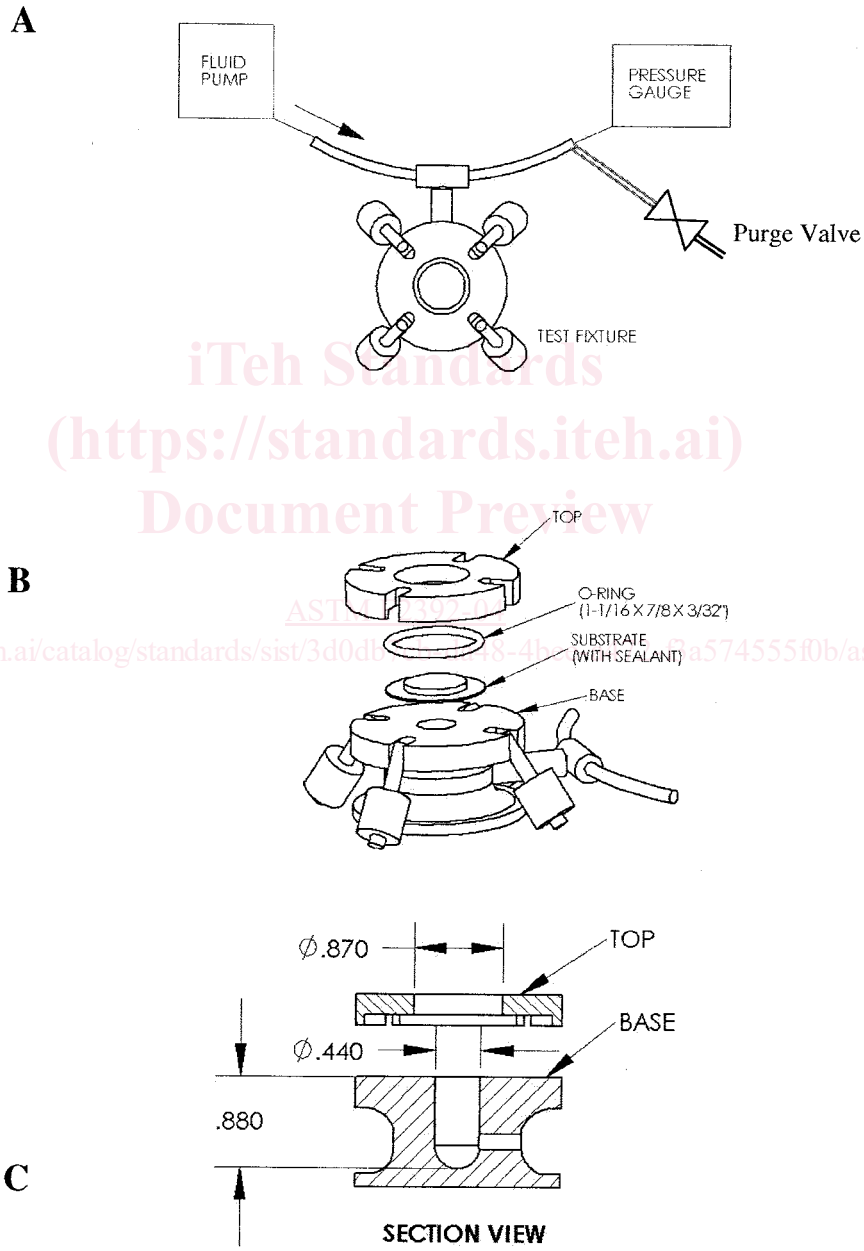

FIG. 1 Burst Test System (A), with an Exploded View of the Assembled Test Fixture (B), and the Test Fixture Cross Sectional View (in.) (C)