



Designation: **F564 – 10 F564 – 10 (Reapproved 2015)**

Standard Specification and Test Methods for Metallic Bone Staples¹

This standard is issued under the fixed designation F564; 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 specification covers characterization of the design and mechanical function of metallic staples used in the internal fixation of the muscular skeletal system. It is not the intention of this specification to describe or specify specific designs for metallic bone staples.

1.2 This specification includes the following four test methods for measuring mechanical properties of metallic bone staples:

1.2.1 Test Method for Constant Amplitude Bending Fatigue Tests of Metallic Bone Staples—**Annex A1**.

1.2.2 Test Method for Pull-Out Fixation Strength of Metallic Bone Staples—**Annex A2**.

1.2.3 Test Method for Soft Tissue Fixation Strength of Metallic Bone Staples—**Annex A3**.

1.2.4 Test Method for Elastic Static Bending of Metallic Bone Staples—**Annex A4**.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *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

E4 Practices for Force Verification of Testing Machines

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F382 Specification and Test Method for Metallic Bone Plates

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

F629 Practice for Radiography of Cast Metallic Surgical Implants

3. Finish

3.1 Staples conforming to this specification shall be finished and identified in accordance with Practice **F86**, as appropriate.

4. Inspection Practices

4.1 Staples made in accordance with Specification **F75** should be inspected in accordance with Practice **F601** or X-rayed in accordance with Practice **F629**.

5. Care and Handling

5.1 Staples should be cared for and handled in accordance with Practice **F565**, as appropriate.

¹ This specification is under the jurisdiction of ASTM Committee **F04** on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee **F04.21** on Osteosynthesis.

Current edition approved ~~Sept. 1, 2010~~ March 1, 2015. Published ~~September 2010~~ April 2015. Originally approved in 1985. Last previous edition approved in 2006 ~~2010~~ as ~~F564 – 02 (2006)~~ **F564 – 10**.¹ DOI: ~~10.1520/F0564-10~~ 10.1520/F0564-10R15.

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.

6. Keywords

6.1 bending test; bone fixation; fatigue test; fixation devices; metallic bone staples; orthopaedic medical devices; pullout test; soft tissue fixation; surgical implants

ANNEXES

(Mandatory Information)

A1. TEST METHOD FOR CONSTANT AMPLITUDE BENDING FATIGUE TESTS OF METALLIC BONE STAPLES

A1.1. Scope

A1.1.1 This test method covers procedures for the performance of constant amplitude fatigue testing of metallic staples used in internal fixation of the musculoskeletal system. This test method may be used when testing in air at ambient temperature or in an aqueous or physiological solution.

A1.1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

A1.1.3 *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.*

A1.2. Summary of Test Method

A1.2.1 Metallic bone staples are tested under bending loads until the specimen fails or a predetermined number of cycles has been applied to it. Bending tests may be performed in one of two modes: either pure, in-plane bending; or tension (or compression) combined with in-plane bending. Tests using either of these methods may be conducted at ambient conditions or in aqueous or physiological solutions (at either room temperature or 37°C).

A1.3. Significance and Use

A1.3.1 This test method is used to determine the fatigue resistance of metallic bone staples when subjected to repetitive loading for large numbers of cycles. This information may also be useful for comparing the effect of variations in staple material, geometry, surface condition, or placement under certain circumstances.

A1.3.2 It is essential that uniform fatigue practices be established in order that such basic fatigue data be comparable and reproducible and can be correlated among laboratories.

A1.3.3 The results of fatigue tests are suitable for direct application to design only when the service conditions parallel the test conditions exactly. This test method may not be appropriate for all types of bone staple applications. The user is cautioned to consider the appropriateness of the test method in view of the materials being tested and their potential application.

A1.4. Apparatus

A1.4.1 *Testing Machines*, conforming to the requirements of Practices E4 and E467. The loads used for determining strengths shall be within the loading range of the testing machine as defined in Practices E4 and E467.

A1.4.2 *Gripping Devices*:

A1.4.2.1 *Staple Extensions*—Pairs of specially designed metal blocks that permit the holding of individual staples for the application of bending fatigue loads. The legs of each staple are fitted into fixation holes in each block with minimal clearance to restrict bending of the staple within the hole. The staple is fixed securely in the block using a moldable filling or grouting agent. The extension design should minimize the weight to reduce the influence on the staple while maintaining sufficient stiffness to transfer the load to the staple without undesirable deflection. Holes for pin and clevis fixation are optional (see Figs. A1.1-A1.3).

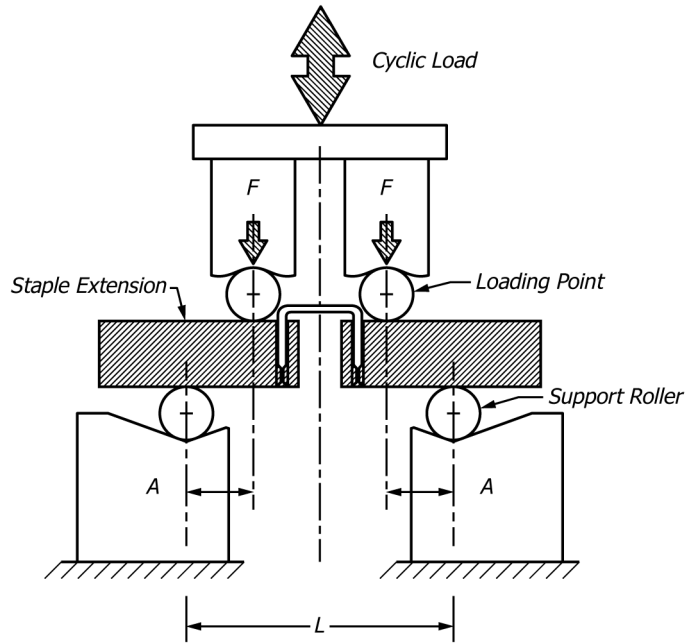


FIG. A1.1 4-Point Bending of Staples in Extension

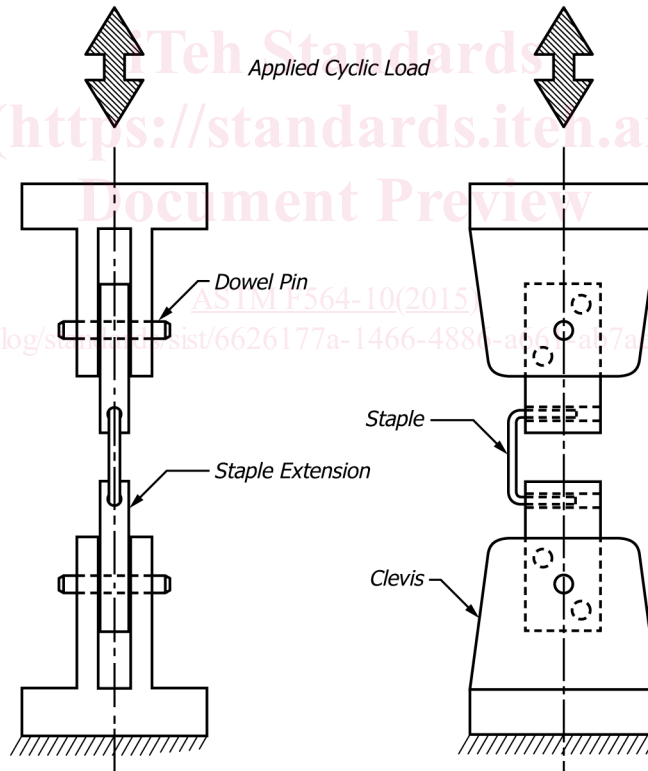


FIG. A1.2 Combined Tension (or Compression) and Bending of Staples

NOTE A1.1—Variations in fixation hole configuration may be required for staple legs with noncircular cross sections. Also, it is necessary to provide a gap between the underside of the staple bridge and edge of the staple extender in most cases. This is necessary to eliminate contact between the staple bridge (or other bridge features such as tissue spikes) and the staple extender. However, this gap should be standardized within any test group as required.

A1.4.2.2 4-Point Bend Fixture—A standard or modified bending fixture that produces pure bending in the staple without appreciable shear or torsion when used to apply load to the staple through the staple extensions.

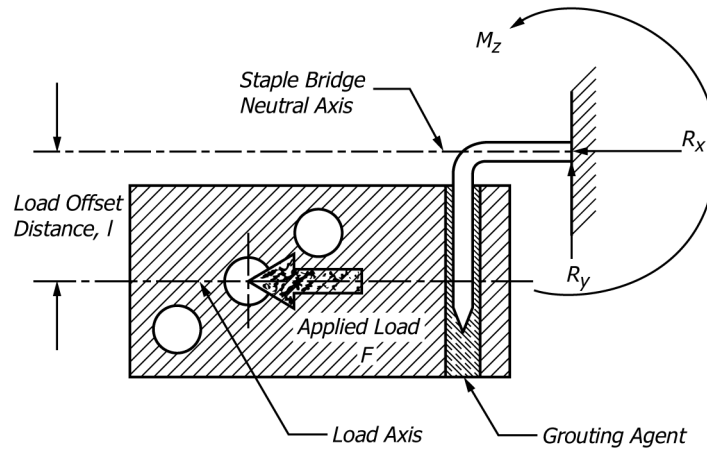


FIG. A1.3 Diagram of Extender-Staple Forces Under Combined Bending and Tension

A1.4.2.3 *Pin and Clevice Fixture*—A standard or modified fixture used to apply a distractive or compressive load to the staple through the staple extensions to produce bending in the staple similar to that seen in vivo.

A1.4.3 *Filling or Grouting Agent*—A stiff, moldable filler, such as epoxy, acrylic cement, or a low-melting point alloy (for example, Wood’s metal) used to secure the staple leg within the staple extension.

A1.4.4 *Aqueous Solution*—Tap water, distilled water, physiological saline, or similar aqueous solutions, used to immerse the test specimens fully during the test.

A1.4.5 *Constant Temperature Bath*—An aqueous bath capable of maintaining the samples and containers at physiologic temperatures, $37 \pm 2^\circ\text{C}$, for the specified testing periods.

A1.5. Test Specimen

A1.5.1 *Staple*—A generally U-shaped metal loop, with at least two legs, that is driven into the surface of bone to either fix or immobilize adjacent pieces of bone or to fasten soft tissue or other material to bone. All test samples shall be representative of the material under evaluation. Samples for comparative tests shall be produced from the same material lot or batch and under the same fabricating conditions, unless noted specifically.

A1.5.2 *Staple Leg*—The parallel or nearly parallel extensions that are intended to penetrate the bone tissue; these may be round, square, or polygonal in cross section, and they may possess serrations or barbs to increase the fixation or purchase strength in the bone.

A1.5.3 *Staple Bridge*—The cross member of the staple connecting the legs; the bridge may be smooth or possess spikes or projections on the underside for the retention of soft tissue or other material.

A1.6. Procedure

A1.6.1 *Mounting the Specimen*—Fix the staple leg in an extension block using the filling agent. A fixture should be used to ensure proper in-plane alignment of the two extensions and the staple during this process. Also, each staple should be fixed such that the bridge is the same distance from the top of each extension.

NOTE A1.2—This distance is at the discretion of the operator, but it determines the portion of the staple subjected to the bending loads.

A1.6.2 4-Point Bend Testing:

A1.6.2.1 Place the staple and attached staple extensions in the 4-point bending fixture such that the loading point and support

rollers contact the staple extensions on either side of the staple; direct contact of the rollers with the staple shall not be permitted during the test. Alignment of the loading point rollers shall be symmetric on the centerline between the support rollers (see Fig. A1.1).

A1.6.2.2 Apply cyclic loads (sinusoidal, sawtooth, and so forth), generating bending moments in the staple without permanent deformation. Appropriate starting loads should be 50 to 75 % of the static bending strength, unless indicated otherwise.

NOTE A1.3—It may be necessary to provide a low-friction means of maintaining the position of the staple and attached extensions. Also, the fixtures should be designed so that loads are applied equally at the loading points during each deflection throughout the test.

A1.6.2.3 Compute the bending moment, M , by the following formula, where F = force applied at each loading point and A = distance between the loading point and support roller, $M_{\text{bending}} = FA$.

A1.6.2.4 Continue the test until failure of the staple, the fixation, or a predetermined number of load cycles has been applied.

A1.6.3 *Combined Tension or (Compression) and Bending:*

A1.6.3.1 Place the staple and attached staple extensions in the axial bending fixture. The pins and clevises should permit free rotation of the staple extensions, with minimal friction, while maintaining alignment of the staple legs (and extensions) in the same plane (see Fig. A1.2).

A1.6.3.2 Apply cyclic loads (sinusoidal, sawtooth, and so forth), generating bending moments in the staple without permanent deformation. Appropriate starting loads should be 50 to 75 % of the static yield strength, unless indicated otherwise.

NOTE A1.4—It may be necessary to maintain a minimum tensile or compressive load on the specimen throughout the test, since operating at or near zero load may result in either loss of machine control due to discontinuity in the load feedback loop or undesirable transient loading of the staple.

A1.6.3.3 Compute the bending moment in the staple bridge, M , by the following formula, where F = force applied at each center of each pin and L = distance between the load application axis, that is, the pin center, and the neutral axis of the staple bridge, $M_{\text{bending}} = FL$ (see Fig. A1.3).

NOTE A1.5—The application of this test method produces bending, tensile (or compressive), and shear stresses in the staple. The direction and magnitudes of these stresses should be analyzed using superposition theory or other suitable methods.

A1.6.3.4 Continue the test until failure of the staple or the fixation or a predetermined number of load cycles has been applied.

A1.6.4 *Stress Verification*—It is recommended that strain gages (or extensometry) be used to measure the bending strains induced in the specimen. This is accomplished most easily on the staple bridge, but it may be possible to perform on a portion of the staple leg or at the leg-bridge junction under certain circumstances and with certain staple designs. The recommended technique is to strain gage the actual fatigue test specimens, if possible, provided that the installation of strain gage will not influence the test results.

A1.7 Test Termination

A1.7.1 Continue the tests until the specimen fails or a predetermined number of cycles has been applied to the specimen. Failure should be defined as complete separation, a crack visible at a specified magnification, a crack of certain dimensions, or by some other criterion. State the criterion selected for defining failure when reporting the results.

A1.7.2 A test shall be considered invalid if loosening of the staple occurs in the embedding medium, if noticeable yielding occurs, or permanent deformation occurs in the specimen.

A1.8. Report

A1.8.1 Report the following information:

A1.8.1.1 *Staple Description*—Type, size, special features (barbs, spikes, and so forth), manufacturer, material, batch or lot number, and dimensions (including leg length, bridge width, and length), as appropriate.

A1.8.1.2 *Test Type*—4-point or combined tension (or compression) and bending.

A1.8.1.3 *Fixation Geometry*—Load point separation distances (4-point bending), load offset distance (combined tension and bending), staple bridge-extension distance, and so forth.

A1.8.1.4 Minimum and maximum cycle loads, test frequency (for example, cycles/s), and forcing function type (sine, ramp, saw tooth, and so forth).

A1.8.1.5 Bending moment, M (N-m).

A1.8.1.6 Load ratio, R , where R = minimum load/maximum load.

A1.8.1.7 *Test Environment*—Ambient air or physiological solution.

A1.8.1.8 Number of cycles at failure or test termination (runout).

A1.8.1.9 Location of fatigue fracture (if applicable).

A1.8.1.10 Reason for test termination, that is, staple failure, fixation failure, runout to specified cycle limit, and so forth.

A1.9. Precision

A1.9.1 Intralaboratory and interlaboratory reproducibility have not been determined systematically.

A1.10 Rationale (Nonmandatory Information)

A1.10.1 This test method is intended to aid in characterizing the fatigue behavior of metallic bone staples used for the fixation of bone to bone or soft tissue to bone. The data obtained using this test method may be used to compare staple materials, designs, or placements under certain circumstances.

<https://standards.iteh.ai/catalog/standards/sist/6626177a-1466-4886-a661-ab7aebd418c6/astm-f564-102015>

A1.10.2 This test method is intended to simulate potential in vivo staple loading conditions. However, in vitro testing of these devices may not duplicate their in vivo behavior adequately.

A2. TEST METHOD FOR PULL-OUT FIXATION STRENGTH OF METALLIC BONE STAPLES

A2.1. Scope

A2.1.1 This test method covers testing of the hard tissue pull-out fixation strength of metallic staples used in the internal fixation of the musculoskeletal system. This test method may be used with physiologic bone or a synthetic substitute. It may also be used when testing in an aqueous or physiological solution.

A2.1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

A2.1.3 *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.*

A2.2. Summary of Test Method

A2.2.1 A thin, flat, flexible metal or fabric strap is fixed to bone (or a substitute) using a single staple. Tension is applied equally