



Designation: ~~F564 – 10~~ (Reapproved 2015) ~~F564 – 17~~

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~~ musculoskeletal 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~~ Any other units of measurement ~~are~~ included in this ~~standard~~ standard are shown for reference only.

1.4 Multiple test methods are included in this standard. However, the user is not necessarily obligated to test using all of the described methods. Instead, the user should only select, with justification, test methods that are appropriate for a particular device design. This may be only a subset of the herein described test methods.

1.5 *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, health and ~~health~~ environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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](#)

[F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment](#)

3. Finish

3.1 Staples conforming to this specification shall be finished and identified in accordance with Practice [F86](#), 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.

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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.

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.

5.2 Consider Practice F2503 to identify potential hazards produced by interactions between the device and the MR environment and for terms that may be used to label the device for safety in the MR environment

6. Materials

6.1 Bone staples shall be fabricated from a metallic material intended for surgical implant applications. In addition, the materials shall be biocompatible for the intended application. Materials should be chosen based on the design requirements of the particular device. ASTM subcommittee F04.12 maintains a number of specifications for materials that are suitable for surgical implant applications.

7. Keywords

7.1 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~~Any other units of measurement are included in this standard. ~~standard~~ are shown for reference only.

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, health and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

A1.1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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).

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.

A1.4.2.3 *Pin and Clevis 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.

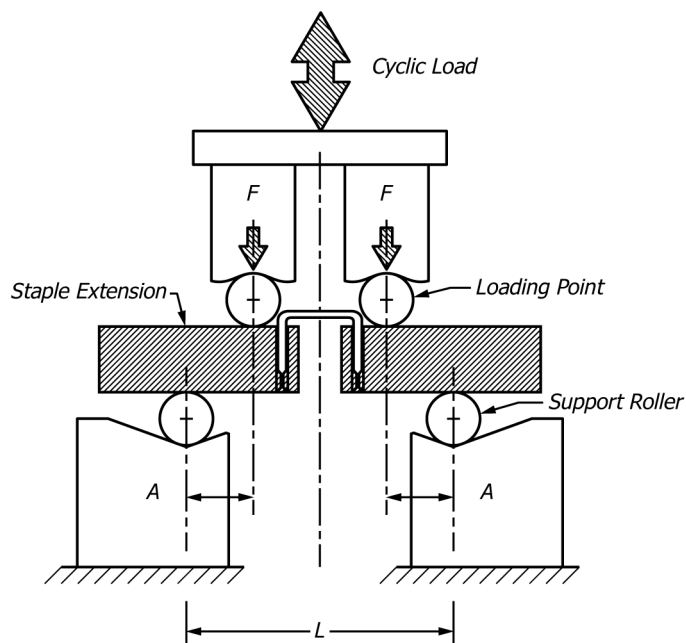


FIG. A1.1 4-Point Bending of Staples in Extension

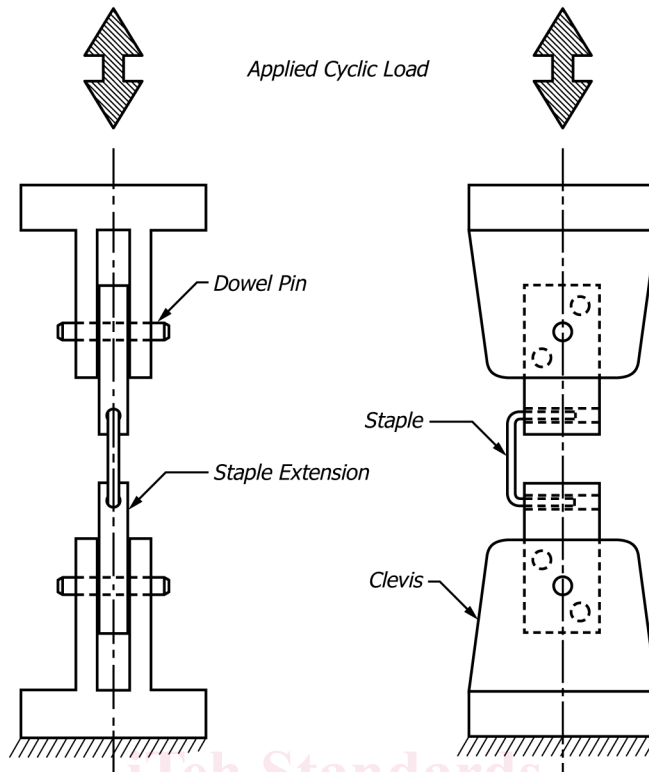


FIG. A1.2 Combined Tension (or Compression) and Bending of Staples

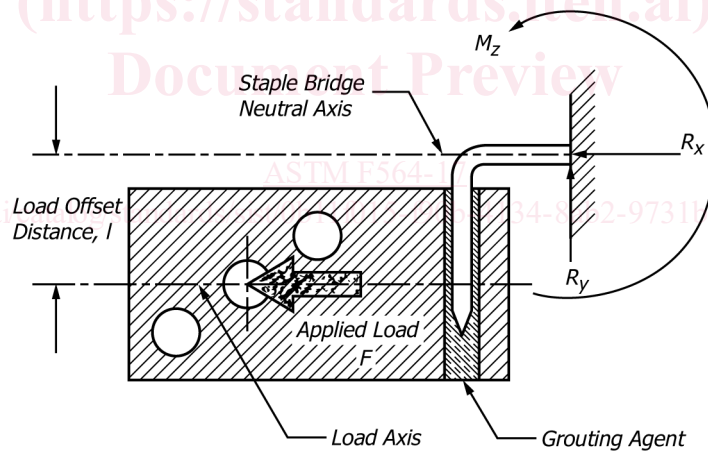


FIG. A1.3 Diagram of Extender-Staple Forces Under Combined Bending and Tension

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:

$$M_{\text{bending}} = FA \quad (\text{A1.1})$$

A1.6.2.4 Continue the test until failure of the staple, the fixation, or a predetermined number of load cycles have 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 axis (that is, the pin center, center) and the neutral axis of the staple bridge:

$$M_{\text{bending}} = FL \quad (\text{see Fig. A1.3}) \quad (\text{A1.2})$$

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~~have 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 the 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~~have 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~~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.