



Designation: F 564 – 00

Standard Specification and Test Methods for Metallic Bone Staples¹

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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 Unless otherwise indicated, the values stated in SI units are to be regarded as standard. The values given in parentheses are given for information only.

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:*

¹ This specification is under the jurisdiction of ASTM Committee F-04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

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E 4 Practices for Force Verification of Testing Machines²

E 122 Practice for Choice of Sample Size to Estimate a Measure of Quality for a Lot or Process³

E 467 Practice for Verification of Constant Amplitude Dynamic Loads in an Axial Load Fatigue Testing Machine²

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications⁴

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants⁴

F 382 Test Method for Static Bending Properties of Metallic Bone Plates⁴

F 565 Standard Practice for Care and Handling of Orthopedic Implants and Instruments⁴

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants⁴

F 629 Practice for Radiography of Cast Metallic Surgical Implants⁴

3. Finish

3.1 Staples conforming to this specification shall be finished and identified in accordance with Practice F 86, as appropriate.

4. Inspection Practices

4.1 Staples made in accordance with Specification F 75 should be inspected in accordance with Practice F 601 or X-rayed in accordance with Practice F 629.

5. Care and Handling

5.1 Staples should be cared for and handled in accordance with F 565, as appropriate.

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

² *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 14.02.

⁴ *Annual Book of ASTM Standards*, Vol 13.01.