



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 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](#)

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.

[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.

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