



Designation: F 564 – 002

Standard Specification and Test Methods for Metallic Bone Staples¹

This standard is issued under the fixed designation F 564; 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 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 F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

Current edition approved ~~May Apr.~~ 10, 2000². Published ~~August 2000~~, June 2002. Originally published as F 564 – 85. Last previous edition ~~F 564 – 85 (1997)~~^{ε1}. F 564 – 00.