



# Standard Specification and Test Methods for Metallic Medical Bone Screws<sup>1</sup>

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<sup>ε1</sup> NOTE—[Annex A6](#) was corrected editorially and portions of the standard were reformatted in December 2013.

## 1. Scope

1.1 This specification provides requirements for materials, finish and marking, care and handling, and the acceptable dimensions and tolerances for metallic bone screws that are implanted into bone. The dimensions and tolerances in this specification are applicable only to metallic bone screws described in this specification.

1.2 This specification provides performance considerations and standard test methods for measuring mechanical properties in torsion of metallic bone screws that are implanted into bone. These test methods may also be applicable to other screws besides those whose dimensions and tolerances are specified here. The following annexes are included:

1.2.1 [Annex A1](#)—Test Method for Determining the Torsional Properties of Metallic Bone Screws.

1.2.2 [Annex A2](#)—Test Method for Driving Torque of Medical Bone Screws.

1.2.3 [Annex A3](#)—Test Method for Determining the Axial Pullout Strength of Medical Bone Screws.

1.2.4 [Annex A4](#)—Test Method for Determining the Self-Tapping Performance of Self-Tapping Medical Bone Screws.

1.2.5 [Annex A5](#)—Specifications for Type HA and Type HB Metallic Bone Screws.

1.2.6 [Annex A6](#)—Specifications for Type HC and Type HD Metallic Bone Screws.

1.2.7 [Annex A7](#)—Specifications for Metallic Bone Screw Drive Connections.

1.3 This specification is based, in part, upon ISO 5835, ISO 6475, and ISO 9268.

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

1.5 Multiple test methods are included in this standard. However, it must be noted that the user is not obligated to test

using all of the described methods. Instead, the user should only select test methods that are appropriate for a particular device design. In most instances, only a subset of the herein described test methods will be required.

1.6 This standard may involve the use of hazardous materials, operations, and equipment. *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:<sup>2</sup>

- [E4 Practices for Force Verification of Testing Machines](#)
- [E6 Terminology Relating to Methods of Mechanical Testing](#)
- [E8 Test Methods for Tension Testing of Metallic Materials](#)
- [E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process](#)
- [F67 Specification for Unalloyed Titanium, for Surgical Implant Applications \(UNS R50250, UNS R50400, UNS R50550, UNS R50700\)](#)
- [F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants](#)
- [F116 Specification for Medical Screwdriver Bits](#)
- [F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI \(Extra Low Interstitial\) Alloy for Surgical Implant Applications \(UNS R56401\)](#)
- [F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants \(UNS S31673\)](#)
- [F565 Practice for Care and Handling of Orthopedic Implants and Instruments](#)
- [F620 Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition](#)
- [F799 Specification for Cobalt-28Chromium-6Molybdenum](#)

<sup>1</sup> 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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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.