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Standard Specification and Test Methods for Metallic Medical Bone Screws¹

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This standard has been approved for use by agencies of the Department of Defense.

^{ε1} NOTE—The drive connections pictured in Figs. A6.6 and A6.7 were inadvertently reversed. This was editorially corrected in July 2001.

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—Specifications for Type HA and Type HB Metallic Bone Screws.

1.2.5 Annex A5—Specifications for Type HC and Type HD Metallic Bone Screws.

1.2.6 Annex A6—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 Unless otherwise indicated, the values stated in SI units are to be regarded as standard. The values in parentheses are given for information only.

1.5 *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:

- E 4 Practices for Force Verification of Testing Machines²
- E 6 Terminology Relating to Methods of Mechanical Testing²
- E 8 Test Methods for Tension Testing of Metallic Materials²
- E 122 Practice for Choice of Sample Size to Estimate a Measure of Quality for a Lot or Process³
- F 67 Specification for Unalloyed Titanium for Surgical Implant Applications⁴
- F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants⁴
- F 116 Specification for Medical Screwdriver Bits⁴
- F 117 Test Method for Driving Torque of Medical Bone Screws⁴
- F 136 Specification for Wrought Titanium – 6 Aluminum – 4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications⁴
- F 138 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)⁴
- F 565 Practice for Care and Handling of Orthopedic Implants and Instruments⁴
- F 620 Specification for Titanium-6 Aluminum-4 Vanadium ELI Alloy Forgings for Surgical Implants [UNS R56401]⁴
- F 799 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)⁴
- F 983 Practice for Permanent Marking of Orthopedic Implant Components⁴
- F 1295 Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications [UNS R56700]⁴
- F 1314 Specification for Wrought Nitrogen Strengthened-22 Chromium-12.5 Nickel-5 Manganese-2.5

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 *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.