



Standard Specification for Metallic Medical Bone Screws¹

This standard is issued under the fixed designation F 543; 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.

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

1. Scope

1.1 This specification provides requirements for materials, finish and marking, care and handling, and some dimensions and tolerances for metallic bone screws which are implanted into bone. The dimensions and tolerances in this specification are applicable only to metallic bone screws with a spherical head, hexagonal driving slot, and a solid core.

1.2 This specification is based, in part, upon ISO 5835.

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

1.4 *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:

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications²

F 116 Specification for Medical Screwdriver Bits²

F 117 Test Method for Driving Torque of Medical Bone Screws²

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants²

F 136 Specification for Wrought Titanium 6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications²

F 138 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)²

F 543 Specification for Cortical Bone Screws²

F 544 Reference Chart for Pictorial Cortical Bone Screw Classification²

F 565 Practice for Care and Handling of Orthopedic Im-

plants and Instruments²

F 620 Specification for Titanium 6Al-4V ELI Alloy Forgings for Surgical Implants²

F 799 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants²

F 983 Practice for Permanent Marking of Orthopedic Implant Components²

F 1295 Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications [UNS R56700]²

F 1314 Specification for Wrought Nitrogen Strengthened-2 Chromium-12.5 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants²

F 1472 Specification for Wrought Ti-6Al-4V Alloy for Surgical Implant Applications²

F 1537 Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants²

F 1586 Specification for Wrought Nitrogen Strengthened-21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants²

F 1622 Test Method for Measuring the Torsional Properties in Metallic Bone Screws²

F 1691 Test Method for Determining the Axial Pull-Out Strength of Medical Bone Screws²

F 1713 Specification for Wrought Titanium 13 Niobium-13 Zirconium Alloy for Surgical Implant Applications²

F 1813 Specification for Wrought Titanium-12 Molybdenum-6 Zirconium-2 Iron Alloy for Surgical Implant Applications²

2.2 ISO Standard:

5835 Implants for Surgery—Metal Bone Screws with Hexagonal Driver Connection, Spherical Under Surface of Head, Asymmetrical Thread—Dimensions³

3. Terminology

3.1 *Definitions*—Some of the terms defined in this section are shown in Fig. 1.

3.1.1 *buttress thread*—an asymmetrical thread profile characterized by a pressure flank which is nearly perpendicular to the screw axis.

3.1.2 *cancellous screw*—a screw designed primarily to gain

¹ This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

Current edition approved Oct. 10, 1998. Published March 1999. Originally published as F 543 – 77. Last previous edition F 543 – 92.

² *Annual Book of ASTM Standards*, Vol 13.01.

³ Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.