



Standard Specification for Medical Screwdriver Bits¹

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1. Scope

1.1 This specification covers the acceptable dimensions and tolerances for bits of screwdrivers to insert and remove metal screws used as surgical implants.

1.2 This specification is based, in part, upon ISO 8319–1, ISO 8319–2, and ISO 10664.

1.3 The screwdrivers with the bits described in this specification are suitable for use with screws described in Specification F543, ISO 5835, 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 *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

E18 Test Methods for Rockwell Hardness of Metallic Materials

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F543 Specification and Test Methods for Metallic Medical Bone Screws

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

F899 Specification for Wrought Stainless Steels for Surgical Instruments

F1744 Guide for Care and Handling of Stainless Steel Surgical Instruments

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.

2.2 ISO Standards:³

ISO 5832–5 Implants for Surgery—Metallic Materials—Part 5: Wrought Cobalt-Chromium-Tungsten-Nickel Alloy

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

ISO 7153–1 Surgical Instruments—Metallic Materials—Part 1: Stainless Steel

ISO 8319–1 Orthopaedic Instruments—Drive Connections—Part 1: Keys for Use with Screws with Hexagon Socket Heads

ISO 8319–2 Orthopaedic Instruments—Drive Connections—Part 2: Screwdrivers for Single Slot Head Screws, screws with Cruciate Slot, and Cross-Recessed Head Screws

ISO 9268 Implants for Surgery—Metal Bone Screws with Conical Under-Surface of Head—Dimensions

ISO 10664 Hexalobular Internal Driving Feature for Bolts and Screws

3. Classification

3.1 This specification includes the following types of bits for medical screwdrivers:

3.1.1 *Type I*—Single-slot bit.

3.1.2 *Type II*—Cruciate-slot bit.

3.1.3 *Type III*—Cross-slot (Modified Phillips) bit.

3.1.4 *Type IV*—Hexagonal bit.

3.1.5 *Type V*—Square bit.

3.1.6 *Type VI*—Hexalobe bit.

4. Dimensions and Tolerances

4.1 Screwdriver bits conforming to this specification shall be fabricated in accordance with the dimensions and tolerances described below:

4.1.1 *Type I*—Single-slot screwdriver bits shall conform to the dimensions and tolerances provided in Table 1, and shown in Fig. 1.

4.1.2 *Type II*—Cruciate-slot screwdriver bits shall conform to the dimensions and tolerances provided in Table 2, and shown in Fig. 2.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.