



Designation: F 116–98

Standard Specification for Designation: F 116 – 00 (Reapproved 2009)

Standard Specification for Medical Screwdriver Bits¹

This standard is issued under the fixed designation F 116; 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 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 and ISO 8319-2.~~

~~1.3 The screwdrivers with the bits described in this standard are suitable for use with screws described in F 543, ISO 5835, and ISO 9268.~~

~~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 associated with its use. It is the responsibility of whoever uses this standard to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.~~

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~~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

E 18 ~~Standard Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials~~ Test Methods for Rockwell Hardness of Metallic Materials

F 90 ~~Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)~~

F 543 ~~Standard Specification and Test Methods for Metallic Medical Bone Screws~~

F 565 ~~Standard Practice for Care and Handling of Orthopaedic Implants and Instruments~~

F 899 ~~Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments~~³ Specification for Wrought Stainless Steels for Surgical Instruments

F 1744 ~~Standard Practice Guide for Care and Handling of Stainless Steel Surgical Instruments~~

2.2 *ISO Standards:*³

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

¹ This specification is under the jurisdiction of ASTM Committee F4/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.

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.

³ Annual Book of ASTM Standards, Vol 13.01.

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

- ISO 5835 Implants for Surgery—Metal Bone Screws with Hexagonal Driver Connection, Spherical Under Surface of Head, Asymmetrical Thread—Dimensions
- 7153-1-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

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 must conform to the dimensions and tolerances provided in Table 1, and described in Fig. 1.
 - 4.1.2 *Type II*—Cruciate-slot screwdriver bits must conform to the dimensions and tolerances provided in Table 2, and described in Fig. 2.
 - 4.1.3 *Type III*—Cross-slot (Modified Phillips) screwdriver bits must conform to the dimensions and tolerances provided in Fig. 3.
 - 4.1.4 *Type IV*—Hexagonal screwdriver bits must conform to the dimensions and tolerances provided in Table 3, and described in Fig. 4.
 - 4.1.5 *Type V*—Square screwdriver bits must conform to the dimensions provided in Table 4, and described in Fig. 5.
 - 4.1.6 *Type VI*—Hexalobe screwdriver bits must conform to the dimensions provided in Table 5, and described in Fig. 6.

5. Material Requirements

- 5.1 The bit and shaft portion of the screwdriver should be fabricated from one of the following materials:
 - 5.1.1 Martensitic stainless steel (Specification F 899 or ISO 7153-1;7153-1).
 - 5.1.2 Cold worked Cobalt-Chromium-Tungsten-Nickel alloy (Specification F 90 or ISO 5832-5;5832-5).
- 5.2 The hardness of the material of the bit and shaft portion shall be 45–55 (stainless steel) or 45–50 (Cobalt-Chromium-Tungsten-Nickel alloy) when measured on the Rockwell C scale according to the procedures described in Test Methods E 18.
- 5.3 The shaft shall be firmly fixed to a handle of appropriate material.

6. Finish and Marking

- 6.1 The bit portion of the screwdriver shall be free of nicks, dents, and scratches.
- 6.2 When size permits, the following information should be legibly marked on the shaft or handle of the screwdriver (in order of preference):
 - 6.2.1 Manufacturer’s name or logo
 - 6.2.2 Size (for Type IV—hexagonal bit screwdrivers)

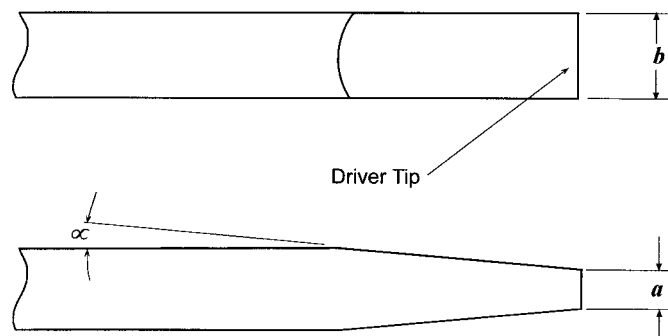


FIG. 1 Dimensions of Single-Slot Screwdriver Bit

TABLE 1 Dimensions and Tolerances of Single-Slot Screwdriver Bit

Slot Thickness, <i>a</i> (mm)	Slot Width, <i>b</i> (mm; maximum)	Slot Angle, α (degrees)
1.10	4.8	+30'
1.10	4.8	+30'
		-30'
		-30'
1.10	5.6	+30'
1.10	5.6	+30'
		-30'
		-30'

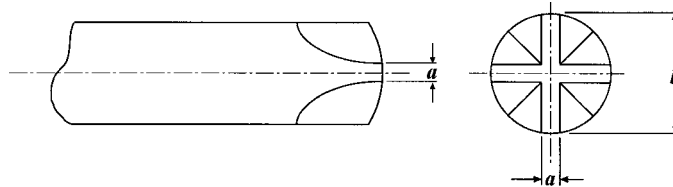


FIG. 2 Dimensions of Cruciate-Slot Screwdriver Bit

TABLE 2 Dimensions and Tolerances of Cruciate-Slot Screwdriver Bit

Slot Thickness, <i>a</i> (mm)	Slot Width, <i>b</i> (mm; maximum)
1.10	4.8
1.10	4.8
1.10	5.6
1.10	5.6

6.2.2 Size (for Type IV through VI screwdriver bits)

6.2.3 Catalog number

6.2.4 Manufacturing lot number

6.2.5 Material (include ASTM designation, as appropriate).

6.3 The marking should be such that the mechanical integrity of the screwdriver is not compromised.

7. Care and Handling

7.1 Screwdrivers should be handled in accordance with Practices F 565 and F 1744, as appropriate.

8. Keywords

8.1 bone screw; orthopaedic medical devices; screwdriver; surgical instruments