



Designation: F 116 – 00

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 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 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 18 Standard Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials²
- F 90 Standard Specification for Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for Surgical Implant Applications³
- F 543 Standard Specification and Test Methods for Metallic Medical Bone Screws³
- F 565 Standard Practice for Care and Handling of Orthopaedic Implants and Instruments³
- F 899 Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments³
- F 1744 Standard Practice for Care and Handling of Stainless Steel Surgical Instruments³

2.2 ISO Standards:

- 5832-5 Implants for Surgery—Metallic Materials—Part 5: Wrought Cobalt-Chromium-Tungsten-Nickel Alloy⁴
- 5835 Implants for Surgery—Metal Bone Screws with Hex-

- agonal Driver Connection, Spherical Under Surface of Head, Asymmetrical Thread—Dimensions⁴
- 7153-1 Surgical Instruments—Metallic Materials—Part 1: Stainless Steel⁴
- 8319-1 Orthopaedic Instruments—Drive Connections—Part 1: Keys for Use with Screws with Hexagon Socket Heads⁴
- 8319-2 Orthopaedic Instruments—Drive Connections—Part 2: Screwdrivers for Single Slot Head Screws, screws with Cruciate Slot, and Cross-Recessed Head Screws⁴
- 9268 Implants for Surgery—Metal Bone Screws with Conical Under-Surface of Head—Dimensions⁴

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.

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² *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 13.01.

⁴ Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

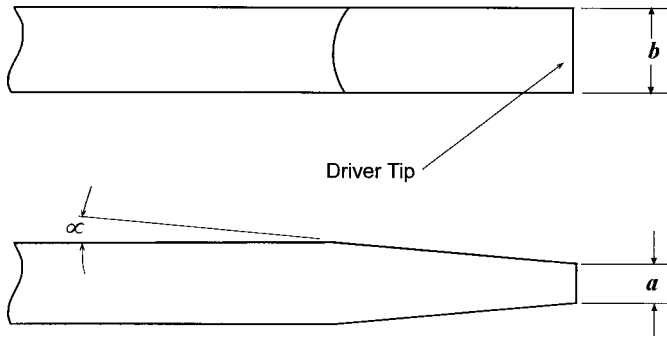


FIG. 1 Dimensions of Single-Slot Screwdriver Bit

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	+ 0.03 - 0.07	4.8
1.10	+ 0.03 - 0.07	5.6

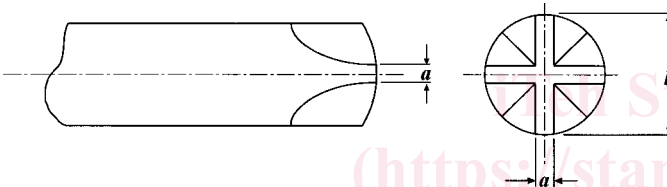


FIG. 2 Dimensions of Cruciate-Slot Screwdriver Bit

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	+ 0.03 - 0.07
1.10	+ 0.03 - 0.07

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 (F 899 or ISO 7153-1).
- 5.1.2 Cold worked Cobalt-Chromium-Tungsten-Nickel alloy (F 90 or ISO 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-

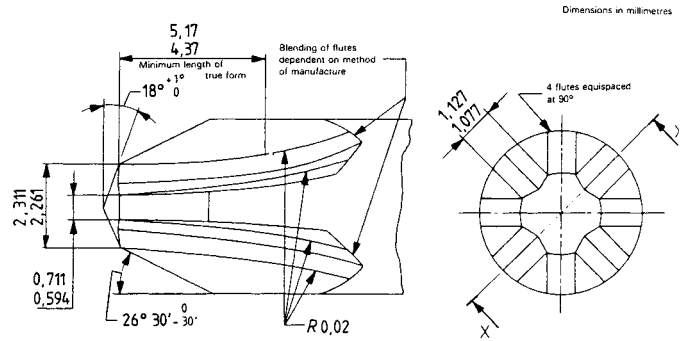


FIG. 3 Dimensions and Tolerances of Cross-Slot (Modified Phillips) Screwdriver Bit

Tungsten-Nickel alloy) when measured on the Rockwell C scale according to the procedures described in 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 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 F 565 and F 1744, as appropriate.

8. Keywords

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