



Designation: F 116 – 00 (Reapproved 2004)

## Standard Specification for Medical Screwdriver Bits<sup>1</sup>

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 ( $\epsilon$ ) 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 specification are suitable for use with screws described in Specification 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:<sup>2</sup>

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

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

F 543 Specification and Test Methods for Metallic Medical Bone Screws

F 565 Practice for Care and Handling of Orthopedic Implants and Instruments

F 899 Specification for Stainless Steel for Surgical Instruments

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

#### 2.2 ISO Standards:

5832-5 Implants for Surgery—Metallic Materials—Part 5: Wrought Cobalt-Chromium-Tungsten-Nickel Alloy<sup>3</sup>

<sup>1</sup> 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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<sup>2</sup> 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.

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

5835 Implants for Surgery—Metal Bone Screws with Hexagonal Driver Connection, Spherical Under Surface of Head, Asymmetrical Thread—Dimensions<sup>3</sup>

7153-1 Surgical Instruments—Metallic Materials—Part 1: Stainless Steel<sup>3</sup>

8319-1 Orthopaedic Instruments—Drive Connections—Part 1: Keys for Use with Screws with Hexagon Socket Heads<sup>3</sup>

8319-2 Orthopaedic Instruments—Drive Connections—Part 2: Screwdrivers for Single Slot Head Screws, screws with Cruciate Slot, and Cross-Recessed Head Screws<sup>3</sup>

9268 Implants for Surgery—Metal Bone Screws with Conical Under-Surface of Head—Dimensions<sup>3</sup>

### 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.

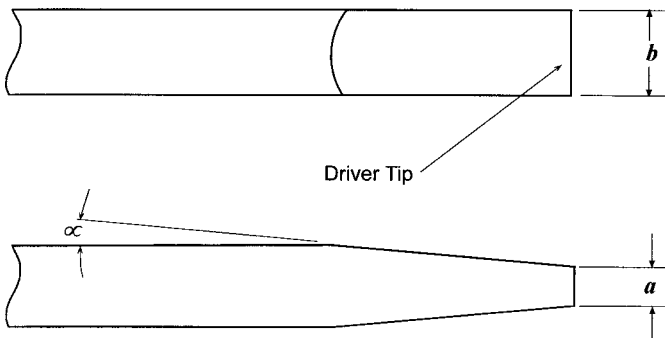


FIG. 1 Dimensions of Single-Slot Screwdriver Bit

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, $\alpha$ (degrees)
1.10	+0.03 -0.07	5.0
1.10	+0.03 -0.07	5.0

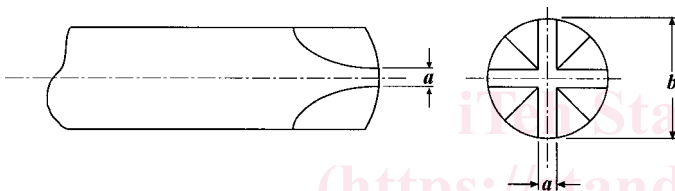


FIG. 2 Dimensions of Cruciate-Slot Screwdriver Bit

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	5.6

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).

5.1.2 Cold worked Cobalt-Chromium-Tungsten-Nickel alloy (Specification 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-

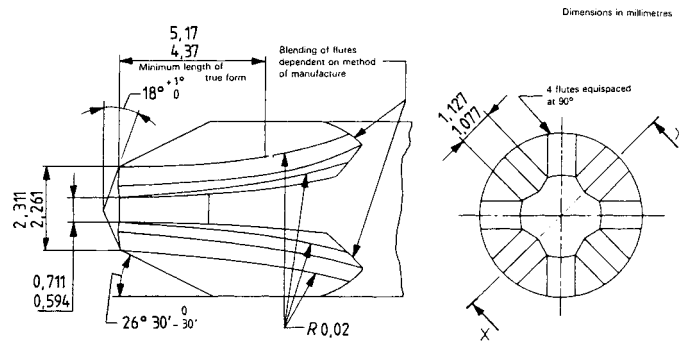


FIG. 3 Dimensions and Tolerances of Cross-Slot (Modified Phillips) Screwdriver Bit

Tungsten-Nickel alloy) when measured on the Rockwell C scale according to the procedures described in 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 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