



## Standard Specification for Metallic Medical Bone Screws<sup>1</sup>

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 ( $\epsilon$ ) 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 Applications<sup>2</sup>

F 116 Specification for Medical Screwdriver Bits<sup>2</sup>

F 117 Test Method for Driving Torque of Medical Bone Screws<sup>2</sup>

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants<sup>2</sup>

F 136 Specification for Wrought Titanium 6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications<sup>2</sup>

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

F 543 Specification for Cortical Bone Screws<sup>2</sup>

F 544 Reference Chart for Pictorial Cortical Bone Screw Classification<sup>2</sup>

F 565 Practice for Care and Handling of Orthopedic Im-

plants and Instruments<sup>2</sup>

F 620 Specification for Titanium 6Al-4V ELI Alloy Forgings for Surgical Implants<sup>2</sup>

F 799 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants<sup>2</sup>

F 983 Practice for Permanent Marking of Orthopedic Implant Components<sup>2</sup>

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

F 1314 Specification for Wrought Nitrogen Strengthened-2 Chromium-12.5 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants<sup>2</sup>

F 1472 Specification for Wrought Ti-6Al-4V Alloy for Surgical Implant Applications<sup>2</sup>

F 1537 Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants<sup>2</sup>

F 1586 Specification for Wrought Nitrogen Strengthened-21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants<sup>2</sup>

F 1622 Test Method for Measuring the Torsional Properties in Metallic Bone Screws<sup>2</sup>

F 1691 Test Method for Determining the Axial Pull-Out Strength of Medical Bone Screws<sup>2</sup>

F 1713 Specification for Wrought Titanium 13 Niobium-13 Zirconium Alloy for Surgical Implant Applications<sup>2</sup>

F 1813 Specification for Wrought Titanium-12 Molybdenum-6 Zirconium-2 Iron Alloy for Surgical Implant Applications<sup>2</sup>

#### 2.2 ISO Standard:

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

### 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

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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 13.01.

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

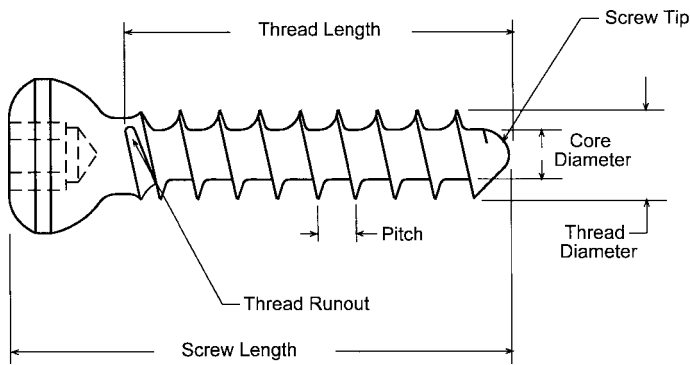


FIG. 1 Schematic of Screw Terms

purchase into cancellous bone. A class of cancellous screws included in this specification are the HB-type screws given in 4.1.2. Cancellous screws may or may not be fully threaded.

3.1.3 *cannulated screw*—a screw which has a through hole drilled along the entire length of its longitudinal axis. Cannulated screws are often inserted into the bone over a guide pin.

3.1.4 *conical head screw*—a screw whose head has a conical undersurface which makes contact with the bone or a plate.

3.1.5 *core diameter*—the smallest diameter of the threaded portion of the screw measured at the thread root. This is also known as the minor diameter or root diameter.

3.1.6 *cortical screw*—a screw designed primarily to gain bicortical purchase into cortical bone. A class of cortical screws included in this specification are the HA-type screws given in 4.1.1. Cortical screws typically are fully threaded.

3.1.7 *non-tapping screw*—a screw which does not contain any design features that act to produce the screw's thread form in the bone upon insertion. Non-tapping screws, by design, usually require a pre-tapped pilot hole for screw insertion.

3.1.8 *partially threaded screw*—a screw whose threaded portion does not extend fully from the screw point to the screw head, but instead has a smooth shaft running between the head and threads.

3.1.9 *pilot hole*—the hole drilled into the bone into which the screw tip is inserted. The pilot hole is normally slightly larger than the screw's core diameter. However, if the screw is to be used to provide compression across a fracture, a portion of the pilot hole may be larger to allow for a clearance fit.

3.1.10 *pitch*—the length between the thread crests.

3.1.11 *screw head*—the end of the screw which is opposite of the tip, and from which the means of inserting the screw is coupled.

3.1.12 *screw length*—the overall length of the screw, measured from the screw head to the screw tip.

3.1.13 *screw thread*—a helical groove on a cylindrical or conical surface. The projecting helical ridge thus formed is called a screw thread, consisting of peaks (crests) and valleys (roots).

3.1.14 *self-drilling screw*—a screw which has the necessary design features (such as cutting flutes) to produce both a pilot hole and compatible thread form for the screw upon the screw's insertion into the bone.

3.1.15 *self-tapping screw*—a screw which has a design (such as a cutting flute) that is intended to produce a thread

form compatible with the screw's thread form upon the screw's insertion into the bone.

3.1.16 *size*—an identification of a screw based on its nominal thread diameter. For HA and HB screws whose dimensions are included in this specification, the size is provided in Section 5

3.1.17 *solid core*—a screw which does not contain a cannulation along its longitudinal axis.

3.1.18 *spherical head screw*—a screw whose head has a constant radius along its undersurface which makes contact with the bone or a plate. This is shown as the bottom head radius,  $r_1$ , Fig. 2 and Fig. 4. All screws whose dimensions are defined in this specification (Type HA and HB) have a screw head with a spherical undersurface.

3.1.19 *thread diameter*—the largest diameter of the threaded portion of the screw measured over the thread crests. This is also known as the major diameter.

3.1.20 *thread length*—the length of the threaded portion of the screw, measured from the thread runout to the screw tip.

3.1.21 *thread runout*—the intersection of the screw thread with either the screw shaft or screw head.

#### 4. Classification

4.1 There are a large variety of medical bone screws currently in use. They may be classified by the definitions provided in Section 3. This specification provides dimensions and tolerances for the following types of screws:

4.1.1 *Type HA*—Shallow, asymmetrical buttress thread and deep screw head.

4.1.2 *Type HB*—Deep, asymmetrical buttress thread and shallow screw head.

#### 5. Dimensions and Tolerances

5.1 There are many types of metallic bone screw designs available, so a complete list of dimensions and tolerances for all screws covered by this specification is unfeasible. However, this specification does provide required dimensions and tolerances for 2 types of screws as classified in 4.1. Screws conforming to this specification, and designated as HA or HB screws, shall be fabricated in accordance with the dimensions and tolerances described as follows:

5.1.1 *Type HA:*

5.1.1.1 *Screw Dimensions*—The dimensions of HA screws are given in Table 1 and Fig. 2.

5.1.1.2 *Screw Thread*—The dimensions of the threads of HA screws are given in Table 2 and Fig. 3.

5.2 *Type HB:*

5.2.1 *Screw Dimensions*—The dimensions of HB screws are given in Table 3 and Fig. 4.

5.2.2 *Screw Thread*—The dimensions of the threads of HB screws are given in Table 4 and Fig. 5.

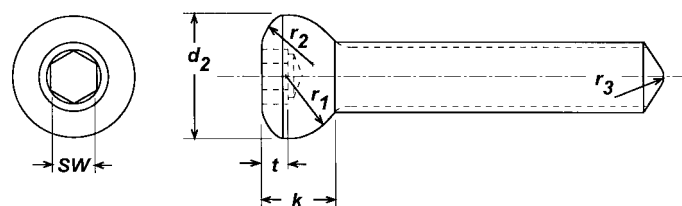


FIG. 2 Schematic of HA Screw Dimensions

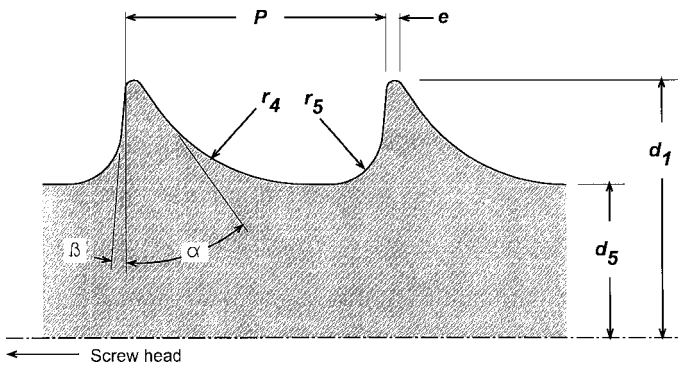


FIG. 3 Schematic of HA Screw Thread Dimensions

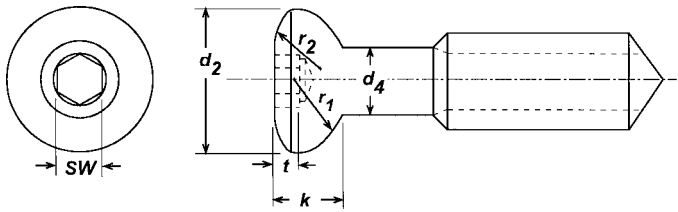


FIG. 4 Schematic of HB Screw Dimensions

## 6. Material

6.1 Screws shall be fabricated from one of the following materials:

- 6.1.1 Stainless steel alloy (Specification F 138)
- 6.1.2 Nitrogen strengthened stainless steel alloy (Specifications F 1314 and F 1586)
- 6.1.3 Unalloyed titanium (Specification F 67)
- 6.1.4 Titanium-aluminum-vanadium alloy (Specifications F 136, F 620, and F 1472)
- 6.1.5 Titanium-aluminum-niobium alloy (Specification F 1295)
- 6.1.6 Titanium-niobium-zirconium alloy (Specification F 1713)

6.1.7 Cobalt-chromium-molybdenum alloy (Specifications F 799, E 1537)

6.1.8 Titanium-molybdenum-zirconium-iron alloy (Specification F 1813).

## 7. Finish and Marking

7.1 The screw shall be free from nicks, dents, and scratches when examined in accordance with Practice F 86. Self-tapping flutes shall be sharp.

7.2 When size permits, the following information should be legibly marked on the head of the screw (in order of preference):

- 7.2.1 Manufacturer's name or logo,
- 7.2.2 Screw size,
- 7.2.3 Material,
- 7.2.4 Catalog number, and
- 7.2.5 Manufacturing lot number.

7.3 Screws shall be marked in accordance with Practice F 983, unless otherwise specified in 7.2, in a manner such that the mechanical integrity of the screw is not compromised.

## 8. Care and Handling

8.1 The screw should be cared for and handled in accordance with Practice F 565, as appropriate.

## 9. Driving Instruments

9.1 A variety of screwdrivers exist for the insertion and removal of bone screws. Specification F 116 provides a specification for several types of medical screwdrivers.

9.2 Screws conforming to this specification, and designated as HA or HB screws, are to be driven in with the hexagonal screwdriver bits (Specification F 116 Type IV) indicated in Section 5.

## 10. Keywords

- 10.1 bone screw; dimensions; terminology

**TABLE 1 Dimensions and Tolerances of HA Screws**

Screw Type and Size	Head Diameter, $d_2$ , mm	Head Height, $k$ , mm $\approx$	Bottom Head Radius, $r_1$ mm	Top Head Radius, $r_2$ , mm $\approx$	Tip Radius, $r_3$ , mm $\approx$	Hex Slot Width, $SW$ , mm	Hex Depth, $t$ , min, mm	Screwdriver Size <sup>A</sup>
HA 1.5	3.00 + 0.00 - 0.10	1.6	1.750 + 0.000 - 0.075	1.5	0.3	1.507 + 0.040 - 0.000	0.8	1.5
HA 2.0	4.00 + 0.00 - 0.10	1.9	2.250 + 0.000 - 0.075	2.0	0.4	1.507 + 0.040 - 0.000	1.0	1.5
HA 2.7	5.00 + 0.00 - 0.15	2.3	2.750 + 0.000 - 0.075	2.5	0.4	2.507 + 0.040 - 0.000	1.2	2.5
HA 3.5	6.00 + 0.00 - 0.15	2.6	3.250 + 0.000 - 0.075	2.5	1.0	2.507 + 0.040 - 0.000	1.5	2.5
HA 4.0	6.00 + 0.00 - 0.15	2.4	3.250 + 0.000 - 0.075	2.5	1.0	2.507 + 0.040 - 0.000	1.5	2.5
HA 4.5	8.00 + 0.00 - 0.15	4.6	4.250 + 0.000 - 0.075	2.5	1.0	3.510 + 0.048 - 0.000	2.8	3.5
HA 5.0	8.00 + 0.00 - 0.15	4.6	4.250 + 0.000 - 0.075	2.5	1.0	3.510 + 0.048 - 0.000	2.8	3.5

<sup>A</sup>Type IV hexagonal screwdriver bit as specified in Specification F 116.

**TABLE 2 Dimensions and Tolerances of HA Screw Thread**

Screw Type and Size	Thread Diameter, $d_1$ , mm	Core Diameter, $d_5$ , mm	Crest Width, $e$ , mm $\approx$	Thread Pitch, $P$ , mm $\approx$	Clearance Flank Radius, $r_4$ , mm $\approx$	Pressure Flank Radius, $r_5$ , mm $\approx$	Clearance Flank Angle $\alpha$ ° $\approx$	Pressure Flank Angle $\beta$ ° $\approx$
HA 1.5	1.50 + 0.00 - 0.15	1.10 + 0.00 - 0.10	0.1	0.5	0.3	0.1	35	3
HA 2.0	2.00 + 0.00 - 0.15	1.30 + 0.00 - 0.10	0.1	0.6	0.4	0.1	35	3
HA 2.7	2.70 + 0.00 - 0.15	1.90 + 0.00 - 0.15	0.1	1.0	0.6	0.2	35	3
HA 3.5	3.50 + 0.00 - 0.15	2.40 + 0.00 - 0.15	0.1	1.25	0.8	0.2	35	3
HA 4.0	4.00 + 0.00 - 0.15	2.90 + 0.00 - 0.15	0.1	1.5	0.8	0.2	35	3
HA 4.5	4.50 + 0.00 - 0.15	3.00 + 0.00 - 0.15	0.1	1.75	1.0	0.3	35	3
HA 5.0	5.00 + 0.00 - 0.15	3.50 + 0.00 - 0.15	0.1	1.75	1.0	0.3	35	3

**TABLE 3 Dimensions and Tolerances of HB Screws**

Screw Type and Size	Head Diameter, $d_2$ , mm	Shaft Diameter, $d_4$ , mm	Head Height, $k$ , mm $\approx$	Bottom Head Radius, $r_1$ , mm	Top Head Radius, $r_2$ , mm $\approx$	Hex Slot Width, $SW$ , mm	Hex Depth, $t$ , min, mm	Screwdriver Size <sup>A</sup>
HB 4.0	6.00 + 0.00 - 0.15	2.40 + 0.00 - 0.15	2.9	3.250 + 0.000 - 0.075	2.5	2.507 + 0.040 - 0.000	1.5	2.5
HB 6.5	8.00 + 0.00 - 0.15	4.50 + 0.00 - 0.15	4.6	4.250 + 0.000 - 0.075	2.5	3.510 + 0.048 - 0.000	2.8	3.5

<sup>A</sup>Type IV hexagonal screwdriver bit as specified in Specification F 116.

TABLE 4 Dimensions and Tolerances of HB Screw Thread

Screw Type and Size	Thread Diameter, $d_1$ , mm	Core Diameter, $d_5$ , mm	Crest Width, $e$ , mm	Thread Pitch, $P$ , mm	Clearance Flank Radius, $r_4$ , mm	Pressure Flank Radius, $r_5$ , mm	Clearance Flank Angle $\alpha$	Pressure Flank Angle $\beta$
HB 4.0	4.00 + 0.00 - 0.15	1.90 + 0.00 - 0.15	0.1	1.75	0.8	0.3	25	5
HB 6.5	6.50 + 0.00 - 0.15	3.00 + 0.00 - 0.15	0.2	2.75	1.2	0.8	25	5

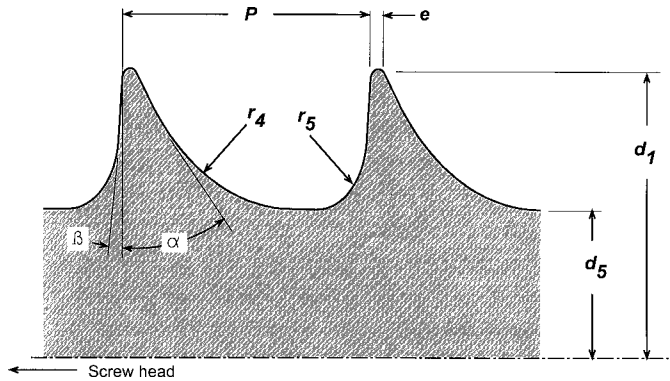


FIG. 5 Schematic of HB Screw Thread Dimensions

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 This specification is intended to provide useful and consistent information related to the terminology, requirements for materials, finish and marking considerations, and care and handling of metallic bone screws. It includes some of the terms and requirements from Specification F 543 - 92 and Reference Chart F 544 - 92. However, none of the dimensions from the screw types in F 543 - 92 are included since the subcommittee could not identify manufacturers who are currently making screws in accordance with Specification F 543 - 92.


X1.2 Dimensional requirements are provided for a specific type of bone screw - those which have a solid core, a spherical head, and a hexagonal driving slot. These screws, specified here as Specification F 543 Type HA and HB, are similar to those specified in ISO 5835. The dimensions of the HA and HB screws were included in this specification because they have achieved widespread clinical use and are offered by several

manufacturers. Standardization of the dimensions and tolerances of the key features of these screws is intended to allow the implants from one manufacturer to be used with the associated instruments (taps, drills, screwdrivers, and so forth) from different manufacturers, and serve as a baseline for future screw products. This may benefit the surgeon and patient by aiding the identification of the appropriate instrumentation for the implantation and removal of screws by the operating-room staff.

X1.3 The task group's future plan is to combine performance considerations, performance levels, and Test Methods F 117, F 1622, and F 1691 for bone screws into one standard for easy reference. Initially, the test methods will be added to this specification as annexes. The task group is currently working to define performance considerations for bone screws and to determine minimum levels of performance.

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