INTERNATIONAL STANDARD

ISO 5835

First edition
1991-01-15

Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions

Implants chirurgicaux — Vis métalliques pour os à raccord d'entraînement hexagonal, à embase sphérique et filetage asymétrique — Dimensions

Reference number
ISO 5835:1991(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5835 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This first edition cancels and replaces the first edition of ISO 5835-1:1985. Clause 5 and the annexes are new.

Annexes A, B and C of this International Standard are for information only.

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Introduction

This International Standard lays down requirements for surgical bone screws as given in clause 1. It is necessary, however, to bear in mind that there may be a need for bone screws for particular applications, which are not covered by this Standard or by ISO 9268. Such special bone screws may differ in part from the standardized forms or may combine parts from these two product standards (see annex A).

However, there are certain areas of the design of screws such as the drive connections, the shape of the under-surface of the head and the thread form that are critical from the point of view of surgical use. These areas are those where there is an interface with bone plates (ISO 5836 and ISO 9269) or with surgical instruments or other devices such as hexagon keys (ISO 8319-1) or taps, drills and countersink cutters. No variation is permitted in these areas.

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Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions

1 Scope

This International Standard specifies dimensions and tolerances for metal bone screws used in surgery, having hexagonal drive connection, spherical under-surface of the head, and shallow and deep asymmetrical threads.

NOTES

1 The mechanical requirements for screws that are cited in this International Standard are specified in ISO 6475.

2 The interrelationship of International Standards dealing with bone screws, bone plates and relevant tools is shown for information in annex B.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6018:1987, *Orthopaedic implants — General requirements for marking, packaging and labelling.*

ISO 6475:1989, *Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods.*

3 Code for screw thread

The following code shall be used to identify the type of screw thread conforming to this International Standard:

Shallow thread (for cortical screws): Code HA

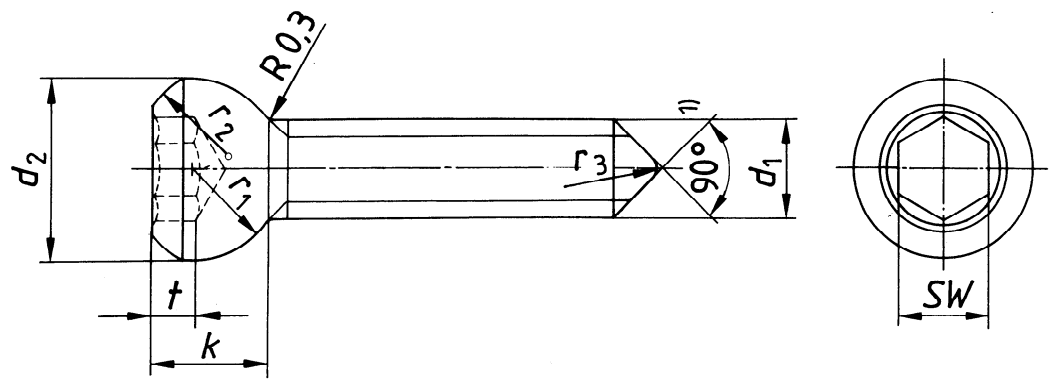
Deep thread (for spongiosa/cancellous screws): Code HB

4 Dimensions and tolerances

All dimensions and tolerances are given in millimetres.

4.1 Screw with shallow thread (HA)

HA screws shall be as given in figures 1 and 2 and tables 1 and 2.



1) This may be 60° for self-cutting screws.

Figure 1 — Screw with shallow thread (HA)

Table 1 — Dimensions of HA series screws

Code and diameter of thread	Nominal diameter d_1	d_2	d_2 tol.	k ≈	r_1 $^{+0,25}_{0}$	r_2 ≈	r_3 ≈	SW F10[1)]	t min.
HA 1,5	1,5	3	0 −0,10	1,6	1,5	1,5	0,3	1,5	0,8
HA 2,0	2	4		1,9	2	2	0,4	1,5	1,0
HA 2,7	2,7	5	0 −0,15	2,3	2,5	2,5	0,4	2,5	1,2
HA 3,5	3,5	6		2,6	3	2,5	1	2,5	1,5
HA 4	4	6		2,4	3	2,5	1	2,5	1,5
HA 4,5	4,5	8		4,6	4	2,5	1	3,5	2,8
HA 5	5	8		4,6	4	2,5	1	3,5	2,8

1) F10 = $\begin{cases} +0,047 \\ +0,007 \end{cases}$ for $SW \leqslant 3$ mm

F10 = $\begin{cases} +0,058 \\ +0,010 \end{cases}$ for $SW > 3$ mm

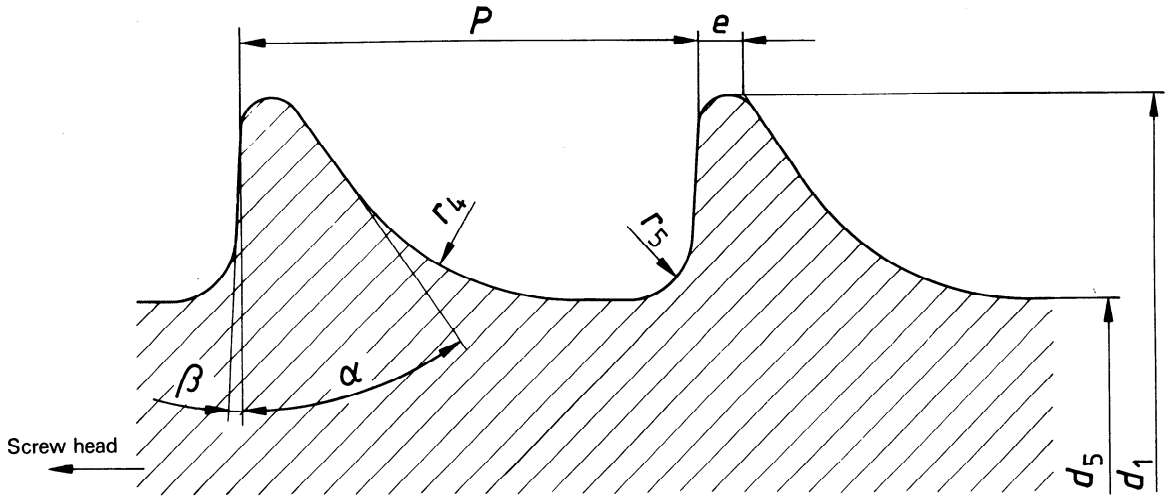


Figure 2 — Shallow thread (HA)

Table 2 — Dimensions of HA thread

Code and diameter of thread	d_1 $^{0}_{-0,15}$	d_5	tol.	e ≃	P	r_4 ≃	r_5 ≃	α ≃	β ≃
HA 1,5	1,5	1,1	0 −0,10	0,1	0,5	0,3	0,1	35°	3°
HA 2,0	2	1,3		0,1	0,6	0,4	0,1	35°	3°
HA 2,7	2,7	1,9	0 −0,15	0,1	1	0,6	0,2	35°	3°
HA 3,5	3,5	2,4		0,1	1,25	0,8	0,2	35°	3°
HA 4	4	2,9		0,1	1,5[1) 2)]	0,8	0,2	35°	3°
HA 4,5	4,5	3		0,1	1,75	1	0,3	35°	3°
HA 5	5	3,5		0,1	1,75	1	0,3	35°	3°

1) Variation in thread profile:

The total parameters of values d_1, d_5, e, r_4, r_5, α and β allow the theoretical maximum thread profile to be defined.

It is recommended that the maximum variation from the theoretical profile at any point on thread from should not exceed:

— 0,050 mm for HA 1,5 and HA 2
— 0,075 mm for HA 2,7 to HA 5

These values may be reconsidered in course of revision.

2) Attention is drawn to the pitch of the HA 4 screw, which is 1,5 mm as compared to that of the HB 4 screw, which is 1,75 mm (see table 4).

4.2 Screw with deep thread (HB)

HB screws shall be as given in figures 3 and 4 and tables 3 and 4.

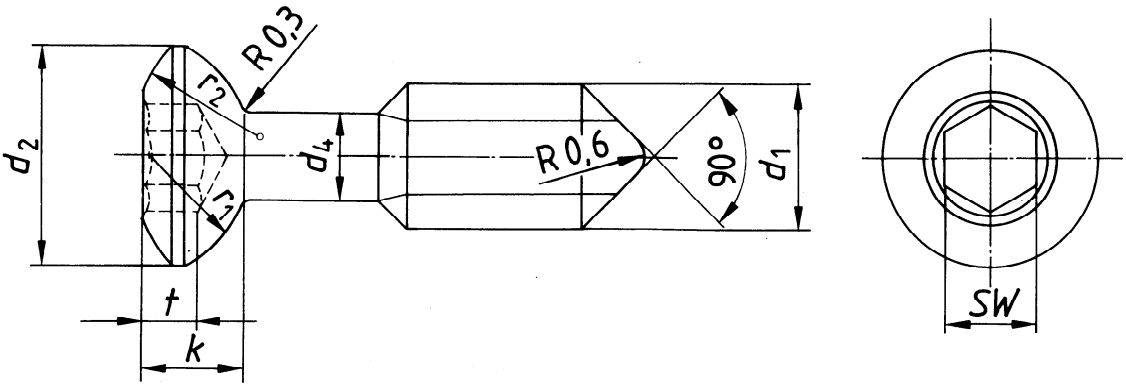


Figure 3 — Screw with deep thread (HB)

Table 3 — Dimensions of HB series screws

Code and diameter of thread	Nominal diameter d_1	d_2 $^{0}_{-0,15}$	d_4 $^{0}_{-0,15}$	k $\simeq$	r_1 $^{+0,25}_{0}$	r_2 $\simeq$	SW F10[1)]	t min.
HB 4	4	6	2,4	2,9	3	2,5	2,5	1,5
HB 6,5	6,5	8	4,5	4,6	4	2,5	3,5	2,8

1) F10 = $\begin{cases} +0,047 \\ +0,007 \end{cases}$ for $SW \leqslant 3$ mm

F10 = $\begin{cases} +0,058 \\ +0,010 \end{cases}$ for $SW > 3$ mm

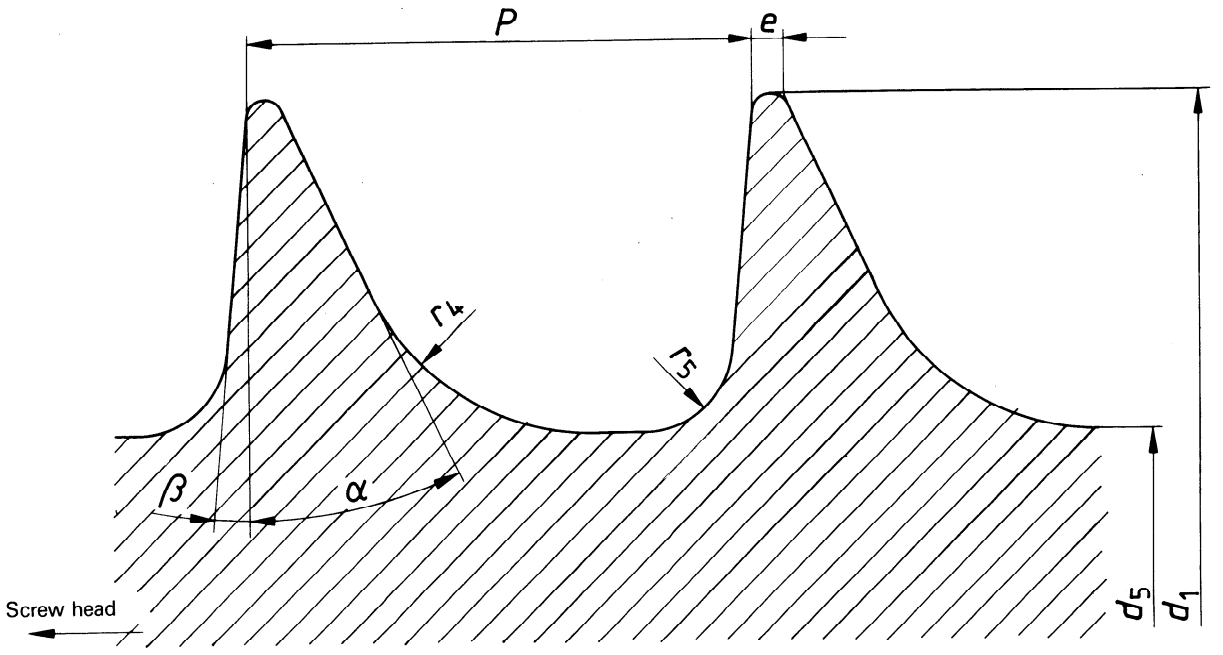


Figure 4 — Deep thread (HB)

Table 4 — Dimensions of HB thread

Code and diameter of thread	d_1 $^{0}_{-0,15}$	d_5 $^{0}_{-0,15}$	e ≃	P	r_4 ≃	r_5 ≃	α ≃	β ≃
HB 4	4	1,9	0,1	1,75[1) 2)]	0,8	0,3	25°	5°
HB 6,5	6,5	3	0,2	2,75	1,2	0,8	25°	5°

1) See footnote 2) in table 2.

2) Variation in thread profile: >

The total parameters of values d_1, d_5, e, r_4, r_5, α and β allow the theoretical maximum thread profile to be defined.

It is recommended that the maximum variation from the theoretical profile at any point on thread form should not exceed:

— 0,075 mm for HB

This value may be reconsidered in course of revision.

5 Marking and packaging

The marking and the packaging shall be in accordance with ISO 6018.

Annex A
(informative)

Example for combined screw

This screw is an example as mentioned in the introduction for a combination of shallow thread HA 4,5 as given in figure 2 and table 2 in this International Standard whereas the cross-recessed drive connection is in accordance with figure 7 and table 6 in ISO 9268:1988. (For information, the illustration and the dimensions of the drive connection are given in tables A.1 and A.2, and figures A.1 and A.2.

The dimensions of head and thread, which are critical from the point of view of interface with screwdrivers, taps, drills, etc., are specified in ISO 9268 and this International Standard respectively, and the mechanical requirements are specified in ISO 6475.

A.1 Dimensions

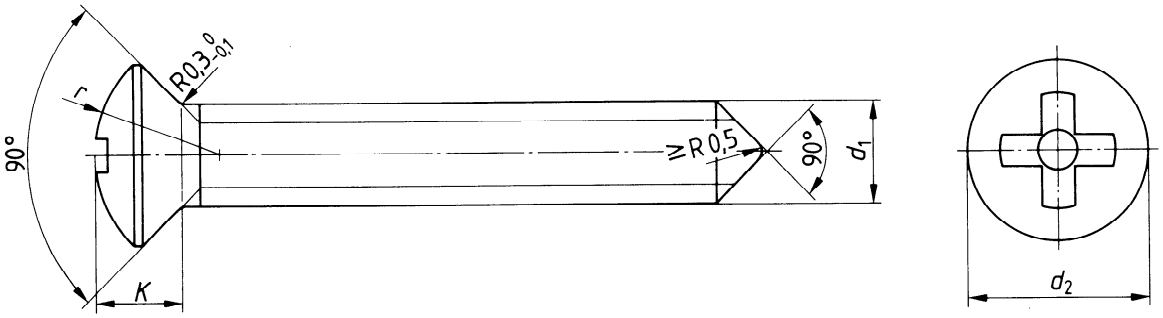


Figure A.1 — Combined screw

Table A.1 — Dimensions of combined screw

Nominal diameter d_1	d_2 $^{0}_{-0,15}$	k max.	r
4,5	8,0	3,8	5,5

A.2 Cross-recessed drive connection

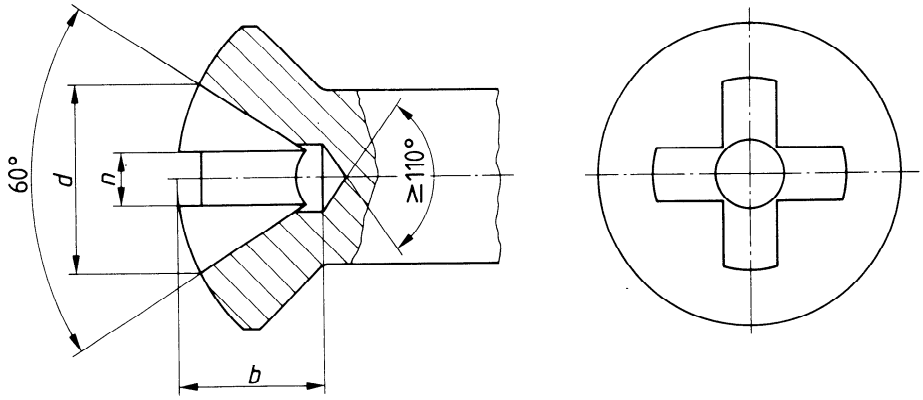


Figure A.2 — Cross-recessed drive connection

Table A.2 — Dimensions of cross-recessed drive connection

d	*b* max.	*n*
5,0	3,8	1,4

Annex B
(informative)

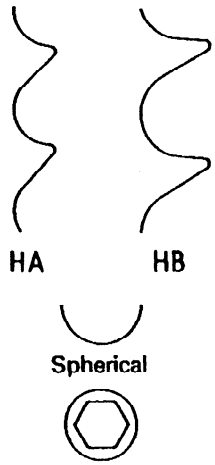
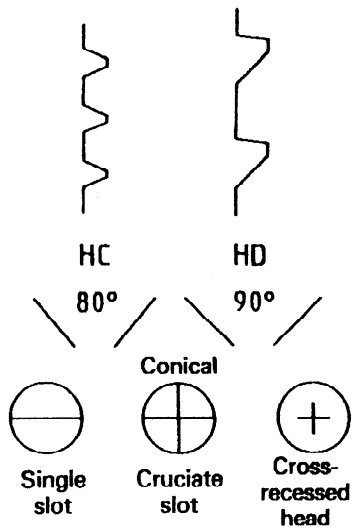
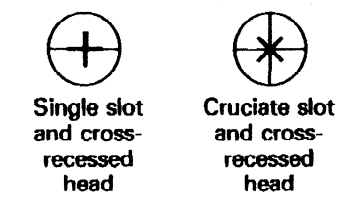
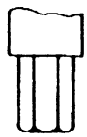
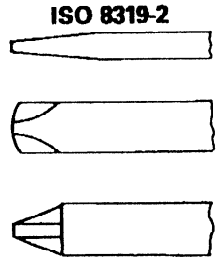
Interrelationship of International Standards dealing with bone screws, bone plates and relevant tools

It has been decided that the set of International Standards dealing with bone screws, bone plates and relevant tools should be divided into two parallel series. The basis of the division into two series is the essentially different designs of the screw threads of the bone screws (HA and HB type screws as opposed to HC and HD type screws).

A simplified schematic guide illustrating the interrelationship between screws, plates and tools covered by the two parallel series of International Standards is given on the following page.

<table>
<tr><td rowspan="3">Screws</td><td>Thread

Head under-surface

Drive connection</td><td rowspan="2">ISO 5835
 
</td><td>ISO 9268
 
</td></tr>
<tr><td> 
</td></tr>
<tr><td>Mechanical requirements</td><td>ISO 6475
Breaking torque/ angle of rotation</td><td>In preparation</td></tr>
<tr><td rowspan="2">Plates</td><td>Holes and slots</td><td>ISO 5836</td><td>ISO 9269</td></tr>
<tr><td>Mechanical requirements</td><td>ISO 9585</td><td>ISO 9585</td></tr>
<tr><td rowspan="2">Driving tools</td><td>Keys and screwdrivers</td><td>ISO 8319-1
 
Hexagon keys</td><td>ISO 8319-2
 
Screwdrivers</td></tr>
<tr><td>Drill bits, taps, countersink cutters</td><td>ISO 9714-1</td><td>In preparation</td></tr>
</table>

Annex C
(informative)

Bibliography: International Standards referred to in table of annex B

[1] ISO 5835:1990, *Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions.*

[2] ISO 5836:1988, *Implants for surgery — Metal bone plates — Holes corresponding to screws with asymmetrical thread and spherical under-surface.*

[3] ISO 6475:1989, *Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods.*

[4] ISO 8319-1:1986, *Orthopaedic instruments — Drive connections — Part 1: Keys for use with screws with hexagon socket heads.*

[5] ISO 8319-2:1986, *Orthopaedic instruments — Drive connections — Part 2: Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws.*

[6] ISO 9268:1988, *Implants for surgery — Metal bone screws with conical under-surface of head — Dimensions.*

[7] ISO 9269:1988, *Implants for surgery — Metal bone plates — Holes and slots corresponding to screws with conical under-surface.*

[8] ISO 9585:1990, *Implants for surgery — Determination of bending strength and stiffness of bone plates.*

[9] ISO 9714-1:1990[1)], *Orthopaedic drilling instruments — Part 1: Drill bits, taps and countersink cutters.*

1) To be published.

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