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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Implants for surgery — Metal bone screws with conical under-surface of head — Dimensions

Implants chirurgicaux — Vis métalliques à embase conique pour os — Dimensions

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Reference number
ISO 9268 : 1988 (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 approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 9268 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This first edition cancels and replaces the first editions of ISO 5835-3 : 1986 and ISO 5835-4 : 1983, of which it constitutes a technical revision.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Implants for surgery — Metal bone screws with conical under-surface of head — Dimensions

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0 Introduction

This International Standard lays down requirements for surgical bone screws as given in the Scope. It is necessary 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 5835. Such special bone screws may differ in part from the standardized forms or may combine parts from these two product Standards.

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 use in surgery. These areas are those in which there is an interface with bone plates (ISO 9269) or other devices or with instruments such as screwdrivers (ISO 8319-2) or taps, drills and countersink cutters. No variation is permitted in these areas.

1 Scope and field of application

This International Standard specifies the dimensions and tolerances of metal bone screws with conical under-surface of the head used in surgery.

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

2 Reference

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

3 Code for screw thread

The following code shall be used to identify the type of screws complying with this International Standard :

Type of thread	Code
Symmetrical thread	HC
Asymmetrical thread	HD

4 Dimensions and tolerances

4.1 Screws with symmetrical thread form HC

4.1.1 Screws with single-slot drive connection

Screws with single-slot drive connections shall be as given in figure 1 and table 1.

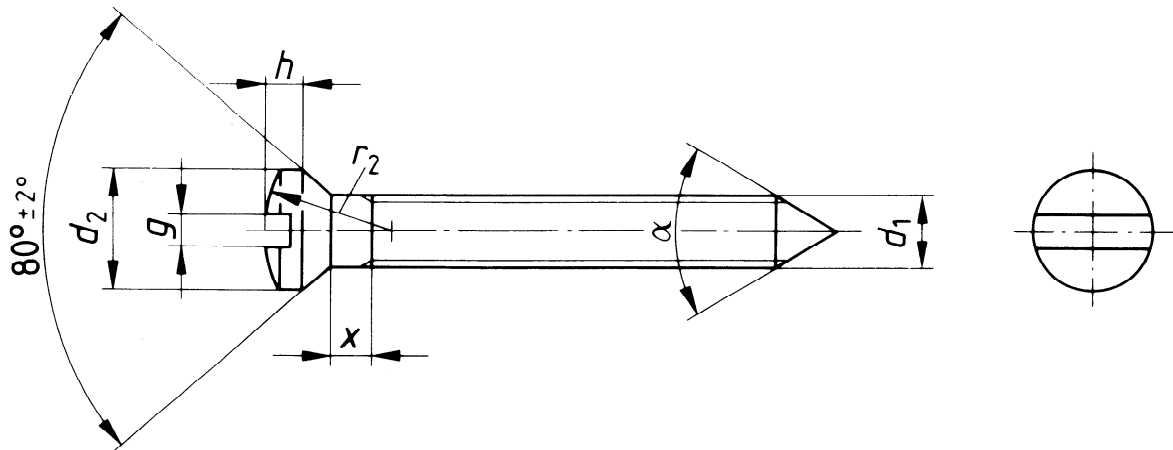


Figure 1 — Screw with single-slot recess

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Table 1 — Dimensions of screw with single-slot recess

Dimensions in millimetres

Type of thread ¹⁾	Nominal diameter d_1	d_2	g	h	r_2	x max.	α degrees
HC	2,9	4,62 to 6,1	1,25 to 1,4	1,5 to 2	5	1,6	Optional : for example > 60°

1) See table 3.

4.1.2 Screws with cruciate-slot drive connection

Screws with cruciate-slot drive connection shall be as given in figure 2 and table 2.

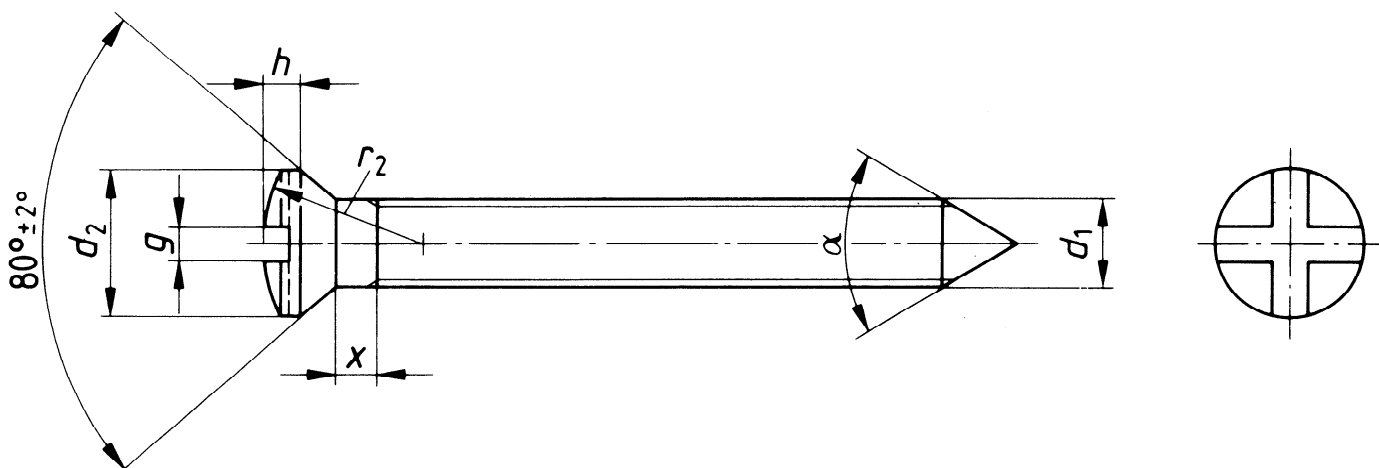


Figure 2 – Screw with cruciate recess

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Table 2 – Dimensions of screw with cruciate recess

Dimensions in millimetres

Type of thread ¹⁾	Nominal diameter d_1	d_2	g	h	r_2	x max.	α degrees
HC	3,5 3,9 4,2	5,8 to 6,5	1,25 to 1,4	1,5 to 2	6,35	1,6	Optional : for example > 60°

1) See table 3.

4.1.3 Screws with combined cruciate-slot and cross-recessed drive connection

NOTE — This cross-recessed drive connection is also called a "modified Philips drive".

The combined cruciate-slot and cross-recessed drive connection shall be as given in figure 3 and the dimensions of the head and screw shall be as given in table 2.

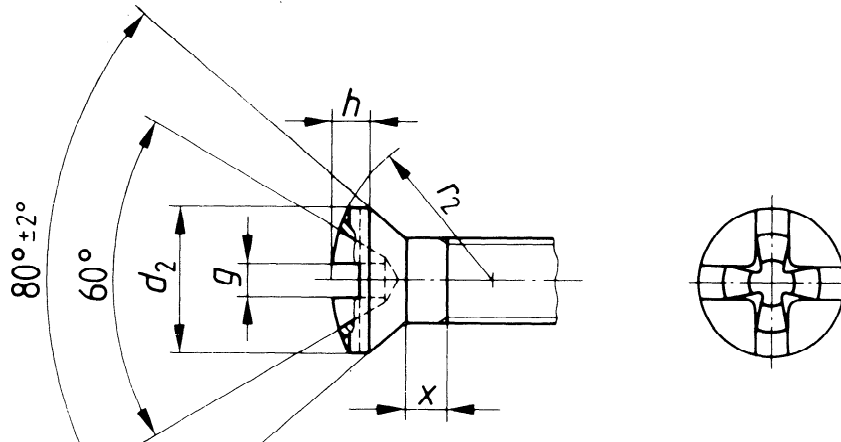


Figure 3 — Screw head with combined cruciate-slot and cross-recessed drive connection

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4.1.4 Dimensions of symmetrical thread form HC

Dimensions of the HC thread shall be as given in figure 4 and table 3.

Suitable flutes may be added to make the screws self-tapping.

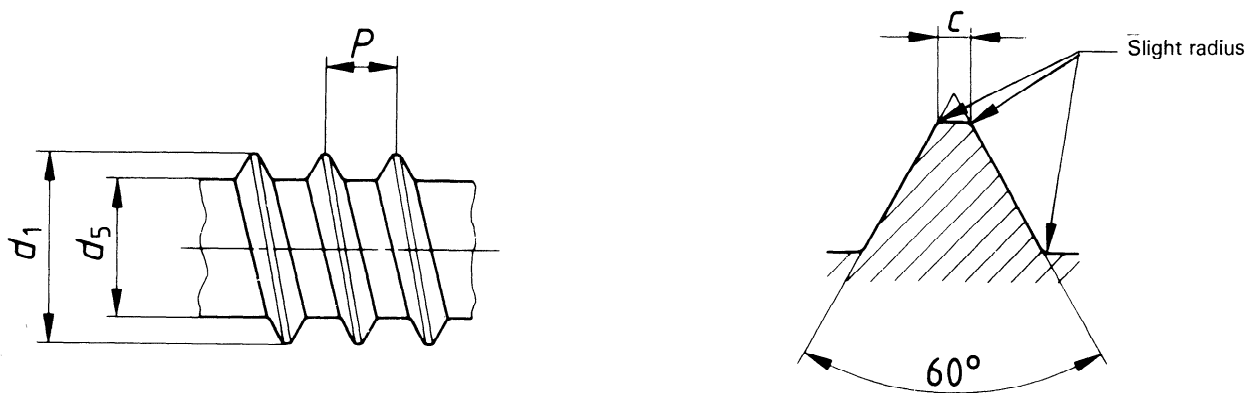


Figure 4 — Illustration of HC thread form

Table 3 – Dimensions of symmetrical thread HC

Dimensions in millimetres

Code and nominal diameter of thread	d_1		d_5		P	c max.
	min.	max.	min.	max.		
HC 2,9	2,79	2,9	2,03	2,18	1,06	0,1
HC 3,5	3,43	3,53	2,51	2,64	1,27	
HC 3,9	3,78	3,91	2,77	2,92		
HC 4,2	4,09	4,22	2,95	3,25		

NOTE – Suitable flutes may be added to make the screws self-tapping.

4.2 Screws with asymmetrical thread form HD

4.2.1 Screws with combined single-slot and cross-recessed drive connection

NOTE – This cross-recessed drive connection is also called a "modified Phillips drive".

Screws with combined single-slot and cross-recessed drive connection shall be as given in figure 5 and table 4.

The slot shall extend into the cylindrical point of the head, but shall not be so deep as to extend into the conical under-surface.

The maximum depth of the recess shall be such that the torque strength of the screw is unaffected.

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Dimensions in millimetres

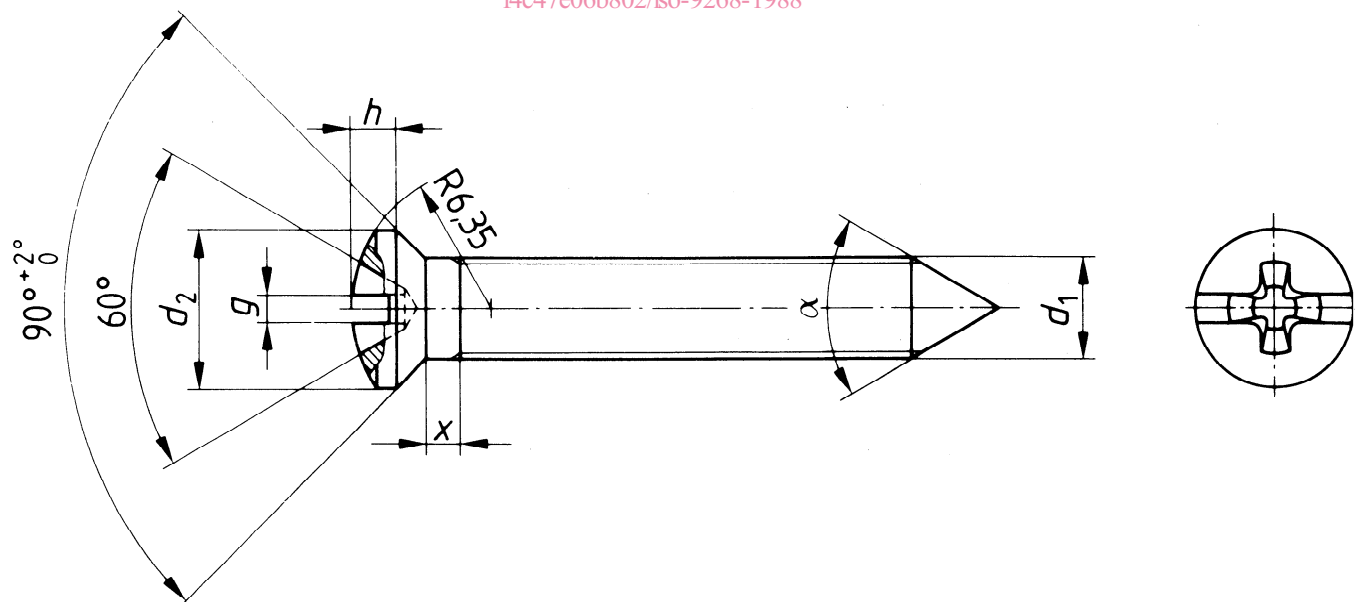


Figure 5 – Screw with cross-recessed head

Table 4 – Dimensions of screw with cross-recessed head

Dimensions in millimetres

Type of thread	Nominal diameter ¹⁾ d_1	d_2	g	x max.	h	α degrees
HD	4 4,5	6,75 to 7,35	1,25 to 1,4	1,6	1,8 to 2,1	Optional : for example > 60°

1) See table 5.

4.2.2 Dimensions of asymmetrical thread form HD

Dimensions of the HD thread shall be as given in figure 6 and table 5.

Suitable flutes may be added to make the screws self-tapping.

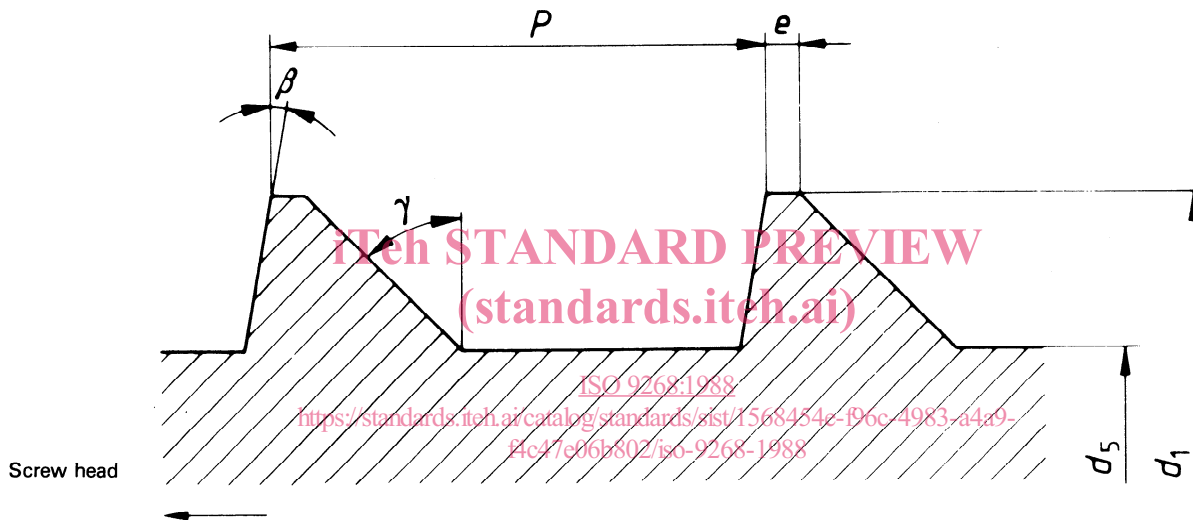


Figure 6 – Asymmetrical thread HD

Table 5 – Dimensions of asymmetrical thread HD

Dimensions in millimetres

Code and nominal diameter of thread	d_1 $\pm 0,03$	d_5 $\pm 0,03$	e	P	r degrees	β degrees
HD 4	4	2,92	0,1	1,59	45°	10°
HD 4,5	4,5			2,18		

NOTE – Suitable flutes may be added to make the screws self-tapping.

4.3 Cross-recessed drive connection

The cross-recessed drive connection shall be as given in figure 7 and table 6.

NOTE — The heads of screws with this drive connection should be of sufficient size to ensure that the torque strength is unaffected.

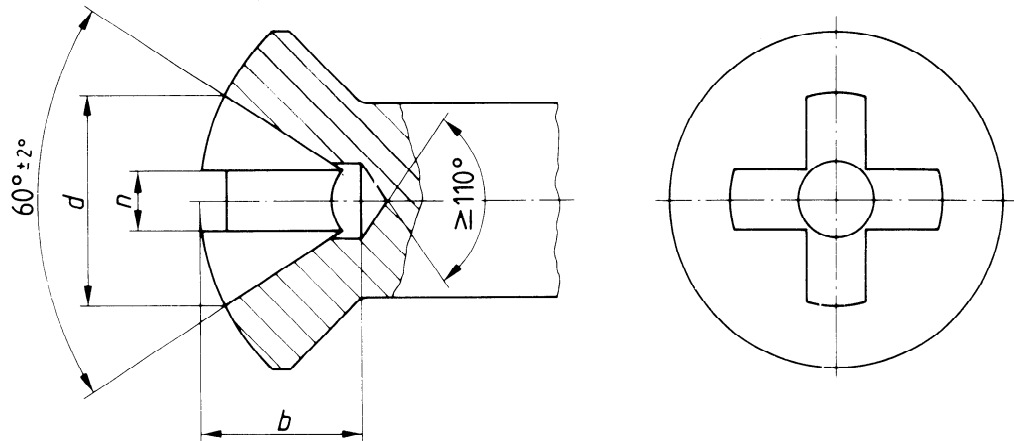


Figure 7 Cross recessed drive connection
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Table 6 — Dimensions of cross-recessed drive connection

Dimensions in millimetres

<i>d</i>	<i>b</i> max.	<i>n</i>
5	3,8	1,4

5 Marking and packaging

Marking and packaging shall be in accordance with ISO 6018.