INTERNATIONAL STANDARD

ISO 9714-1

Second edition
2012-06-01

Orthopaedic drilling instruments —

Part 1: Drill bits, taps and countersink cutters

Instruments de forage orthopédiques —

Partie 1: Tarauds, forets et fraises à lamer

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9714-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

This second edition cancels and replaces the first edition (ISO 9714-1:1991), which has been technically revised.

ISO 9714 consists of the following parts, under the general title *Orthopaedic drilling instruments*:

— *Part 1: Drill bits, taps and countersink cutters*

Orthopaedic drilling instruments —

Part 1:
Drill bits, taps and countersink cutters

1 Scope

This part of ISO 9714 specifies materials and mechanical properties, and dimension and marking requirements for drill bits, taps and countersink cutters made of stainless steel for use in orthopaedic surgery with bone screws specified in ISO 5835.

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

This part of ISO 9714 is not applicable to self-drilling pins, such as those used in external fixation, and self-drilling guide pins.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5835:1991, *Implants for surgery — Metal bone screws with hexagonal drive connection, spherical undersurface of head, asymmetrical thread — Dimensions*

3 Materials and dimensions

3.1 Material

Drill bits, taps and countersink cutters may be made from metal complying with the requirements given in Table 1.

Table 1 — Steel grades and chemical compositions

Steel grade in accordance with:				Chemical composition % [a]								
ISO 7153-1: 1991 ref. letter	EN 10088-3: 2005	AISI [b]	ASTM F899: 2011	C max.	Si max.	Mn max.	P max.	S	Cr	Mo	Ni	Other elements
				Austenitic stainless steels								
M	1.4301	304	304	0,07	1	2	0,045	0,03 max.	17 to 19	–	8 to 11	N: 0,10 max.
N	–	303	303	0,12	1	2	0,06	0,15 to 0,35	17 to 19	0,7 max. [c]	8 to 10	–
O	1.4310	301	301	0,15	1	2	0,045	0,03 max.	16 to 18	–	6 to 8	–
P	1.4408	316	316	0,07	1	2	0,045	0,03 max.	16,5 to 18,5	2 to 2,5	10,5 to 13,5	N: 0,10 max.
–	1.4404 or 1.4435	316L	–	0,03	1	2	0,045	0,03 max.	16 to 19	2,0 to 3	10,0 to 15	–
				Martensitic steels								
–	–	–	420A	0,16 to 0,25	1	1	0,04	0,03 max.	12 to 14	–	1 max.	–
–	–	–	420B	0,26 to 0,35	1	1	0,04	0,03 max.	12 to 14	–	1 max.	–
D	–	420C	420C	0,42 to 0,50	1	1	0,04	0,03 max.	12,5 to 14,5	–	1 max.	–
H	–	–		0,35 to 0,4	1	1	0,045	0,03 max.	14 to 15	0,4 to 0,6	–	V: 0,1 to 0,15
I	–	–		0,42 to 0,55	1	1	0,045	0,03 max.	12 to 15	0,45 to 0,90	–	V: 0,1 to 0,15
R	1.4112	440B		0,85 to 0,95	1	1	0,045	0,03 max.	17 to 19	0,9 to 1,3	–	V: 0,07 to 0,12
–	–	–	440B	0,75 to 0,95	1	1	0,04	0,03 max.	16 to 18	0,75 max.	–	–
S		440A	440A	0,60 to 0,75	1	1	0,040	0,03 max.	16 to 18	0,75 max.	–	–

[a] Chemical composition data are extracted from ISO 7153-1:1991, ASTM F899:2011, AISI 316L and EN 10088-3:2005.

[b] American Iron and Steel Institute.

[c] At the option of the steelmaker, the Mo content for steel grade N can be up to 0,7 %.

3.2 Dimensions

3.2.1 Drill bits

The diameter of the drill bit shall be as given in Table 2. The point angle shall be (90 ± 10)°.

3.2.2 Taps

The core diameter and outside diameter shall be as given in Table 2. The thread form and pitch shall be that of the appropriate screw as specified in ISO 5835.

3.2.3 Countersink cutters

The diameter of the pin and cutter head shall be as given in Table 2 and Figure 1. The cutter shall be either of conical form with an angle of (90 ± 2)° or of spherical form.

Table 2 — Dimensions of drill bits, taps and countersink cutters

Dimensions in millimetres

Screws (These data are extracted from ISO 5835 and are given here for information)				Drill bits		Taps [a]			Countersink cutters	
ISO 5835:1991 code	Nominal diameter	Core diameter	Pitch	Diameter of drill intended for drilling clearance hole $^{0}_{-0,02}$	Diameter of drill intended for drilling pilot hole $^{0}_{-0,02}$	Outside diameter $^{0}_{-0,15}$	Core diameter $^{0}_{-0,15}$	Pitch	Pin diameter d_1 $^{0}_{-0,1}$	Cutter head diameter d_2
Screws with shallow head										
HA 1,5	1,5	1,1	0,5	1,5	1,1	1,5	1,1	0,5	1,1	4
HA 2	2	1,3	0,6	2	1,5	2	1,3	0,6	1,1	4
HA 2,7	2,7	1.9	1	2,7	2	2,7	1,9	1	2,5	6
HA 3,5	3,5	2,4	1,25	3,5	2,5	3,5	2,4	1,25	2,5	6
HA 4	4	2,9	1,5	4	3	4	2,9	1,5	2,5	6
HA 4,5	4,5	3	1,75	4,5	3,2	4,5	3	1,75	3,2	8
HA 5	5	3,5	1,75	5	3,7	5	3,5	1,75	3,2	8
Screws with deep thread										
HB 4	4	1,9	1,75	Not applicable to HB screws	2	4	1,9	1,75	Not required for HB screws	
HB 6,5	6,5	3	2,75		3,2	6,5	3	2,75		

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

– 0,050 mm for HA 1,5 and HA 2;

– 0,075 mm for HA 2,7 to HA 5;

– 0,075 mm for HB 4 and HB 6,5.

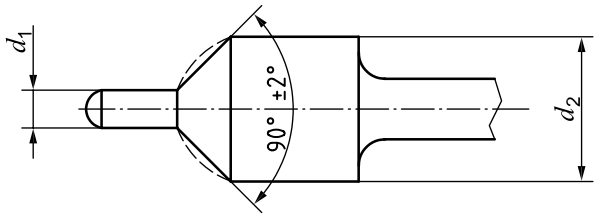

Figure 1 — Countersink cutter

4 Marking

4.1 Drill bits

Drill bits shall be marked with the diameter of the bit expressed in millimetres.

4.2 Taps

Taps shall be marked with the code and nominal size of the screw, as specified in ISO 5835:1991, with which they are intended to be used.

4.3 Countersink cutters

Countersink cutters shall be marked with the nominal sizes of the screw, as specified in ISO 5835:1991, with which they are intended to be used.

Annex A
(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 parallel series of International Standards is given in Figure A.1.