भारतीय मानक
Indian Standard

IS 14239 (Part 1) : 2018
ISO 9714-1 : 2012

अस्थि वेधीय उपकरण

भाग 1 वेधीय यंत्र, पेंचतराश और काउंटरसिंक कर्तक

(पहला पुनरीक्षण)

Orthopaedic Drilling Instruments

Part 1 Drill Bits, Taps and Countersink Cutters

(First Revision)

ICS 11.040.40

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Orthopaedic Instruments, Implant and Accessories Sectional Committee, MHD 02

NATIONAL FOREWORD

This Indian Standard (Part 1) (First Revision) which is identical with ISO 9714-1 : 2012 'Orthopaedic drilling instruments — Part 1: Drill bits, taps and countersink cutters' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Orthopaedic Instruments, Implant and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published as IS 14239 : 1995 identical with ISO 9714-1 : 1991. The first revision of this standard has been published as IS 14239 (Part 1) to align it with the latest version of ISO 9714-1.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
b) Comma (,) has been used as a decimal marker while in Indian Standard, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to the following International Standard for which Indian Standard also exists. The corresponding Indian Standard, which is to be substituted in its place, is listed below along with its degree of equivalence for edition indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 5835 : 1991 Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions	IS 9829 (Part 1) : 1996 Implants for surgery — Metal bone screws: Part 1 With hexagonal drive connection, spherical under surface of head, asymmetrical thread — Dimensions (*first revision*)	Identical

This standard also makes a reference to the BIS Certification Marking of the product. Details of which are given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

ORTHOPAEDIC DRILLING INSTRUMENTS

PART 1 DRILL BITS, TAPS AND COUNTERSINK CUTTERS

(First Revision)

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 under-surface 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		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.

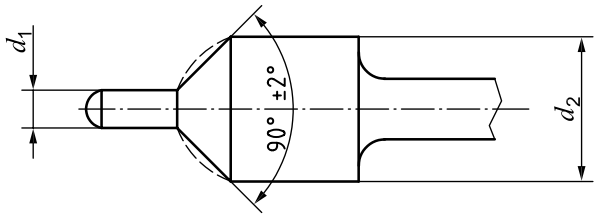


Figure 1 — Countersink cutter

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.

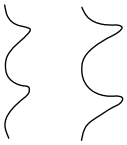
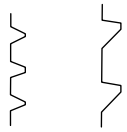
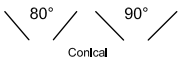
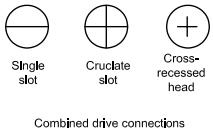
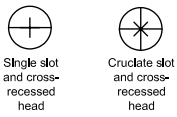
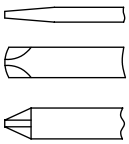
<table>
<tr><th>Device</th><th>Attribute</th><th>Thread Series 1</th><th>Thread Series 2</th></tr>
<tr><td rowspan="5">Screws</td><td>Thread</td><td>ISO 5835:1991
 
HA HB</td><td>ISO 9268:1988
 
HC HD</td></tr>
<tr><td>Head under surface</td><td> 
Spherical</td><td> 
80° 90°
Conical</td></tr>
<tr><td rowspan="3">Drive connection</td><td rowspan="3"> 
Hexagon socket</td><td> 
Single slot
Cruciate slot
Cross-recessed head
Combined drive connections
 
Single slot and cross-recessed head
Cruciate slot and cross-recessed head</td></tr>
<tr><td>ISO 14583:2011
 
Hexalobular socket</td></tr>
<tr><td>Mechanical requirements</td><td>ISO 6475:1989
Breaking torque/ angle of rotation</td><td></td></tr>
<tr><td rowspan="2">Plates</td><td>Holds and slots</td><td>ISO 5836:1988</td><td>ISO 9269:1988</td></tr>
<tr><td>Mechanical requirements</td><td>ISO 9585:1990</td><td>ISO 9585:1990</td></tr>
<tr><td rowspan="2">Driving tools</td><td rowspan="2">Keys and screwdrivers</td><td rowspan="2">ISO 8319-1:1996
 
Hexagon keys</td><td>ISO 8319-2:1986
 
Screwdrivers</td></tr>
<tr><td>ISO 10664:2005
 
Hexalobular drive tool</td></tr>
<tr><td>Drill bits, taps and countersink cutters</td><td></td><td>ISO 9714-1</td><td></td></tr>
</table>

Figure A.1 — Interrelationship between screws, plates and tools covered by the parallel series of International Standards

Bibliography

[1] ISO 4957, *Tool steels*

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

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

[4] ISO 7153-1:1991, *Surgical instruments — Metallic materials — Part 1: Stainless steel*

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

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

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

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

[9] ISO 9585, *Implants for surgery — Determination of bending strength and stiffness of bone plates*

[10] ISO 10664, *Hexalobular internal driving feature for bolts and screws*

[11] ISO 14583, *Hexalobular socket pan head screws*

[12] EN 10088-3:2005, *Stainless steels — Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steels for general purposes*

[13] ASTM F899: 2011, *Standard Specification for Wrought Stainless Steels for Surgical Instruments*

NATIONAL ANNEX A
(*National Foreword*)

A-1 BIS CERTIFICATION MARKING

The product may also be marked with the Standard Mark.

A-1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act,* 2016 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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Amendments Issued Since Publication

Amendment No.	Date of Issue	Text Affected

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