International Standard 8319/1

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

Orthopaedic instruments — Drive connections — Part 1: Keys for use with screws with hexagon socket heads

Instruments orthopédiques — Raccords d'entraînement — Partie 1: Clés à utiliser pour les vis à tête à six pans creux

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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.

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 8319/1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery.*

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.

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Orthopaedic instruments — Drive connections — Part 1: Keys for use with screws with hexagon socket heads

0 Introduction

Essential requirements for all varieties of screw keys are the following:

— the working end of the screw key should accurately engage the head of the screw;

— the materials used for the manufacture of the screw keys should be satisfactory from all clinical aspects;

— the screw key should have adequate strength.

The purpose of this part of ISO 8319 is to ensure that this is achieved without imposing undue restriction on design features.

1 Scope and field of application

This part of ISO 8319 specifies the dimensions, tolerances, mechanical properties and performance requirements of the working end of keys to be used for inserting and removing metal bone screws with hexagonal drive sockets, used as surgical implants.

Screw keys with a working end specified in this part of ISO 8319 are suitable for use with screws which conform to ISO 5835/1.

2 References

ISO 683/13, *Heat-treated steels, alloy steels and free-cutting steels — Part 13: Wrought stainless steels.*

ISO 5832/5, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.*

ISO 5835/1, *Implants for surgery — Metal bone screws — Dimensions — Part 1: Screws with asymmetrical thread, spherical under-surfaces.* [1]

ISO 6508, *Metallic materials — Hardness test — Rockwell test (scales A — B — C — D — E — F — G — H — K).* [2]

1) See the annex for information on the interrelationship between International Standards dealing with bone screws, bone plates and relevant tools.

2) At present at the stage of draft. (Revision of ISO/R 80-1968 and ISO 2718-1973.)

3 Dimensions and tolerances

The dimensions and tolerances shall be as specified in the figure and table 1.

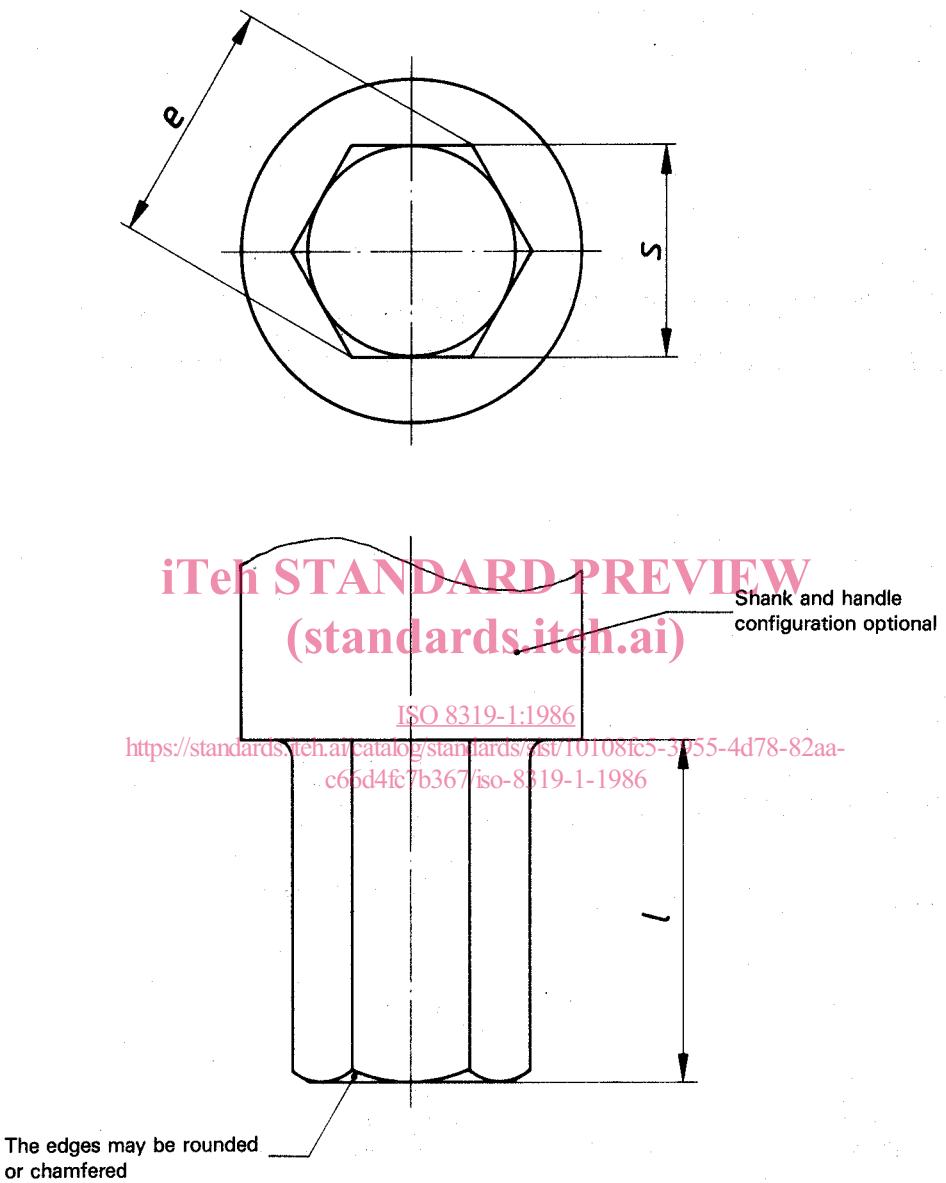


Figure — Designation of dimensions of screw keys

Table 1 — Dimensions and tolerances of screw keys

Dimensions in millimetres

Screw keys						Screws in accordance with ISO 5835/1
	s		*e*		*l*	
nom.	max.	min.	max.	min.	min.	
1,5	1,500	1,475	1,690	1,650	2	HA 1,5*; HA 2,0*
2,5	2,500	2,475	2,840	2,800	4	HA 2,7; HA 3,5; HB 4
3,5	3,500	3,470	3,980	3,932	5	HA 4; HA 4,5; HA 5; HB 6; HB 6,5

* Provisional (dependent on the revision of ISO 5835/1; see the annex).

4 Materials and grades

Screw keys shall be made of one of the following metals:

a) martensitic stainless steel (for example, in accordance with grade 5, 6 or 6a of ISO 683/13);

b) cold-worked wrought cobalt-chromium-tungsten-nickel alloy in accordance with ISO 5832/5.

5 Performance requirements

5.1 Hardness

The Rockwell hardness shall be within the range given in table 2 when tested in accordance with ISO 6508.

Table 2 — Hardness of screw keys

Material	Rockwell hardness HRC
Stainless steel	48 to 54
Wrought cobalt-chromium-tungsten-nickel alloy	45 to 50

5.2 Torque test requirements

Following the application of the minimum test torque as given in table 3, the key for screws with hexagon socket heads shall not fracture or show permanent deformation.

6 Torque test

6.1 Apparatus

The following apparatus is required:

Female hexagon socket adaptor, with an opening in accordance with table 3. The socket adaptor shall be hardened to a Rockwell hardness of not less than 60 HRC.

6.2 Procedure

Insert the working end of the key in the adaptor and apply the corresponding torque as given in table 3. Do not jerk or strike the key when testing. Apply the load gradually until the minimum testing torque is reached.

Table 3 — Dimensions and torques used in testing

Key *s* nom.	Width across flats: Female hexagon socket adaptor	tol.	Maximum depth of key engagement	Minimum torque
	mm		mm	N·m
1,5	1,5	+0,046 +0,006	0,9	0,7
2,5	2,5		1,2	3,8
3,5	3,5	+0,058 +0,010	2,8	9,7

7 Marking

The screw shall be permanently and legibly marked with the following information:

a) the size of the screw (code and thread diameter), in accordance with ISO 5835/1 with which is intended to be used;

b) the manufacturer's name or trademark;

c) the number of this part of ISO 8319, if there is space available;

d) the material of which it is made, if there is space available.

Annex

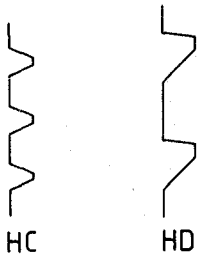
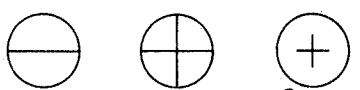
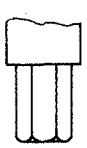
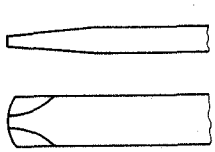
Interrelationship of International Standards dealing with bone screws, bone plates and relevant tools

(This annex does not form an integral part of the standard.)

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 below.

NOTE — Attention is drawn to the fact that the breakdown of these International Standards into two parallel series is different from the way in which they were previously categorized; footnotes have been added to clarify these modifications.

		ISO 5835 [1]	ISO 9268 [2]
Screws	**Thread**		
	Head under-surface		80° 90° Conical
	Drive connection	Spherical 	 Single slot; Cruciate slot; Cross-recessed head
	Mechanical requirements	**ISO 6475** [3] Breaking torque/ angle of rotation	In preparation
Plates	**Holes and slots**	**ISO 5836** [4]	**ISO 9269** [5]
	Mechanical requirements	In preparation	In preparation
Driving tools	**Keys and screwdrivers**	**ISO 8319/1**  Hexagon keys	**ISO 8319/2**  Screwdrivers

1) Will cancel and replace ISO 5835/1 at next revision stage. (ISO 5835/1-1985 cancelled and replaced ISO 5835/1-1978 and ISO 5835/2-1978.)

2) At present at the stage of draft; will cancel and replace ISO/DIS 5835/3 and ISO 5835/4-1983.

3) At present at the stage of draft; will cancel and replace ISO 6475/1-1980 and ISO 6475/2-1980.

4) At present at the stage of draft.

5) At present at the stage of draft; will cancel and replace ISO/DIS 5836/3 and ISO 5836/4-1984.