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International Standard



8319/1

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

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**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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**Descriptors :** medical equipment, surgical implants, screwed connections, hexagonal head screws, socket head screws, surgical equipment, wrenches, specifications, dimensions, dimensional tolerances, tests, torsion tests, marking.

Price based on 4 pages

## 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.*<sup>1)</sup>

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

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.

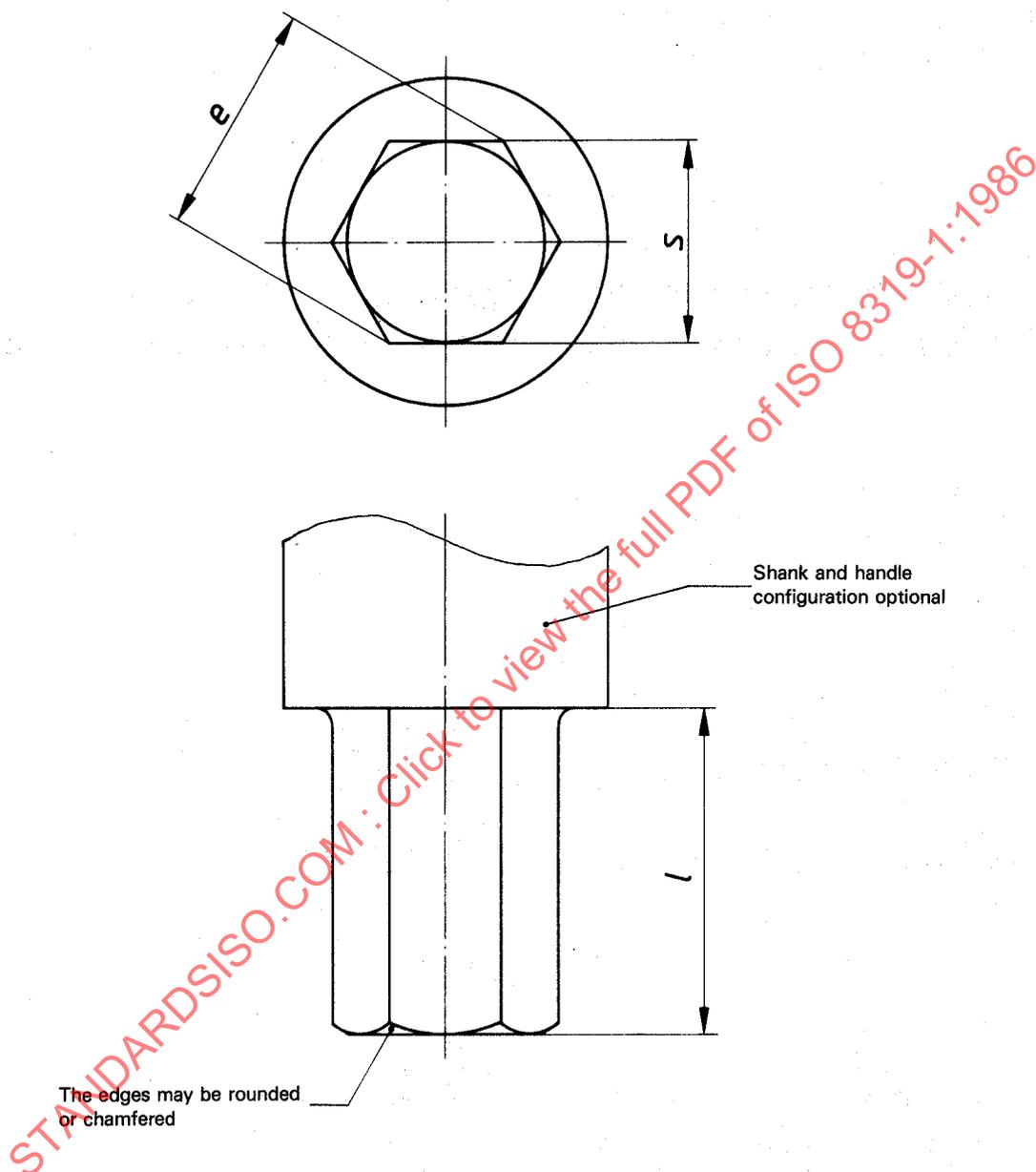


Figure — Designation of dimensions of screw keys

Table 1 — Dimensions and tolerances of screw keys

Dimensions in millimetres

Screw keys						Screws in accordance with ISO 5835/1
nom.	$s$ max.	min.	$e$ max.	min.	$l$ 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).