INTERNATIONAL STANDARD

**ISO 8319-1**

Second edition
1996-05-15

# 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*



Reference number
ISO 8319-1:1996(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 voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 8319-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis*.

This second edition cancels and replaces the first edition (ISO 8319-1:1986), which has been technically revised.

ISO 8319 consists of the following parts, under the general title *Orthopaedic instruments — Drive connections*:

— *Part 1: Keys for use with screws with hexagon socket heads*

— *Part 2: Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws*

Annexes A and B of this part of ISO 8319 are for information only.





International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland

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## Introduction

Essential requirements for all varieties of screw keys are that

a) the working end of the screw key should accurately engage the head of the screw;

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

c) 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.

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# Orthopaedic instruments — Drive connections —

# Part 1:
Keys for use with screws with hexagon socket heads



## 1 Scope

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 hexagon 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 that conform to ISO 5835.

## 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8319. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8319 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 5832-5:1993, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.*

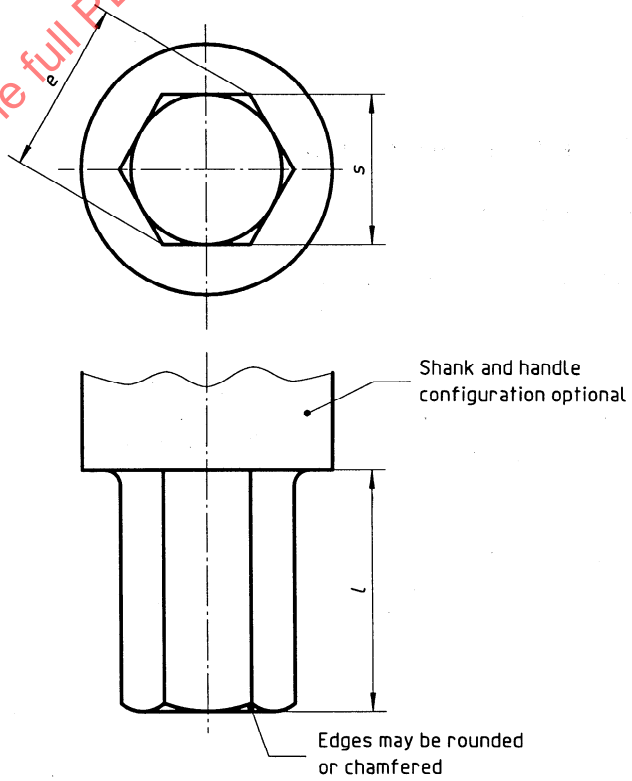
ISO 5835:1991, *Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions*[1].

ISO 6508:1986, *Metallic materials — Hardness test — Rockwell test (scales A - B - C - D - E - F - G - H - K).*

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

## 3 Dimensions and tolerances

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




*e* Peak-to-peak diameter of the hexagon
*s* Width across flats of the hexagon
*l* Length of the hexagonal part

**Figure 1 — Designation of dimensions of screw keys**

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

**Table 1 — Dimensions and tolerances of screw keys**

Dimensions in millimetres

| Screws in accordance with ISO 5835 | Screw key dimensions | | | | | |
|---|---|---|---|---|---|---|
| | *s* | | | *e* | | *l* |
| | nom. | max. | min. | max. | min. | min. |
| HA 1,5; HA 2,0 | 1,5 | 1,500 | 1,475 | 1,690 | 1,650 | 2 |
| HA 2,7; HA 3,5; HB 4; | 2,5 | 2,500 | 2,475 | 2,840 | 2,800 | 4 |
| HA 4; HA 4,5; HA 5; HB 6; HB 6,5; | 3,5 | 3,500 | 3,470 | 3,980 | 3,932 | 5 |
| | 4,5 | 4,500 | 4,470 | 5,130 | 5,082 | 6 |

## 4 Material and grades

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

a) martensitic stainless steel (for example, in accordance with grade reference letters C, D, H or I of ISO 7153-1).

b) cold-worked wrought cobalt-chromium-tungsten-nickel alloy in accordance with ISO 5832-5, or other equivalent cobalt alloy.

## 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 clause 6 and table 3, the key for screws with hexagon socket heads shall not fracture or show permanent deformation.

## 6 Torque test

### 6.1 Apparatus

**6.1.1 Female hexagon socket adaptor,** with an opening in accordance with table 3. The socket adaptor shall be hardened to a Rockwell hardness higher than that of the screw key.

### 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**

| Width across flats, *s* | | | Depth of key engagement | Torque |
|---|---|---|---|---|
| Key | Female hexagon socket adaptor | | | |
| nom. | nom. | tol. | min. | min. |
| mm | mm | | mm | N·m |
| 1,5 | 1,5 | + 0,046<br>+ 0,006 | 0,9 | 0,7 |
| 2,5 | 2,5 | | 1,2 | 3,8 |
| 3,5 | 3,5 | + 0,058<br>+ 0,010 | 2,8 | 9,7 |
| 4,5 | 4,5 | + 0,058<br>+ 0,010 | 3,8 | 12 |

## 7 Marking

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

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

b) manufacturer's name or trademark;

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

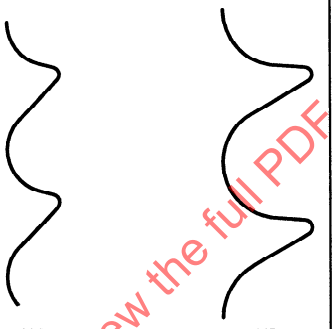
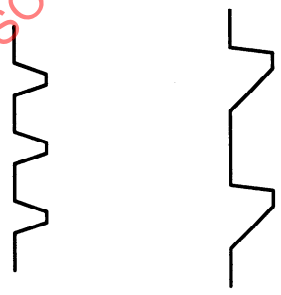
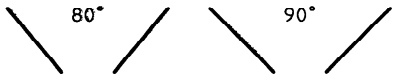
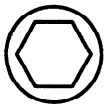
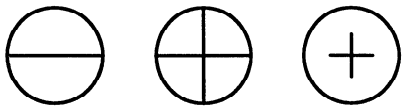
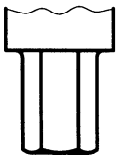
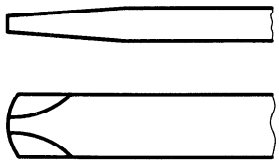
d) material of which it is made, if there is space available.

# 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, based on the essentially different designs of the threads of the bone screws (HA and HB type screws as opposed to HC to 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.

<table>
<tr><td rowspan="5">Screws</td><td>Thread</td><td>ISO 5835<br>  <br>HA HB</td><td>ISO 9268<br>  <br>HC HD</td></tr>
<tr><td>Head undersurface</td><td>  <br>Spherical</td><td>  <br>80° 90°<br>Conical</td></tr>
<tr><td>Drive connection</td><td>  <br>Hexagon</td><td>  <br>Single slot Cruciate slot Cross-recessed head</td></tr>
<tr><td>Mechanical requirements</td><td>ISO 6475<br>Breaking torque/ angle of rotation</td><td>In preparation</td></tr>
<tr><td>Holes and slots</td><td>ISO 5836</td><td>ISO 9269</td></tr>
<tr><td>Plates</td><td>Mechanical requirements</td><td>In preparation</td><td>In preparation</td></tr>
<tr><td>Driving tools</td><td>Keys and screwdrivers</td><td>ISO 8319-1<br>  <br>Hexagon keys</td><td>ISO 8319-2<br>  <br>Screwdrivers</td></tr>
</table>

# Annex B
(informative)

# Bibliography

[1] ISO 5836:1988, *Implants for surgery — Metal bone plates — Holes corresponding to screws with asymmetrical thread and spherical under-surface.*

[2] ISO 6475:1989, *Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods.*

[3] ISO 8319-2:1986, *Orthopaedic instruments — Drive connections — Part 2: Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws.*

[4] ISO 9268:1988, *Implants for surgery — Metal bone screws with conical under-surface of head — Dimensions.*

[5] ISO 9269:1988, *Implants for surgery — Metal bone plates — Holes and slots corresponding to screws with conical under-surface.*