INTERNATIONAL STANDARD

ISO 6475

First edition
1989-11-01

Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods

Implants chirurgicaux — Vis métalliques à filetage asymétrique et à embase sphérique pour os — Caractéristiques mécaniques et méthodes d'essai

Reference number
ISO 6475 : 1989 (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 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 6475 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This first edition of ISO 6475 cancels and replaces the first editions of ISO 6475-1 : 1980 and ISO 6475-2 : 1980, of which it constitutes a revision and amalgamation.

Annex A forms an integral part of this International Standard. Annexes B and C are for information only.

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Introduction

This International Standard does not purport to address all of the safety problems associated with its use. It is the responsibility of whoever uses it to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

The results obtained in this method bear no direct correlation to the use of the subject bone screw. This test method is used only for purposes of maintaining the uniformity of the product tested.

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Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods

1 Scope

This International Standard specifies the test methods for determining breaking torque and angle of rotation at failure for metal bone screws for surgery. Mechanical requirements for bone screws are specified in annex A.

NOTES

1 At present data are only available for bone screws with dimensions according to ISO 5835 and made from stainless steel according to ISO 5832-1. If data become available for bone screws made from other materials and/or with other standardized dimensions, they will be added in further annexes.

2 The interrelationship of International Standards dealing with bone plates, bone screws and relevant tools is shown for information in annex B.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard 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 5832-1 : 1987, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel.*

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

3 Test method

3.1 Apparatus

A test machine having the following characteristics shall be used:

a) a maximum sensitivity on the lowest measuring range of not less than 0,01 N·m or equivalent, and on other scales of not less than 1 % of full scale reading;

b) a selection of measuring ranges (see 3.2.4);

c) the capability of recording the maximum torque attained during the test;

d) a device to prevent the screw becoming disengaged from the component by means of which the torque is applied.

NOTE — In some countries the test machine must comply with the requirements laid down by the national test or verification authority.

3.2 Procedure

3.2.1 Insert the screw under test into the test block and clamp it so that the following conditions are met:

a) if possible, five full threads from the thread run-out shall be exposed;

b) movement of the clamped portion shall be prevented;

c) the axes of the screw and the component by means of which the torque is applied shall be coincident.

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

3.2.2 Apply torque so that the screw head rotates at a uniform angular velocity within the range from 1 r/min to 5 r/min [1] with continuous augmentation until fracture occurs.

3.2.3 Record the maximum breaking torque and the angle of rotation at failure.

3.2.4 If the maximum torque recorded is less than 20 % of the full scale reading of the test machine, disregard this result and repeat the test using a lower range.

4 Test report

The test report shall include the following particulars:

a) a reference to this International Standard;

b) the maximum breaking torque, expressed to the nearest 0,1 N·m;

c) the angle of rotation at failure, expressed to the nearest 10°;

d) a statement of the precise test conditions if less than five full threads are exposed.

1) 1 r/min = 0,104 rad/s

Annex A
(normative)

Mechanical requirements for stainless steel bone screws

A.1 Scope

This annex specifies the mechanical requirements for unused non-self-tapping bone screws for surgery, complying with ISO 5835 and made from stainless steel according to ISO 5832-1.

A.2 Test specimens

Each screw in the test sample shall be examined to check that they all comply with the dimensional requirements specified in ISO 5835-1; only those screws with dimensions that do so comply shall be tested.

A.3 Surface finish

When examined by normal or corrected vision, the surface of metal bone screws shall be free from imperfections, such as nicks, scratches and other defects that would impair the serviceability of the screw.

When examined by normal or corrected vision, the surface finish shall be uniform and free from marks which have been caused by previous operations, such as grinding, polishing, burnishing, tumbling, etc.

A.4 Breaking torque and angle of rotation at failure

Each screw in the test sample shall be tested in accordance with clause 3 to determine the minimum breaking torque and minimum angle of rotation to failure.

The minimum breaking torque and minimum angle of rotation to failure of each screw shall be as specified in table A.1.

Table A.1 — Minimum breaking torque and minimum angle of rotation at failure

Screw in accordance with ISO 5835-1 (Code and nominal thread diameter)	Minimum breaking torque N·m	Minimum angle of rotation at failure (if five threads are exposed)
HA 1,5	0,2	150°
HA 2,0	0,35	150°
HA 2,7	1	180°
HA 3,5	2,3	180°
HA 4	4	180°
HA 4,5	4,4	180°
HA 5	5,5	180°
HB 4	1,3	90°
HB 6,5	6,2	90°

A.5 Compliance and re-tests

Should any of the screws in the test sample not comply with any of the requirements, a further sample, comprising at least twice the number of screws of the original test sample, shall be taken from the lot in question and all tests described in this International Standard shall be carried out on the new test sample.

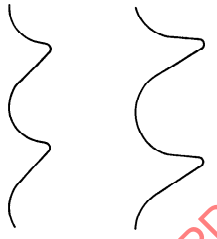
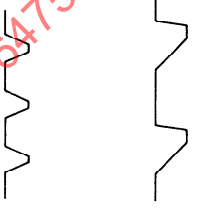
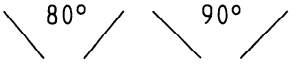
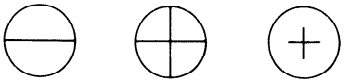
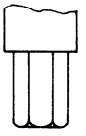
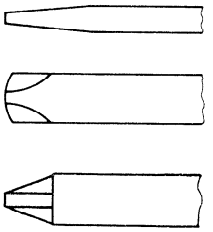
Any failure amongst the second sample of screws shall constitute failure of the particular lot of screws to comply with this International Standard.

Annex B
(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 two parallel series of International Standards is given below.

<table>
<tr><td rowspan="4">Screws</td><td>Thread</td><td>ISO 5835
 
HA HB</td><td>ISO 9268
 
HC HD</td></tr>
<tr><td>Head under-surface</td><td> 
Spherical</td><td> 
80° 90°
Conical</td></tr>
<tr><td>Drive connection</td><td>  </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>Mechanical requirements</td><td>ISO 6475
Breaking torque/ angle of rotation</td><td>In preparation</td></tr>
<tr><td>Plates</td><td>Holes and slots</td><td>ISO 5836</td><td>ISO 9269</td></tr>
<tr><td></td><td>Mechanical requirements</td><td>ISO 9585</td><td>ISO 9585</td></tr>
<tr><td rowspan="2">Driving tools</td><td>Keys and screwdrivers</td><td>ISO 8319-1
 
Hexagon keys</td><td>ISO 8319-2
 
Screwdrivers</td></tr>
<tr><td>Drill bits, taps, countersink cutters</td><td>ISO 9714-1</td><td>In preparation</td></tr>
</table>

Annex C
(informative)

Bibliography: International Standards referred to in table of annex B

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

ISO 5836 : 1989, *Implants for surgery — Metal bone plates — Holes corresponding to screws with asymmetrical thread and spherical under-surface.*

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

ISO 8319-1 : 1986, *Orthopaedic instruments — Drive connections — Part 1 : Keys for use with screws with hexagon socket heads.*

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.*

ISO 9268 : — [2], *Implants for surgery — Metal bone screws with conical under-surface of head — Dimensions.*

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

ISO 9585 : — [2], *Implants for surgery — Method for testing bending strength and stiffness of bone plates.*

ISO 9714-1 : — [2], *Orthopaedic instruments — Drilling instruments — Part 1: Drill bits, taps and countersink cutters.*

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

2) To be published.