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International Standard



6475/2

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**Implants for surgery — Metal bone screws — Mechanical requirements and methods of test —  
Part 2 : Screws with asymmetrical thread, constant fitting (spherical), stainless steel**

*Implants chirurgicaux — Vis métalliques pour os — Propriétés mécaniques et méthodes d'essai — Partie 2 : Vis à filet asymétrique, embase (sphérique) constante, en acier inoxydable*

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## Foreword

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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.

International Standard ISO 6475/2 was developed by Technical Committee ISO/TC 150, *Implants for surgery*, and was circulated to the member bodies in August 1979.

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It has been approved by the member bodies of the following countries :

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Australia	India	Spain
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No member body expressed disapproval of the document.

# Implants for surgery — Metal bone screws — Mechanical requirements and methods of test — Part 2 : Screws with asymmetrical thread, constant fitting (spherical), stainless steel

## 1 Scope and field of application

This International Standard specifies the characteristics of, and corresponding mechanical test methods for metal bone screws used in surgery.

It applies to screws of stainless steel conforming to the dimensional requirements of ISO 5835/2.

## 2 References

ISO 5832/1, *Implants for surgery — Metallic materials — Part 1 : Wrought stainless steel.*

ISO 5835/2, *Implants for surgery — Metal bone screws — Dimensions — Part 2 : Screws with asymmetrical thread, constant fitting (spherical).*

## 3 Material

Bone screws conforming to this specification shall be manufactured from stainless steel, composition B, covered by ISO 5832/1.

## 4 Dimensions

Each of the screws in the test sample shall be examined for conformity with the dimensional requirements specified in ISO 5835/2.

## 5 Mechanical properties

Each of the screws in the test sample shall be tested for the minimum breaking torque and minimum angle of rotation to failure (see clause 8).

The minimum breaking torque and minimum angle of rotation to failure shall be as specified in the table.

Table — Mechanical properties

Code and diameter of thread	Breaking torque min.	Angle of rotation to failure min.
	N·m	° of arc
HA 2,7	1,0	180
HA 3,5	2,3	180
HA 5,0	5,5	180
HB 4,0	1,3	90

## 6 Surface finish

The surface of metal bone screws shall be free, when examined with the naked eye, of imperfections such as nicks, scratches and other defects that would impair the serviceability of the screw.

The final finish shall be continuous and free, when examined with the naked eye, of marks which are the results of previous operations such as grinding, polishing, burnishing, tumbling, etc.

## 7 Compliance and retests

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 tested as described above.

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

## 8 Method of test — Determination of breaking torque and angle of rotation at failure

### 8.1 Test equipment

The testing equipment shall be acceptable to a national testing or verification authority.

a) The maximum sensitivity on the lowest measuring range shall be not less than 0,01 N·m or its equivalent, and on other scales not less than 1 % of full range deflection.

b) For selection of loading scale range, see 8.2.4.

c) The measuring device shall be capable of registering and indicating the reading of the maximum torque attained during the test.

d) Unless the device, through which the torque is applied to the screw head, is capable of being clamped to prevent movement in the vertical direction, a device to prevent "cam out" of the driver from the screw head should be incorporated into the system.

e) The screw shall be clamped in such a manner as to prevent movement of the clamped portion of the screw and to ensure correct alignment.

## 8.2 Procedure

8.2.1 Insert the screw under test in the test block so that five full threads from the thread run-out are exposed. If less than five full threads are available, the results shall be accompanied by a statement of the precise test conditions.

8.2.2 Apply torque at a uniform rotational frequency within the range 1 to 5 min<sup>-1</sup>.\*

8.2.3 Load until fracture occurs and record the maximum torsional moment and the angle of rotation at failure.

8.2.4 Should the maximum torque recorded be less than 20 % of the full range deflection of the scale, the test shall be repeated at a lower scale range.

## 8.3 Test report

The test report shall include the following particulars :

a) reference to this International Standard;

b) maximum torsional moment, expressed to the nearest 0,1 N·m and given as the "breaking torque";

c) 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 (see 8.2.1).

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\* 1 min<sup>-1</sup> = 1 r/min