

Australian Standard™

**Implants for surgery—Metal bone
screws with hexagonal drive
connection, spherical under-surface of
head, asymmetrical thread—Dimensions**

This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 1 April, 2003 and published on 23 May 2003.

The following are represented on Committee HE-012:

Australian College of Operating Room Nurses
Australian Dental Association
Australian Industry Group
Australian Orthopaedic Association
Australian Society for Biomaterials
Commonwealth Department of Health and Ageing
Department of Defence (Australia)
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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-012, Surgical Implants, to supersede AS 2255—1979, *Metal bone screws*. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from ISO 5835:1991, *Implants for surgery—Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions*.

As this Standard is reproduced from an International Standard, the following modifications apply:

- (a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- (b) In the source text ‘this International Standard’ should read ‘this Australian Standard’.
- (c) A full point should be substituted for a comma when referring to a decimal marker.

The term ‘informative’ has been used to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

References to International Standards should be replaced by references to the following Australian Standard:

| <i>Reference to International Standard*</i> | | <i>Australian Standard</i> | |
|---|--|----------------------------|--|
| ISO | | AS | |
| 6018 | Orthopaedic implants—General requirements for marking, packaging and labelling | 3872 | Orthopaedic implants—General requirements for marking, packaging and labelling |

* Any international Standards not listed do not have an Australian equivalent.

INTRODUCTION

This International Standard lays down requirements for surgical bone screws as given in clause 1. It is necessary, however, to bear in mind that there may be a need for bone screws for particular applications, which are not covered by this Standard or by ISO 9268. Such special bone screws may differ in part from the standardized forms or may combine parts from these two product standards (see annex A).

However, there are certain areas of the design of screws such as the drive connections, the shape of the under-surface of the head and the thread form that are critical from the point of view of surgical use. These areas are those where there is an interface with bone plates (ISO 5836 and ISO 9269) or with surgical instruments or other devices such as hexagon keys (ISO 8319-1) or taps, drills and countersink cutters. No variation is permitted in these areas.

NOTES

AUSTRALIAN STANDARD

Implants for surgery—Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread—Dimensions

1 Scope

This International Standard specifies dimensions and tolerances for metal bone screws used in surgery, having hexagonal drive connection, spherical under-surface of the head, and shallow and deep asymmetrical threads.

NOTES

- 1 The mechanical requirements for screws that are cited in this International Standard are specified in ISO 6475.
- 2 The interrelationship of International Standards dealing with bone screws, bone plates 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 6018:1987, *Orthopaedic implants — General requirements for marking, packaging and labelling*.

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

3 Code for screw thread

The following code shall be used to identify the type of screw thread conforming to this International Standard:

Shallow thread (for cortical screws): Code HA

Deep thread (for spongiosa/cancellous screws): Code HB

4 Dimensions and tolerances

All dimensions and tolerances are given in millimetres.

4.1 Screw with shallow thread (HA)

HA screws shall be as given in figures 1 and 2 and tables 1 and 2.