AS 2255—1979

Australian Standard®

METAL SURGICAL BONE SCREWS

The following scientific, industrial and governmental organizations and departments were officially represented on the committee entrusted with the preparation of this standard:

Australian Orthopaedic Association
Bureau of Steel Manufacturers of Australia
Confederation of Australian Industry
Department of Defence
Department of Health
Metal Trades Industry Association of Australia
Plastics Institute of Australia Incorporated
Royal Australasian College of Surgeons
Royal Newcastle Hospital
University of Melbourne
University of Newcastle
University of New South Wales
University of Sydney

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METAL SURGICAL BONE SCREWS

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PREFACE

This standard was prepared by the Association's Committee on Surgical Implants at the request of the Medical Materials and Equipment Standards Committee. It is one of a series of standards for surgical implants which will implement for Australian purposes International standards emanating from ISO/TC 150, Implants for Surgery.

The dimensional requirements specified herein are identical with those given in ISO 5835/I, Implants for Surgery—Metal Bone Screws—Dimensions—Part 1: Screws with Asymmetrical Thread, Variable Fitting (Spherical), with the exception that this Australian standard prescribes concentricity tolerances for the head and drive elements which are not included in the ISO standard.

The minimum values given for ultimate torsional strength and angle of rotation at failure are based on work done at the School of Metallurgy, University of New South Wales. It is anticipated that these limits will be adopted in the relevant product standard being developed by ISO/TC 150.

The committee wished to specify quantitative limits for surface finish but was unable to do so because of the absence of authoritative data at the time of publication on the acceptability of surfaces of varying finenesses. More work is needed in this area.

This standard may require reference to the following standards:

AS 1654	Limits and Fits for Engineering
AS T35	Metals for the Manufacture of Surgical Implants*
ISO 6018	Implants for Surgery—Marking and Packaging†

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* In course of revision.

† In course of preparation.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
METAL SURGICAL BONE SCREWS

1 SCOPE. This standard specifies requirements for metal surgical screws for bones. The screws are provided with asymmetrical threads and hexagonal socket drives.

2 DEFINITIONS. For the purpose of this standard, the following definitions apply:

Unit pack—a pack containing a single screw.

Multiple pack—a pack containing a number of unit packs.

3 TYPES AND DESIGNATIONS. The screws shall be designated in terms of nominal external diameter and thread type as follows:

Designation	*Type of thread*
(dia.)/HA	Shallow threaded or *cortical* screws
(dia.)/HB	Deep threaded or *cancellous* screws

4 MATERIAL. The metal used in the manufacture of the screws shall be one of those specified in AS T35.

5 PROCESS OF MANUFACTURE.

5.1 Stainless Steel Screws. Stainless steel screws shall be machined or cold-formed (including thread rolling) from wrought stainless steel.

NOTES:

1. As stainless steels may be susceptible to stress-corrosion cracking after cold forming, it is recommended that heavily cold-worked screws be given a stress-relieving treatment.
2. A test for susceptibility to stress-corrosion cracking is recognized as desirable and will be included when available.

5.2 Cast Cobalt-chromium-molybdenum Screws. Cast cobalt-chromium-molybdenum screws shall be cast from cobalt-chromium-molybdenum alloy by investment casting or other suitable process.

5.3 Wrought Cobalt-chromium-tungsten-nickel Screws. Wrought cobalt-chromium-tungsten-nickel screws shall be machined or cold-formed from wrought cobalt-chromium-tungsten-nickel alloy.

5.4 Titanium Screws. Titanium screws shall be machined or cold-formed from annealed and descaled unalloyed titanium or from bright annealed unalloyed titanium.

The annealing treatment shall consist of heating to 675 ±25°C and cooling under conditions that will prevent the formation of an oxide scale.

5.5 Titanium Alloy Screws. Titanium alloy screws shall be machined or cold-formed from annealed and descaled material or from bright annealed material.

The heat treatment shall be carried out under conditions that will prevent the formation of an oxide scale.

6 SURFACE FINISH. All surfaces of screws shall be free from draw marks and pits. The final finish shall be continuous and free from marks associated with grinding, polishing, burnishing or other finishing processes. The final finish may range from dull to bright. Mechanical polishing, if used, should be carried out with an iron-free abrasive.

7 DESIGN.

7.1 Principal Dimensions. The design and principal dimensions of screws shall be as follows:

(a) For cortical screws . . . . as specified in Fig. 1 and Table 1.

(b) For cancellous screws . . as specified in Fig. 2 and Table 2.

7.2 Length. The length of the screw shall be taken to be the length measured from the underside of the head of the tip of the screw.

NOTE: The length is governed by the surgical application of the screw.

The measured length of the screw shall be within 0.5 mm of the length stated on the pack in accordance with Clause 10.

7.3 Screw Thread. The screw threads shall be smooth and regular in form with an asymmetrical profile conforming to the dimensional requirements as follows:

(a) For cortical screws .... Fig. 3 and Table 3.

(b) For cancellous screws .... Fig. 4 and Table 4.

The screw threads shall be right-handed threads, i.e. the screw penetrates the bone when driven in a clockwise direction.

7.4 Drive. The screws shall be provided with hexagonal socket drives in accordance with the relevant requirements of Figs 1 and 2.

7.5 Concentricity Tolerances. The concentricity tolerances for head and drive elements shall be as specified in Table 5 and Fig. 5.

7.6 Self-tapping Slots. Self-tapping slots having the dimensions shown in Fig. 6 may be optionally applied to the screws.