

Australian Standard™

Implants for surgery—Metallic materials

**Part 6: Wrought cobalt-nickel-
chromium-molybdenum alloy**

This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 14 October 2003 and published on 8 December 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
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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 2320.6—1981, *Metals for the manufacture of surgical implants, Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*.

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 has been reproduced from, and is identical with, ISO 5832—6:1997, *Implants for surgery—Metallic materials, Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*.

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 part of ISO 5832’ should read ‘this Australian Standard’.
- (c) A full point should be substituted for a comma when referring to a decimal marker.

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
643 Steels—Micrographic determination of the ferritic or austenitic grain size	1733 Methods for the determination of grain size in metals

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

INTRODUCTION

No known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body. However, long-term clinical experience of the use of the material referred to in this part of ISO 5832 has shown that an acceptable level of biological response can be expected, when the material is used in appropriate applications.

AUSTRALIAN STANDARD

Implants for surgery—Metallic materials

Part 6:

Wrought cobalt-nickel-chromium-molybdenum alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, wrought cobalt-nickel-chromium-molybdenum alloy for use in the manufacture of surgical implants.

NOTE — The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with the specifications given in this part of ISO 5832.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5832. 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 5832 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 643:1983, *Steels — Micrographic determination of the ferritic or austenitic grain size.*

ISO 6892:—¹⁾, *Metallic materials — Tensile testing at ambient temperatures.*

3 Chemical composition

The heat analysis of a representative sample of the alloy when determined in accordance with clause 6 shall comply with the chemical composition specified in table 1.

Table 1 — Chemical composition

Element	Compositional limits, % (m/m)
Nickel	33,0 to 37,0
Chromium	19,0 to 21,0
Molybdenum	9,0 to 10,5
Iron	1,0 max.
Titanium	1,0 max.
Manganese	0,15 max.
Silicon	0,15 max.
Carbon	0,025 max.
Phosphorus	0,015 max.
Sulfur	0,010 max.
Cobalt	Balance

1) To be published. (Revision of ISO 6892:1984)