AS 2320.5—2003
ISO 5832-5:1993

Australian Standard™

Implants for surgery—Metallic materials

Part 5: Wrought cobalt-chromium-tungsten-nickel alloy

Standards Australia

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

Department of Defence (Australia)

Medical Industry Association of Australia

Neurosurgical Society of Australasia

Royal Australasian College of Surgeons

Royal Perth Hospital

The University of New South Wales

The University of Sydney

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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 2320.5—1979, *Metals for the manufacture of surgical implants*, Part 5: *Wrought cobalt-chromium-tungsten-nickel 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 5832-5:1993, *Implants for surgery—Metallic materials,* Part 5: *Wrought cobalt-chromium-tungsten-nickel 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:

*Reference to International Standard**	*Australian Standard*
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 be completely free of adverse reactions in the human body. However, long-term clinical experience of use of the material referred to in this part of ISO 5832 has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

NOTES

AUSTRALIAN STANDARD

Implants for surgery—Metallic materials
Part 5:
Wrought cobalt-chromium-tungsten-nickel alloy

1 Scope

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

NOTE 1 The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with those specified 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 4967:1979, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams.*

ISO 6892:1984, *Metallic materials — Tensile testing.*

3 Chemical composition

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

Table 1 — Chemical composition

Element	Compositional limits, % (*m/m*)
Chromium	19 to 21
Tungsten	14 to 16
Nickel	9 to 11
Iron	3 max.
Carbon	0,15 max.
Silicon	1 max.
Manganese	2 max.
Cobalt	Balance

4 Microstructure

4.1 Grain size

Samples shall be prepared and etched for examination by any recognized technique. The grain size measured in accordance with ISO 643 shall be No. 5 or finer.[1)]

1) ISO 643 is given as a reference even though the material dealt with in this part of ISO 5832 is not iron-based.