AS 2320.2—2003
ISO 5832-2:1999

Australian Standard™

Implants for surgery—Metallic materials

Part 2: Unalloyed titanium

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 1 April 2003 and published on 23 May 2003.

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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 2320.2—1983, *Metals for the manufacture of surgical implants,* Part 2: *Unalloyed titanium.* 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 to, ISO 5832-2:1999, *Implants for surgery—Metallic materials,* Part 2*: Unalloyed titanium.*

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' and 'this part of ISO 5832' should read 'this Australian Standard'.

None of the Standards listed in Clause 2 have been adopted as Australian or Australian/New Zealand Standards.

INTRODUCTION

No known surgical implant material has ever been shown to cause absolutely no adverse reaction 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.

NOTES

AUSTRALIAN STANDARD

Implants for surgery — Metallic materials

Part 2:

Unalloyed titanium

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, unalloyed titanium for use in the manufacture of surgical implants.

Provision is made for six grades of titanium based on tensile strength (see Table 2).

NOTE The mechanical properties of a sample obtained from a finished product made of this metal may not necessarily comply with those specified in this part of ISO 5832.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 6892:1998*, Metallic materials — Tensile testing at ambient temperature.*

ISO 7438:1995*, Metallic materials — Bend test.*

ASTM E 112:1988*, Standard Test Methods for Determining Average Grain Size.*

3 Chemical composition

The heat analysis when determined as specified in clause 6 shall conform to the requirements as to chemical composition specified in Table 1. Ingot analysis may be used for reporting all chemical requirements except hydrogen, which shall be determined after the last heat treatment and pickling procedure.

4 Microstructure

The microscopic structure of the titanium in the annealed condition shall be uniform. The grain size, determined as specified in clause 6, shall be no coarser than grain size No. 5.

At a magnification of 100×, no inclusions or foreign phases shall be visible.

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