

Australian Standard™

Implants for surgery—Metallic materials

**Part 3: Wrought titanium 6-aluminium
4-vanadium 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
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

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Australia web site at www.standards.com.au and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Global Standard*, has a full listing of revisions and amendments published each month.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.com.au, or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

This Standard was issued in draft form for comment as DR 03146.

Australian Standard™

Implants for surgery—Metallic materials

**Part 3: Wrought titanium 6-aluminium
4-vanadium alloy**

Originated as part of AS T35—1966.
Previous edition AS 2320.3—1979.
Second edition 2003.

COPYRIGHT

© Standards Australia International

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher.

Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5584 4

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 2320.3—1979, *Metals for the manufacture of surgical implants, Part 3: Wrought titanium 6-aluminium 4-vanadium 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 5832-3:1996, *Implants for surgery—Metallic materials, Part 3: Wrought titanium 6-aluminium 4-vanadium 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.

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 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 3:****Wrought titanium 6-aluminium 4-vanadium alloy****1 Scope**

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 4-vanadium alloy (Ti 6-Al 4-V 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 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 6892:1984, *Metallic materials — Tensile testing*.

ISO 7438:1985, *Metallic materials — Bend test*.

ETTC¹⁾ Publication 2, 1979, *Microstructural standards for $\alpha + \beta$ titanium alloy bars*²⁾.

1) European Titanium Producers' Technical Committee (ETTC).

2) Available commercially from: Deutsche Titan GmbH, Essen, Germany and IMI-Titanium Ltd., Birmingham, UK. This information is given for the convenience of users of this part of ISO 5832, and does not constitute an endorsement by ISO of these products.

3 Chemical composition

The heat/ingot 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.

NOTE 2 Ingot analysis may be used for determining all chemical requirements except hydrogen.

The analysis of hydrogen shall be carried out after the final heat treatment and final surface treatment.

Requirements for the major and minor elemental constituents for titanium 6-aluminium 4-vanadium alloy are listed in table 1.

Table 1 — Chemical composition

Element	Compositional limits
	% (m/m)
Aluminium	5,5 to 6,75
Vanadium	3,5 to 4,5
Iron	0,3 max.
Oxygen	0,2 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,015 max. ¹⁾
Titanium	Balance

1) Except for billets, for which the maximum hydrogen content shall be 0,010 % (m/m).