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(JSB)

Titanium materials for surgical implant applications Part 2 : Wrought titanium 6-aluminium 4-vanadium alloy

ICS 11.040.40; 77.150.50

Reference number : JIS T 7401-2 : 2002 (E)

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare, and Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from the Japanese Society for Biomaterials (JSB), with a draft of Industrial Standard based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

This Standard has been made based on **ISO 5832-3** : 1996 *Implants for surgery—Metallic materials—Part 3 : Wrought titanium 6-aluminium 4-vanadium alloy* for the purposes of making easy to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of International Standard which is based on Japanese Industrial Standard.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

JIS T 7401 series consist of the following six parts with the general title of *Titanium materials for surgical implant applications.*

Part 1 : Unalloyed titanium
Part 2 : Wrought titanium 6-aluminium 4-vanadium alloy
Part 3 : Wrought titanium 6-aluminium 2-niobium 1-tantalum alloy
Part 4 : Wrought titanium 15-zirconium 4-niobium 4-tantalum alloy
Part 5 : Wrought titanium 6-aluminium 7-niobium alloy
Part 6 : Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy

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In the event of any doubts arising as to the contents, the original JIS is to be the final authority.

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Titanium materials for surgical implant applications Part 2 : Wrought titanium 6-aluminium 4-vanadium alloy

Introduction This Japanese Industrial Standard has been prepared based on the third edition of **ISO 5832-3** *Implants for surgery—Metallic materials—Part 3 : Wrought titanium 6-aluminium 4-vanadium* published in 1996 without modifying the technical contents, but some items which not specified in the original International Standard are added.

The portions underlined with dots are the matters not stated in the said International Standard.

1 Scope This Standard specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 4-vanadium alloy (Ti-6Al-4V alloy) for use in the manufacture of surgical implants, especially its chemical composition, metallic properties, mechanical properties and internal properties. It is required to use this alloy clinically after investigating the safety corresponding to the environment where implants are used. 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 Standard.

Remarks : The International Standard corresponding to this Standard is as follows.

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21**.

ISO 5832-3 : 1996 *Implants for surgery—Metallic materials—Part 3 : Wrought titanium 6-aluminium 4-vanadium alloy* (MOD)

2 Normative references The following standards contain provisions which, through reference in this Standard, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS H 0321 *General rules for inspection of non-ferrous metal materials*

JIS H 1610 *Titanium and titanium alloys—Sampling methods*

JIS H 1611 *Titanium and titanium alloys—General rules for chemical analysis*

JIS H 1612 *Methods for determination of nitrogen in titanium and titanium alloys*

JIS H 1614 *Methods for determination of iron in titanium and titanium alloys*

JIS H 1617 *Methods for determination of carbon in titanium and titanium alloys*

JIS H 1619 *Methods for determination of hydrogen in titanium and titanium alloys*

JIS H 1620 *Methods for determination of oxygen in titanium and titanium alloys*

JIS H 1622 *Titanium alloys—Methods for determination of aluminium*