

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 7403-1 : 2005

(JSB/JSA)

**Iron based alloys for surgical
implant applications—
Part 1:Wrought stainless steel**

ICS 11.040.40

Reference number : JIS T 7403-1 : 2005 (E)

PROTECTED BY COPYRIGHT

 **Documents**
Document Sharing Hub

85

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare and the 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 Japanese Society for Biomaterials (JSB)/Japanese Standards Association (JSA), with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

This Standard has been made based on **ISO 5832-1:1997** *Implants for surgery—Metallic materials—Part 1: Wrought stainless steel* for the purpose of making it easier to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of an 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 7403 consists of the following 2 parts:

Iron based alloys for surgical implant applications—Part 1 : Wrought stainless steel
Stainless steel based alloys for surgical implant applications—Part 2 : Wrought high nitrogen stainless steel

Date of Establishment: 2005-03-25

Date of Public Notice in Official Gazette: 2005-03-25

Investigated by: Japanese Industrial Standards Committee
Standards Board
Technical Committee on Medical Equipment

JIS T 7403-1 : 2005, First English edition published in 2006-08

Translated and published by: Japanese Standards Association
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

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

© JSA 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Printed in Japan

MT

PROTECTED BY COPYRIGHT



Documents
Document Sharing Hub

Contents

	Page
Introduction	1
1 Scope	1
2 Normative references.....	1
3 Terms and definitions	3
4 Quality	3
4.1 Cast analysis.....	3
4.2 Microstructure in fully annealed condition	3
4.3 Mechanical properties	4
5 Test methods.....	6
5.1 Chemical analysis test of molten steel	6
5.2 Tensile test.....	6
6 Inspection	6
7 Report	6
Annex (informative) Comparison table between JIS and corresponding International Standard	7

Iron based alloys for surgical implant applications—

Part 1: Wrought stainless steel

Introduction This Japanese Industrial Standard has been prepared based on the third edition of *ISO 5832-1 Implants for surgery—Metallic materials—Part 1: Wrought stainless steel* published in 1997 by employing corresponding part in the International Standard without modifying the technical contents. For concretization, it adds some provisions that are not specified in the International Standard.

The portions underlined with dots are the matters not stated in the original International Standard. A list of modifications with the explanations is given in Annex (informative).

1 Scope The part of **JIS T 7403** specifies the characteristics of, and corresponding test methods for, wrought stainless steel for use in the manufacture of surgical implants.

Remarks 1 The proven stainless steel for surgical implants includes SUS 316L stainless steel specified in JIS G 4303. This part of JIS T 7403 shall not eliminate usage of the SUS 316L and other proven stainless steel.

2 The mechanical properties of a sample obtained from a finished product made of this wrought stainless steel may not necessarily comply with the specifications given in this part of **JIS T 7403**.

3 The International Standard corresponding to this part of **JIS T 7403** 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 5832-1:1997 Implants for surgery—Metallic materials—Part 1: Wrought stainless steel (MOD)

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this part of **JIS T 7403**. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS G 0201 Glossary of terms used in iron and steel (Heat treatment)

JIS G 0202 Glossary of terms used in iron and steel (testing)

JIS G 0404 *Steel and steel products—General technical delivery requirements*

Remarks : ISO 404:1992 *Steel and steel products—General technical delivery requirements* is equivalent to the said standard.

JIS G 0416 *Steel and steel products—Location and preparation of samples and test pieces for mechanical testing*