
**Implants for surgery — Metallic
materials —**

**Part 1:
Wrought stainless steel**

Implants chirurgicaux — Produits à base de métaux —

Partie 1: Acier inoxydable corroyé

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

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This fifth edition cancels and replaces the fourth edition (ISO 5832-1:2007), which has been technically revised. It also incorporates the Technical Corrigendum ISO 5832-1:2007/Cor 1:2008.

ISO 5832 consists of the following parts, under the general title *Implants for surgery — Metallic materials*:

- *Part 1: Wrought stainless steel*
- *Part 2: Unalloyed titanium*
- *Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*
- *Part 4: Cobalt-chromium-molybdenum casting alloy*
- *Part 5: Wrought cobalt-chromium-tungsten-nickel alloy*
- *Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*
- *Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy*
- *Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy*
- *Part 9: Wrought high nitrogen stainless steel*
- *Part 11: Wrought titanium 6-aluminium 7-niobium alloy*
- *Part 12: Wrought cobalt-chromium-molybdenum alloy*
- *Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy*

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 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.

The following definitions apply in understanding how to implement an ISO International Standard and other normative ISO deliverables (TS, PAS, IWA):

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” is used to indicate that something is permitted;
- “can” is used to indicate that something is possible, for example, that an organization or individual is able to do something.

3.3.1 of the ISO/IEC Directives, Part 2 (sixth edition, 2011) defines a requirement as an “expression in the content of a document conveying criteria to be fulfilled if compliance with the document is to be claimed and from which no deviation is permitted.”

3.3.2 of the ISO/IEC Directives, Part 2 (sixth edition, 2011) defines a recommendation as an “expression in the content of a document conveying that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action is deprecated but not prohibited.”

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