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Implants for surgery — Metallic materials —

Part 1:
Wrought stainless steel

Implants chirurgicaux — Matériaux métalliques —

Partie 1: Acier inoxydable corroyé

ICS: 11.040.40

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 5832-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This fifth edition cancels and replaces the fourth edition (ISO 5832-1:2007), which has been technically revised.

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.

Implants for surgery — Metallic materials —

Part 1:
Wrought stainless steel

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, wrought stainless steel 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 can differ from those specified in this part of ISO 5832.

NOTE 2 The alloy described in this part of ISO 5832 corresponds to UNS S31673 referred to in ASTM F 138 [1]/ ASTM F 139 [2] and to alloy code 1.4441 given in the withdrawn DIN 17443.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 377, *Steel and steel products — Location and preparation of samples and test pieces for mechanical testing*

ISO 404, *Steel and steel products — General technical delivery requirements*

ISO 437, *Steel and cast iron — Determination of total carbon content — Combustion gravimetric method*

ISO 439, *Steel and iron — Determination of total silicon content — Gravimetric method*

ISO 629, *Steel and cast iron — Determination of manganese content — Spectrophotometric method*

ISO 643, *Steels — Micrographic determination of the apparent grain size*

ISO 671, *Steel and cast iron — Determination of sulphur content — Combustion titrimetric method*

ISO 4967:1998, *Steel — Determination of content of nonmetallic inclusions — Micrographic method using standard diagrams*

ISO 6892-1:201X[1)], *Metallic materials — Tensile testing— Part 1: Method of test at room temperature*

ISO 10714, *Steel and iron — Determination of phosphorus content — Phosphovanadomolybdate spectrophotometric method*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

1) ISO 6892-1 is currently under revision and the revised version is expected to be published in 2015.

3.1
original gauge length
length between gauge length marks on the test piece measured at room temperature before the test

[SOURCE: ISO 6892-1:201X, definition 3.1.1]

4 Chemical composition

4.1 Test samples

The selection of samples for analysis shall be carried out in accordance with ISO 377.

4.2 Cast analysis

The cast analysis of the steel when determined in accordance with Clause 6 shall comply with the chemical composition specified in Table 1. The molybdenum and chromium contents shall be such that the C value obtained from the formula given below is not less than 26.

$$C = 3{,}3 w_{\mathrm{Mo}} + w_{\mathrm{Cr}}$$

where

w_{Mo} is the molybdenum content, expressed as a percentage by mass;

w_{Cr} is the chromium content, expressed as a percentage by mass.

Table 1 — Chemical Composition

Element	Mass fraction %
Carbon	0,030 max.
Silicon	1,0 max.
Manganese	2,0 max.
Phosphorus	0,025 max.
Sulfur	0,010 max.
Nitrogen	0,10 max.
Chromium	17,0 to 19,0 max.
Molybdenum	2,25 to 3,00
Nickel	13,0 to 15,0
Copper	0,50 max.
Iron	Balance

5 Microstructure in the fully annealed condition

5.1 Grain size

The austenitic grain size, determined in accordance with Clause 6, shall not be coarser than grain size No. 5.

5.2 Microstructure

The steel shall have a structure free from delta ferrite, chi or sigma phase, when examined in accordance with Clause 6.

5.3 Inclusion content

The non-metallic inclusion content of the steel, determined at finished size after a hot-rolling process stage, and in accordance with Clause 6, shall not exceed the limits given in Table 2.

NOTE It can be necessary to use vacuum or electroslag melting to produce a steel complying with these cleanliness requirements.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content reference number	
	Thin	Thick
A – Sulfides	1,5	1
B – Aluminates	1,5	1
C – Silicates	1,5	1
D – Oxides, globular	1,5	1

6 Mechanical properties

6.1 Test pieces

The selection and preparation of samples and test pieces for tensile testing shall be in accordance with ISO 377.

6.2 Tensile test

The tensile properties of the steel in the form of bars, wires, and sheet and strip, when tested in accordance with Clause 6, shall comply with the values specified in Tables 3, 4 and 5 respectively.

Should any of the test pieces not meet the specified requirements or break outside the gauge limits, retests shall be carried out in accordance with ISO 404.

6.3 Gauge length

Original gauge length l_0 shall be either $5{,}65\times\sqrt{S_0}$ or 50 mm, where S_0 is defined as the original cross-sectional area in square millimetres..

7 Test methods

The test methods to be used in determining compliance with the requirements of this part of ISO 5832 shall be those given in Table 6.