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Fifth edition
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Implants for surgery — Metallic materials —

Part 1: Wrought stainless steel

Implants chirurgicaux — Produits à base de métaux —

Partie 1: Acier inoxydable corroyé

Reference number
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Foreword

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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).

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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*.

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.”

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 F138/ASTM F139 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 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 4967:2013, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams*

ISO 6892-1:2016, *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.

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

[SOURCE: ISO 6892-1:2016, 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 Formula (1) is not less than 26.

$$C = 3{,}3w_{\mathrm{Mo}} + w_{\mathrm{Cr}} \tag{1}$$

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. The gauge length chosen for testing shall be reported with the test results.

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.

Table 3 — Mechanical properties of bars

Condition	Diameter or thickness d mm	Tensile strength R_m MPa	0,2 % proof stress of non-proportional elongation $R_{p0,2}$ min. MPa	Elongation after fracture/ gauge length A min. %
Annealed	All	$490 \leq R_m \leq 690$	190	40
Cold-worked	≤22	$860 \leq R_m \leq 1\,100$	690	12
Extra-hard	≤8	≥1 400	—	—

Table 4 — Mechanical properties of wires

Condition	Diameter d mm	Tensile strength R_m MPa	Elongation after fracture/ gauge length A min. %
Annealed	$0,025 \leq d \leq 0,13$	≤1 000	30
	$0,13 < d \leq 0,23$	≤930	30
	$0,23 < d \leq 0,38$	≤890	35
	$0,38 < d \leq 0,5$	≤860	40
	$0,5 < d \leq 0,65$	≤820	40
	$d > 0,65$	≤800	40
Cold drawn[a]	$0,2 \leq d \leq 0,7$	$1\,600 \leq R_m \leq 1\,850$	—
	$0,7 < d \leq 1$	$1\,500 \leq R_m \leq 1\,750$	—
	$1 < d \leq 1,5$	$1\,400 \leq R_m \leq 1\,650$	—
	$1,5 < d \leq 2$	$1\,350 \leq R_m \leq 1\,600$	—

[a] Wire ordered in the cold-drawn condition can be supplied to higher tensile strength levels as specified by the purchaser.

Table 5 — Mechanical properties of strip and sheet

Condition	Tensile strength R_m MPa	0,2 % proof stress of non-proportional elongation $R_{p0,2}$ min. MPa	Elongation after fracture/ gauge length A min. %
Annealed	$490 \leq R_m \leq 690$	190	40
Cold worked	$860 \leq R_m \leq 1\,100$	690	10

Table 6 — Test methods

Parameter	Relevant clause or subclause	Test method
Chemical composition	Clause 4	
silicon		ISO 439
manganese		ISO 629
sulfur		ISO 671
phosphorus		ISO 10714
other elements		Recognized analytical procedures (ISO methods, where these exist).
Grain size	5.1	ISO 643[a]
Microstructure	5.2	a) Metallographically prepare specimens in the annealed condition from longitudinal and transverse sections. b) Using recognized techniques, examine the specimens at 100× magnification for the presence or absence of delta ferrite and carbides.
Inclusion content	5.3	ISO 4967:2013, Method A
Mechanical properties	Clause 6	
— tensile strength		ISO 6892-1
— proof stress of non-proportional		
— elongation		
— elongation after fracture		

[a] It is preferred that samples for grain size determination be selected after the last annealing operation and prior to the final cold-working operation. If samples are selected after a final cold-working operation, transverse specimens should be prepared.

Bibliography

[1] ASTM F138, *Standard Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)*

[2] ASTM F139, *Standard Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)*

[3] DIN 17443[1)], *Rolled and wrought stainless steel products for surgical implants; technical delivery conditions*

1) Withdrawn.

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