INTERNATIONAL STANDARD

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Implants for surgery — Metallic materials —

Part 1: Wrought stainless steel

Implants chirurgicaux — Matériaux métalliques —

Partie 1: Acier inoxydable corroyé

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Foreword

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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 fourth edition cancels and replaces the third edition (ISO 5832-1:1997), 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 referenced documents are indispensable for the application of this document. 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, *Metallic materials — Tensile testing at ambient temperature*

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

3 Chemical composition

3.1 Test samples

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

3.2 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.

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

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 3,0
Nickel	13,0 to 15,0
Copper	0,50 max.
Iron	Balance

4 Microstructure in the fully annealed condition

4.1 Grain size

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

4.2 Microstructure

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

4.3 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

5 Mechanical properties

5.1 Test pieces

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

5.2 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, 5 and 6 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.

5.3 Gauge length

S_0 is defined as the original cross-sectional area in square millimetres. In accordance with test piece diameter, d, or section profile, S_0, respectively, the gauge length shall be either $5{,}65 \times \sqrt{S_0}$ or 50 mm (see Tables 4 and 7).

6 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 8.

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 $R_{p0,2min}$ MPa	Elongation after fracture/ Gauge length A_{min} %
Annealed	All	$490 \leqslant R_m \leqslant 690$	190	40
Cold-worked	$\leqslant 22$	$860 \leqslant R_m \leqslant 1\,100$	690	12
Extra-hard	$\leqslant 8$	$\leqslant 1\,400$	—	—

Table 4 — Correspondence between gauge length and product

Product	Gauge length	
	50 mm	$5{,}65 \times \sqrt{S_0}$
Round bar, wires	$d > 5$ mm	$d \leqslant 5$ mm
Sections, profiles	$S_0 > 40$ mm^2	$S_0 \leqslant 40$ mm^2

Table 5 — Mechanical properties of wires

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

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

Table 6 — Mechanical properties of strip and sheet

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

Table 7 — Correspondence between gauge length and thickness of the product

Product	Gauge length	
	50 mm	$5{,}65 \times \sqrt{S_0}$
Round bar, wires	$d > 1{,}5$ mm	$d \leqslant 1{,}5$ mm

Table 8 — Test methods

Parameter	Relevant clause or subclause	Test method
Chemical composition		
carbon		ISO 437
silicon		ISO 439
manganese		ISO 629
sulfur		ISO 671
phosphorus		ISO 10714
other elements		Recognized analytical procedures (ISO methods, where these exists).
Grain size	4.1	ISO 643 [a]
Microstructure	4.2	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	4.3	ISO 4967:1998, Method A, Plate II
Mechanical properties — tensile strength — proof stress of non-proportional — elongation — elongation after fracture	5	ISO 6892

[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.