INTERNATIONAL STANDARD

ISO 5832-1

Third 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 corroyé inoxydable

Reference number
ISO 5832-1:1997(E)

Contents

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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.

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.

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

This third edition cancels and replaces the second edition (ISO 5832-1:1987), 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 10: Wrought titanium 5-aluminium 2,5-iron alloy*

— *Part 11: Wrought titanium 6-aluminium 7-niobium alloy*

— *Part 12: Wrought cobalt-chromium-molybdenum alloy*

Introduction

No known surgical implant material has ever been shown to cause absolutely no 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.

Provision is made for two types of stainless steel based on chemical composition (see table 1).

NOTE — The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with the specifications given in this part of ISO 5832.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5832. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5832 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 377-1:1989, *Selection and preparation of samples and test pieces of wrought stainless steels — Part 1: Samples and test pieces for mechanical tests.*

ISO 404:1992, *Steel and steel products — General technical delivery requirements.*

ISO 437:1982, *Steel and cast iron — Determination of total carbon content — Combustion gravimetric method.*

ISO 439:1982, *Steel and cast iron — Determination of total silicon — Gravimetric method.*

ISO 629:1982, *Steel and cast iron — Determination of manganese content — Spectrophotometric method.*

ISO 643:1983, *Steels — Micrographic determination of the ferritic or austenitic grain size.*

ISO 671:1982, *Steel and cast iron — Determination of sulphur content — Combustion titrimetric method.*

ISO 10714:1992, *Steels and cast iron — Determination of phosphorus content — Phosphovanadomolybdate spectrophotometric method.*

ISO 4967:—[1], *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams.*

ISO 6892:—[2], *Metallic materials — Tensile testing at ambient temperatures.*

1) To be published. (Revision of ISO 4967:1979)

2) To be published. (Revision of ISO 6892:1984)

3 Chemical composition

3.1 Test samples

The selection of samples for analysis shall be carried out in accordance with ISO 377-1.

3.2 Cast analysis

The cast analysis of the steel when determined in accordance with clause 7 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.

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

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	Compositional limits, % (m/m)	
	Composition D	Composition E
Carbon	0,030 max.	0,030 max.
Silicon	1,0 max.	1,0 max.
Manganese	2,0 max.	2,0 max.
Phosphorus	0,025 max.	0,025 max.
Sulfur	0,010 max.	0,010 max.
Nitrogen	0,10 max.	0,10 to 0,20
Chromium	17,0 to 19,0	17,0 to 19,0
Molybdenum	2,25 to 3,5	2,35 to 4,2
Nickel	13,0 to 15,0	14,0 to 16,0
Copper	0,50 max.	0,50 max.
Iron	Balance	Balance

4 Microstructure in 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. 4.

4.2 Absence of delta ferrite

The steel shall have a structure free from delta ferrite when examined in accordance with clause 6.

4.3 Inclusion content

The non-metallic inclusion content of the steel, determined at the billet stage, from a billet not exceeding 15 cm thickness, and in accordance with clause 6, shall not exceed the limits given in table 2.

NOTE — It may be necessary to use a special manufacturing technique, such as 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 377-1.

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, 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 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	Steel composition	Diameter or thickness d mm	Tensile strength R_m MPa	Proof stress of nonproportional elongation R_p 0,2 min. MPa	Percentage elongation after fracture[2] A min. %
Annealed	D	all	$490 \leqslant R_m \leqslant 690$	190	40
	E		$590 \leqslant R_m \leqslant 800$	285	40
Cold-worked	D and E	< 19	$860 \leqslant R_m \leqslant 1\,100$ [1]	690	12

1) For special implants, higher strength may be required. In such cases the elongation may be correspondingly low.

2) Gauge length $= 5{,}65\sqrt{S_0}$ or 50 mm, where S_0 is the original cross-sectional area, in square millimetres.

Table 4 — Mechanical properties of wires

Condition	Steel composition	Diameter d mm	Tensile strength R_m MPa	Percentage elongation after fracture[2] A min. %
Annealed	D and E	$0,025 \leqslant d \leqslant 0,13$	$\leqslant 1\,000$	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
		$> 0,65$	$\leqslant 800$	40
Cold-drawn[1]	D and E	$0,2 \leqslant d \leqslant 0,7$	$1\,600 \leqslant R_m \leqslant 1\,850$	—
		$0,7 < d \leqslant 1$	$1\,500 \leqslant R_m \leqslant 1\,750$	—
		$1 < d \leqslant 1,5$	$1\,400 \leqslant R_m \leqslant 1\,650$	—
		$1,5 < d \leqslant 2$	$1\,350 \leqslant R_m \leqslant 1\,600$	—

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

2) Gauge length $= 5,65\sqrt{S_0}$ or 50 mm, where S_0 is the original cross-sectional area, in square millimetres.

Table 5 —Mechanical properties of sheet and strip

Condition	Steel composition	Tensile strength R_m MPa	Proof stress of non-proportional elongation R_p 0,2 min. MPa	Percentage elongation after fracture[1] A min. %
Annealed	D	$490 \leqslant R_m \leqslant 690$	190	40 [2]
	E	$600 \leqslant R_m \leqslant 800$	300	40 [2]
Cold-finished	D	$\geqslant 610$	300	35
	E	$\geqslant 650$	390	35
Cold-worked	D and E	$860 \leqslant R_m \leqslant 1\,100$	690	12

1) Gauge length $= 5,65\sqrt{S_0}$ or 50 mm, where S_0 is the original cross-sectional area, in square millimetres.

2) For thickness less than 3 mm: 38 %.

Table 6 — Test methods

Parameter	Relevant clause or subclause	Test method
Chemical composition	3	
Carbon		ISO 437
Silicon		ISO 439
Manganese		ISO 629
Sulfur		ISO 671
Phosphorus		ISO 10714
Other elements		Recognized analytical procedures (ISO methods where these exist)
Grain size	4.1	ISO 643 NOTE — 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.
Absence of delta ferrite	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.
Inclusion content	4.3	ISO 4967, Method A, Plate II
Mechanical properties	5	
Tensile strength		ISO 6892
Proof stress of nonproportional elongation		
Percentage elongation		