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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Implants for surgery — Metallic materials —

Part 1 :
Wrought stainless steel

Implants chirurgicaux — Produits à base de métaux —

Partie 1 : Acier à forger inoxydable

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

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

This second edition cancels and replaces the first edition (ISO 5832-1 : 1980), of which it constitutes a technical revision.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Implants for surgery — Metallic materials —

Part 1 : Wrought stainless steel

1 Scope and field of application

This part of ISO 5832 specifies the characteristics of, and the 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 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 those specified in this part of ISO 5832.

2 References

ISO 377, *Wrought steel — Selection and preparation of samples and test pieces.*

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 cast iron — Determination of total silicon — Gravimetric method.*

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

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

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

ISO 2732, *Steels and cast iron — Determination of phosphorus content — Phosphovanadomolybdate spectrophotometric method.*

ISO 3651-2, *Austenitic stainless steels — Determination of resistance to intergranular corrosion — Part 2 : Corrosion test in a sulphuric acid/copper sulphate medium in the presence of copper turnings (Monypenny Strauss test).*

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

ISO 6892, *Metallic materials — Tensile testing.*

3 Chemical composition

3.1 Test samples

The selection of samples for analysis shall be in accordance with the provisions of ISO 377.

3.2 Cast analysis

When tested in accordance with the methods specified in clause 7, the cast analysis of the steel shall comply with the relevant chemical composition specified in table 1, and the molybdenum and chromium contents shall be such that the value obtained from the formula given below is not less than 26.

$$3{,}3\ w_{Mo} + w_{Cr}$$

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 as specified in clause 7 shall be no coarser than grain size No. 4.

4.2 Absence of delta ferrite

The steel shall have a structure free from delta ferrite when examined as described in clause 7.

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 as specified in clause 7, 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 cleanness 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 Corrosion resistance

The steel, in the "as delivered" condition, shall be capable of passing the intergranular corrosion test specified in clause 7.

6 Mechanical properties

6.1 Test pieces

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

6.2 Tensile test

The tensile properties of the steel in the form of bars, wires, and sheet and strip, determined as specified in clause 7, shall be in accordance with the requirements of 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 the provisions of ISO 404.

7 Test methods

The test methods to be used for 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, d, or thickness, a	Tensile strength R_m	Proof stress of non-proportional elongation $R_{p0,2}$ min.	Percentage elongation after fracture A min.
		mm	N/mm²*	N/mm²*	%
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	d or $a \leqslant 19$	$860 \leqslant R_m \leqslant 1\,100$**	690	12

* 1 N/mm² = 1MPa

** For special implants higher strength may be required, in such cases the elongation may be correspondingly low.

Table 4 — Mechanical properties of wires

Condition	Steel composition	Diameter d	Tensile strength R_m	Percentage elongation after fracture A min.
		mm	N/mm²	%
Annealed	D and E	$0{,}025 \leqslant d \leqslant 0{,}13$	$R_m \leqslant 1\,000$	30
		$0{,}13 < d \leqslant 0{,}23$	$R_m \leqslant 930$	30
		$0{,}23 < d \leqslant 0{,}38$	$R_m \leqslant 890$	35
		$0{,}38 < d \leqslant 0{,}5$	$R_m \leqslant 860$	40
		$0{,}5 < d \leqslant 0{,}65$	$R_m \leqslant 820$	40
		$0{,}65 < d$	$R_m \leqslant 800$	40
Cold drawn*	D and E	$0{,}2 \leqslant d \leqslant 0{,}7$	$1\,600 \leqslant R_m \leqslant 1\,850$	—
		$0{,}7 < d \leqslant 1$	$1\,500 \leqslant R_m \leqslant 1\,750$	—
		$1 < d \leqslant 1{,}5$	$1\,400 \leqslant R_m \leqslant 1\,650$	—
		$1{,}5 < d \leqslant 2$	$1\,350 \leqslant R_m \leqslant 1\,600$	—

* 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 sheet and strip

Condition	Steel composition	Tensile strength R_m	Proof stress of non-proportional elongation $R_{p0,2}$ min.	Percentage elongation after fracture A min.
		N/mm²	N/mm²	%
Annealed	D	$490 \leqslant R_m \leqslant 690$	190	40*
	E	$600 \leqslant R_m \leqslant 800$	300	40*
Cold finished	D	$R_m \geqslant 610$	300	35
	E	$R_m \geqslant 650$	390	35
Cold worked	D and E	$860 \leqslant R_m \leqslant 1\,100$	690	12

* For thicknesses less than 3 mm : 38 %

Table 6 — Test methods

Requirement	Relevant clause or sub-clause	Test method
Chemical composition Carbon Silicon Manganese Sulfur Phosphorus Other elements	3	ISO 437 ISO 439 ISO 629 ISO 671 ISO 2732 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 X100 magnification for the presence or absence of delta ferrite.
Inclusion content	4.3	ISO 4967, Method A, Plate II
Corrosion resistance	5	ISO 3651-2
Mechanical properties Tensile strength Proof stress of non-proportional elongation Percentage elongation after fracture	6	ISO 6892