INTERNATIONAL STANDARD

ISO 5832-9

First edition
1992-10-15

Corrected and reprinted
1995-05-15

Implants for surgery — Metallic materials —

Part 9:
Wrought high nitrogen stainless steel

Implants chirurgicaux — Produits à base de métaux —

Partie 9: Acier à forger inoxydable à haute teneur en azote

Reference number
ISO 5832-9:1992(E)

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 5832-9 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

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*

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Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

— *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*

— *Part 13: Wrought austenitic-ferritic stainless steel*

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, if the material is used in appropriate applications.

Patent licences

The International Organization for Standardization (ISO) calls attention to the fact that it is claimed that the composition of the steel given in this International Standard is the subject of a patent owned by Special Melted Products Ltd. The International Organization for Standardization takes no position with respect to the validity of this patent. The patent owner has assured the International Organization for Standardization that he is willing to grant licences under this patent on reasonable and non-discriminatory terms and conditions to manufacturers wishing to obtain such licences. The patent holder's undertakings in this respect are being placed on file with the International Organization for Standardization and licence details may be obtained from Special Melted Products Ltd., whose address is:

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Implants for surgery — Metallic materials —

Part 9:
Wrought high nitrogen stainless steel

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, wrought stainless steel containing 0,25 % and 0,5 % nitrogen for use in the manufacture of surgical implants for which high levels of strength and corrosion resistance are required.

NOTES

1 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 Requirements for other stainless steels for implants for surgery may be found in ISO 5832-1.

3 With regard to annealed wires, this part of ISO 5832 covers the mechanical properties of only those sizes for which data are available at present. Sizes other than those in table 4 may be requested by the purchaser, who should also state the ultimate tensile strength and elongation values required.

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 steels — Part 1: Samples and test pieces for mechanical test.*

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 439:1994, *Steel and iron — Determination of total silicon content — 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 3651-2:1976, *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 4967:1979, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams.*

ISO 6892:1984, *Metallic materials — Tensile testing.*

ISO 10714:1992, *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 in accordance with the provisions of ISO 377-1.

3.2 Cast analysis

The cast analysis of the steel when determined as specified in clause 6 shall comply with the relevant chemical composition specified in table 1.

Table 1 — Chemical composition

Element	Compositional limits, % (*m/m*)
Carbon	0,08 max.
Silicon	0,75 max.
Manganese	2 to 4,25
Nickel	9 to 11
Chromium	19,5 to 22
Molybdenum	2 to 3
Niobium	0,25 to 0,8
Sulfur	0,01 max.
Phosphorus	0,025 max.
Copper	0,25 max.
Nitrogen	0,25 to 0,5
Iron	Balance
Residuals	
each	0,1 max.
total	0,4 max.

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 table 6.

4.3 Inclusion content

The non-metallic inclusion content of steel, determined at the billet stage, from a billet not exceeding 15 cm thickness, and specified in clause 7, shall not exceed the limits given in table 2.

NOTE 4 General practice is to use electroslag remelted steel to comply with these cleanliness requirements and to give other additional benefits.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content	
	Thin	Thick
A — Sulfides	1,5	1,5
B — Aluminates	2	1,5
C — Silicates	2	1,5
D — Oxides, globular	2,5	1,5

5 Corrosion resistance

The steel shall be capable of passing the intergranular Monypenny Strauss corrosion test specified in clause 7 when the test piece is heat-treated at 650 °C for 30 min and air-cooled prior to test.

6 Mechanical properties

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 table 3, table 4 and table 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 sub-clause 6.5 of ISO 404:1981.

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.

The selection and preparation of samples and test pieces for tensile testing shall be in accordance with the provisions of ISO 377-1.

Table 3 — Mechanical properties of bars

Condition	Diameter or thickness mm	Ultimate tensile strength min. MPa	Yield strength 0,2 % offset min. MPa	Elongation min. %
Annealed	Up to 80 mm	740	430	35

Table 4 — Mechanical properties of wires and rods

Condition	Diameter d mm	Ultimate tensile strength min. MPa	Elongation min. %
Annealed wire	$0{,}025 \leqslant d \leqslant 0{,}229$	See note 3 to Scope	
	$0{,}229 < d \leqslant 0{,}381$	1 340	25
	$0{,}381 < d \leqslant 0{,}508$	See note 3 to Scope	
	$0{,}508 < d \leqslant 0{,}635$	1 040	25
	$0{,}635 < d \leqslant 0{,}889$	1 030	25
	$0{,}889 < d$	1 030	25
	d	1 020	25
Cold-drawn rod[1)]	3	1 800	4
	3,5	1 740	4
	4	1 600	4
	4,5	1 460	4
	5	1 320	6
	5,5	1 200	8
	6	1 060	12

1) Original wire diameter 6,5 mm.

Table 5 — Mechanical properties of sheet and strip

Condition	Ultimate tensile strength min. MPa	Yield strength 0,2 % offset min. MPa	Elongation min. %
Annealed	770	465	35

Table 6 — Test methods

Requirement	Relevant clause or sub-clause	Test method
Chemical composition	3	
Carbon		ISO 437
Silicon		ISO 439
Manganese		ISO 629
Sulfur		ISO 671
Phosphorus		ISO 10714
Other elements		Recognized analytical procedure (ISO methods where these exist)
Grain size	4.1	ISO 643
Absence of delta ferrite	4.2	a) Metallographically prepared specimens in the annealed condition from longitudinal and transverse sections. b) Using recognized techniques, examine the specimen at × 100 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	6	
Ultimate tensile strength		ISO 6892, as appropriate to the form of the steel
Yield strength		
Elongation		

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