INTERNATIONAL STANDARD

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Second edition
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Implants for surgery — Metallic materials —

Part 9: Wrought high nitrogen stainless steel

Implants chirurgicaux — Matériaux métalliques

Partie 9: Acier inoxydable corroyé à haute teneur en azote

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

This second edition cancels and replaces the first edition (ISO 5832-9:1992), 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 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 a mass fraction of 0,25 % to 0,50 % nitrogen for use in the manufacture of surgical implants for which high levels of strength and corrosion resistance are required.

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

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 404:1992, *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 3651-2, *Determination of resistance to intergranular corrosion of stainless steels — Part 2: Ferritic, austenitic and ferritic-austenitic (duplex) stainless steels — Corrosion test in media containing sulfuric acid*

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 in accordance with the provisions of ISO 377.

3.2 Cast analysis

The cast analysis of the steel when determined in accordance with Clause 6 shall comply with the relevant chemical composition specified in Table 1.

Table 1 — Chemical composition

Element	Mass fraction %
Carbon	0,08 max.
Silicon	0,75 max.
Manganese	2 to 4,25
Nickel	9 to 11
Chromium	19,5 to 22
Molybdenum	2,0 to 3,0
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 in accordance with 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 on representative billet or bar samples from the heat, not exceeding 150 mm thickness, and specified in Clause 7, shall not exceed the limits given in Table 2.

NOTE 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 675 °C for 1 h and air-cooled prior to the test.

6 Mechanical properties

The tensile properties of the steel in the form of bars, when tested in accordance with Clause 7, shall be in accordance with the requirements of Tables 3, 4 or 5.

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 8.3.4.3 of ISO 404:1992.

Table 3 — Mechanical properties of bars

Condition	Diameter or thickness	Ultimate tensile strength	Yield strength 0,2 % offset	Elongation
	d	$R_{m,min}$	$R_{p0,2min}$	A_{min}
	mm	MPa	MPa	%
Annealed	$\leqslant$ 80 mm	740	430	35
Medium hard	$\leqslant$ 20 mm [a]	1 000	700	20
Hard	$\leqslant$ 20 mm [a]	1 100	1 000	10

[a] Other sizes may be furnished by agreement between the producer and the purchaser.

Table 4 — Mechanical properties of wires and rods

Condition	Diameter d mm	Ultimate tensile strength $R_{m,min}$ MPa	Elongation A_{min} %
Annealed wire	$0{,}229 < d \leqslant 0{,}381$	1 340	25
	$0{,}381 < d \leqslant 0{,}508$	By agreement	
	$0{,}508 < d \leqslant 0{,}635$	1 040	25
	$0{,}635 < d \leqslant 0{,}889$	1 030	25
	$0{,}889 < d$	1 020	25
Cold-drawn rod	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

Table 5 — Mechanical properties of sheet and strip

Condition	Ultimate tensile strength R_m MPa	Yield strength 0,2% offset $R_{p0,2min}$ MPa	Elongation A_{min} %
Annealed	770	465	35

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.