



**International
Standard**

ISO 5832-1

**Implants for surgery — Metallic
materials —**

**Part 1:
Wrought stainless steel**

Implants chirurgicaux — Matériaux métalliques —

Partie 1: Acier inoxydable corroyé

**Sixth edition
2024-04**

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This sixth edition cancels and replaces the fifth edition (ISO 5832-1:2016), which has been technically revised.

The main changes are as follows:

- the introduction has been updated;
- normative references have been updated;
- the requirement for silicon in [Table 1](#) has been changed to 0,75 max;
- the requirement for cobalt in [Table 1](#) has been added;
- requirements for mechanical properties in [Table 4](#) have been updated;
- this document has been harmonized with the ISO 5832 series.

A list of all parts in the ISO 5832 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

While no known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body, long-term clinical experience with the material referred to in this document has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications. However, this document covers the raw material and not finished medical devices, where the design and fabrication of the device can impact biological response.

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Implants for surgery — Metallic materials —

Part 1: Wrought stainless steel

1 Scope

This document 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 document.

NOTE 2 The alloy described in this document corresponds to UNS S31673 in ASTM F138 and ASTM F139.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 439, *Steel and cast iron — Determination of 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 4967:2013, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams*

ISO 6892-1:2019, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 6892-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 original gauge length

L_0

length between gauge length marks on the test piece measured at room temperature before the test

[SOURCE: ISO 6892-1:2019, 3.1.1, modified — Note 1 to entry has been deleted.]

4 Chemical composition

4.1 Test samples

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

4.2 Cast analysis

The cast analysis of the steel when determined in accordance with [Clause 7](#) shall conform to the chemical composition specified in [Table 1](#). The molybdenum and chromium contents shall be such that the C value obtained from [Formula \(1\)](#) is not less than 26.

$$C = 3,3w_{Mo} + w_{Cr} \quad (1)$$

where

w_{Mo} is the mass fraction of molybdenum, expressed as a percentage;

w_{Cr} is the mass fraction of chromium content, expressed as a percentage.

Table 1 — Chemical composition

Element	Mass fraction of compositional limits %
Carbon	0,030 max.
Silicon	0,75 max. ^a
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 3,00
Nickel	13,0 to 15,0
Copper	0,50 max.
Cobalt	<0,10 ^a
Iron	Balance

^a Values adjusted to ASTM F138 and ASTM F139. Reprinted with permission from ASTM F138, copyright ASTM International. A copy of the complete standard may be obtained from www.astm.org.

5 Microstructure in the fully annealed condition

5.1 Grain size

The austenitic grain size, determined in accordance with [Clause 7](#), shall not be coarser than grain size No. 5.

5.2 Microstructure

The steel shall have a structure free from delta ferrite, chi or sigma phase, when examined in accordance with [Clause 7](#).

5.3 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 7](#), shall not exceed the limits given in [Table 2](#).

NOTE It can be necessary to use vacuum or electroslag melting to produce a steel conforming 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

6 Mechanical properties

6.1 Test pieces

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

6.2 Tensile test

The tensile properties of the steel in the form of bars, wires, and sheet and strip, when tested in accordance with [Clause 7](#), shall conform to the values specified in [Tables 3, 4](#) and [5](#), respectively.

If any of the test pieces do not meet the specified requirements or break outside the gauge limits, retests shall be carried out in accordance with ISO 404.

6.3 Gauge length

Original gauge length, L_0 , shall be either $5,65 \times \sqrt{S_0}$ or 50 mm, where S_0 is defined as the original cross-sectional area in square millimetres. The gauge length chosen for testing shall be reported with the test results.

7 Test methods

The test methods to be used in determining conformity with the requirements of this document shall be those given in [Table 6](#).

Table 3 — Mechanical properties of bars

Condition	Diameter or thickness d mm	Tensile strength R_m MPa	Minimum proof strength or yield strength $R_{p0,2,min}$ MPa	Minimum percentage elongation after fracture A_{min} %
Annealed	All	$490 \leq R_m \leq 690$	190	40
Cold-worked	≤ 22	$860 \leq R_m \leq 1\,100$	690	12
Extra-hard	≤ 8	$\geq 1\,400$	—	—

Table 4 — Mechanical properties of wires

Condition	Diameter d mm	Tensile strength R_m MPa	Minimum percentage elongation after fracture A_{min} %
Annealed	$0,025 \leq d \leq 0,13$	$490 \leq R_m \leq 1\,000^b$	30
	$0,13 < d \leq 0,23$	≤ 930	30
	$0,23 < d \leq 0,38$	≤ 890	35
	$0,38 < d \leq 0,5$	≤ 860	40
	$0,5 < d \leq 0,65$	≤ 820	40
	$d > 0,65$	≤ 800	40
Cold-drawn ^a	$0,2 \leq d \leq 0,7$	$1\,600 \leq R_m \leq 1\,850$	—
	$0,7 < d \leq 1$	$1\,500 \leq R_m \leq 1\,750$	—
	$1 < d \leq 1,5$	$1\,400 \leq R_m \leq 1\,650$	—
	$1,5 < d \leq 2$	$1\,350 \leq R_m \leq 1\,600$	—

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

^b Values adjusted to ASTM F138 and ASTM F 139. Reprinted with permission from ASTM F138, copyright ASTM International. A copy of the complete standard may be obtained from www.astm.org

Table 5 — Mechanical properties of strip and sheet

Condition	Tensile strength R_m MPa	Minimum proof strength or yield strength $R_{p0,2,min}$ MPa	Minimum percentage elongation after fracture A_{min} %
Annealed	$490 \leq R_m \leq 690$	190	40
Cold-worked	$860 \leq R_m \leq 1\,100$	690	10

Table 6 — Test methods

Parameter	(Sub)clause	Test method
Chemical composition — silicon — manganese — sulfur — phosphorus — other elements	Clause 4	ISO 439 ISO 629 ISO 671 ISO 10714 Recognized analytical procedures (ISO methods, where these exist)
Grain size	5.1	ISO 643 ^a
Microstructure	5.2	a) Metallographically prepared 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	5.3	ISO 4967:2013, Method A
Mechanical properties — tensile strength — proof strength or yield strength — percentage elongation after fracture	Clause 6	ISO 6892-1
^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.		