INTERNATIONAL STANDARD

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Third edition
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Implants for surgery — Metallic materials —

Part 5: Wrought cobalt-chromium-tungsten-nickel alloy

Implants chirurgicaux — Produits à base de métaux —

Partie 5: Alliage corroyé à base de cobalt, de chrome, de tungstène et de nickel

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 5832-5 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 5832-5:1993), 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*

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.

Implants for surgery — Metallic materials —

Part 5: Wrought cobalt-chromium-tungsten-nickel alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, wrought cobalt-chromium-tungsten-nickel alloy for use in the manufacture of surgical implants.

NOTE The tensile properties of a sample obtained from a finished product made of this alloy might not necessarily comply with those specified in this part of ISO 5832.

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 643, *Steels — Micrographic determination of the apparent grain size*

ISO 4967:1998, *Steel — Determination of content of nonmetallic inclusions — Micrographic method using standard diagrams*

ISO 6892, *Metallic materials — Tensile testing at ambient temperature*

3 Chemical composition

The analysis of a representative sample of the alloy when determined as specified in Clause 6 shall comply with the chemical composition specified in Table 1.

Table 1 — Chemical composition

Element	Compositional limits mass fraction %
Chromium	19 to 21
Tungsten	14 to 16
Nickel	9 to 11
Iron	$\leqslant$ 3
Carbon	$\leqslant$ 0,15
Silicon	$\leqslant$ 1
Manganese	$\leqslant$ 2
Sulfur	0,03
Phosphorus	0,04
Cobalt	Balance

4 Microstructure

4.1 Grain size index

Samples shall be prepared and etched for examination by any recognized technique. The grain size measured in accordance with ISO 643 shall be 5 or finer.

NOTE ISO 643 is given as a reference even though the material dealt with in this part of ISO 5832 is not iron-based.

4.2 Inclusion content

A longitudinal sample suitably polished shall be examined in accordance with ISO 4967, Method A, and shall not exhibit inclusions in excess of those specified in Table 2.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content: thin [a]
A — Sulfides	1
B — Aluminates	3
C — Silicates	1
D — Oxides (globular)	3
[a] Thick inclusions are allowed until 0,5.	

5 Tensile properties

The tensile properties of the alloy, determined as specified in Clause 6, shall be in accordance with the requirements of Table 3.

The level of mechanical properties for material in other than the annealed condition shall be specified in the purchase order.

Table 3 — Tensile properties

Condition	Tensile strength MPa	0,2 % offset proof stress MPa	Percentage elongation %
Annealed	$\geqslant$ 860	$\geqslant$ 310	$\geqslant$ 30

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 4.

Representative test pieces for the determination of tensile properties shall be prepared in accordance with ISO 6892.

Table 4 — Test methods

Requirement	Relevant clause or subclause	Test methods
Chemical composition	Clause 3	Recognized analytical procedures (ISO methods where these exist)
Tensile properties	Clause 5	ISO 6892
Grain size	4.1	ISO 643
Inclusion content	4.2	ISO 4967

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