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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 à forger à base de cobalt, de chrome, de tungstène et de
nickel*



Reference number
ISO 5832-5:1993(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 5832-5 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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- *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*

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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 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.

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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 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 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 643:1983, *Steels — Micrographic determination of the ferritic or austenitic grain size*.

ISO 4967:1979, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams*.

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

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, % (m/m)
Chromium	19 to 21
Tungsten	14 to 16
Nickel	9 to 11
Iron	3 max.
Carbon	0,15 max.
Silicon	1 max.
Manganese	2 max.
Cobalt	Balance

4 Microstructure

4.1 Grain size

Samples shall be prepared and etched for examination by any recognized technique. The grain size measured in accordance with ISO 643 shall be No. 5 or finer.¹⁾

1) 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 4967:1979, method A, plate 2; it shall not exhibit inclusions in excess of those allowed in table 2.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content: thin ¹⁾
A — Sulfides	1
B — Aluminates	3
C — Silicates	1
D — Oxides (globular)	3
1) There shall be no thick inclusions.	

5 Mechanical properties: tensile

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

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 3 — Mechanical properties

Condition	Tensile strength	Proof stress of non-proportional elongation	Percentage elongation
	min. MPa	min. MPa	min. %
annealed	860	310	10

Table 4 — Test methods

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