

INTERNATIONAL
STANDARD

ISO
5832-7

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**Implants for surgery — Metallic
materials —**

Part 7:

Forgeable and cold-formed
cobalt-chromium-nickel-molybdenum-iron alloy

Implants chirurgicaux — Produits à base de métaux —

*Partie 7: Alliage à forger mis en forme à froid à base de cobalt, de chrome,
de nickel, de molybdène et de fer*



Reference number
ISO 5832-7:1994(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 5832-7 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*

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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 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 conditions.

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Implants for surgery — Metallic materials —

Part 7:

Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron 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 heat analysis of the alloy when determined as specified in clause 6 shall comply with the chemical composition specified in table 1. The analysis of samples taken from products manufactured from the alloy shall also comply with table 1.

Table 1 — Chemical composition

Element	Compositional limits, % (m/m)
Cobalt	39 to 42
Chromium	18,5 to 21,5
Nickel	14 to 18
Molybdenum	6,5 to 8
Manganese	1 to 2,5
Silicon	1 max.
Carbon	0,15 max.
Phosphorus	0,015 max.
Sulfur	0,015 max.
Beryllium	0,001 max.
Iron	Balance

4 Microstructure

4.1 Grain size

The microscopic structure shall be uniform. The grain size, determined as specified in clause 6, shall be no coarser than grain size No. 5.

4.2 Inclusion content

The non-metallic inclusion content of the alloy, determined as specified in clause 6, shall not exceed the limits given 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

The mechanical properties, 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.

Table 3 — Mechanical properties

Condition	Tensile strength min. MPa	Proof stress of non-proportional elongation min. MPa	Percentage elongation min. %
Annealed	950	450	65
30 % cold-worked	1 450	1 300	8
Spring temper ¹⁾	1 650	1 400	1
1) for specific applications.			

Table 4 — Test methods

Requirement	Relevant clause or subclause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Inclusion content	4.2	ISO 4967
Grain size	4.1	ISO 643
Mechanical properties	5	ISO 6892
Tensile strength		
Percentage elongation		
Proof stress of non-proportional elongation		