INTERNATIONAL STANDARD

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Implants for surgery — Metallic materials —

Part 12:
Wrought cobalt-chromium-molybdenum alloy

Implants chirurgicaux — Produits à base de métaux —

Partie 12: Alliage à forger à base de cobalt, de chrome et de molybdène

Reference number
ISO 5832-12:1996(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 5832-12 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*

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— *Part 9: Wrought high nitrogen stainless steel*

— *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*

Introduction

No known surgical implant material has ever been shown to cause absolutely no 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 12:
Wrought cobalt-chromium-molybdenum alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, wrought cobalt-chromium-molybdenum 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 the specifications given 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 6892:1984, *Metallic materials — Tensile testing.*

3 Chemical composition

The heat analysis of a representative sample of the alloy when determined in accordance with clause 6 shall comply with the chemical composition specified in table 1.

Requirements for the major and minor elemental constituents for cobalt-chromium-molybdenum alloy are listed in table 1.

Table 1 — Chemical composition

Element	Compositional limits, % (*m/m*)
Nickel	1,0 max.
Chromium	26,0 to 30,0
Molybdenum	5,0 to 7,0
Iron	0,75 max.
Manganese	1,0 max.
Silicon	1,0 max.
Carbon	0,35 max.
Nitrogen	0,25 max.
Cobalt	Balance

4 Microstructure

The microstructure of the alloy shall be uniform. The grain size, determined in accordance with clause 6, shall not be coarser than grain size No. 5.

5 Mechanical properties

5.1 Tensile

The tensile properties of the alloy, when tested in accordance with clause 6, shall comply with the values specified in table 2.

6 Test methods

The test methods used in determining compliance with this part of ISO 5832 shall be those given in table 3.

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

Table 2 — Mechanical properties

Condition	Tensile strength R_m min. MPa	Proof stress of nonproportional elongation $R_{p0,2}$ min. MPa	Percentage elongation after fracture [1] A min.
Annealed	750	550	16
Hot-worked	1 000	700	12
Cold-worked [2]	1 172	827	12

1) Gauge length $= 5{,}65\sqrt{S_0}$ or 50 mm, where S_0 is the original cross-sectional area, in square millimetres.

2) Material ordered in the cold-drawn condition can be supplied to a higher strength and corresponding lower elongation levels, as specified by the purchaser.

Table 3 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Grain size	4	ISO 643
Mechanical properties	5	ISO 6892