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Implants for surgery — Metallic materials —

Part 4: Cobalt-chromium-molybdenum casting alloy

Implants chirurgicaux — Produits à base de métaux —

Partie 4: Alliage à couler à base de cobalt, de chrome et de molybdène

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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 documents 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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This third edition cancels and replaces the second edition (ISO 5832-4:1996), 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*

— *Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium 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 4:
Cobalt-chromium-molybdenum casting alloy

1 Scope

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

NOTE The mechanical properties of a sample obtained from a finished product made of this alloy might not necessarily comply with the specifications given in this part of ISO 5832.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Chemical composition

The heat analysis of a representative sample of the alloy when determined in accordance with Clause 5 shall comply with the chemical composition specified in Table 1.

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

Table 1 — Chemical composition

Element	Compositional limits % (m/m)
Chromium	26,5 to 30,0
Molybdenum	4,5 to 7,0
Nickel	1,0 max.
Iron	1,0 max.
Carbon	0,35 max.
Manganese	1,0 max.
Silicon	1,0 max.
Cobalt	Balance

4 Mechanical properties

The tensile properties of the alloy, when tested in accordance with Clause 5, shall comply with the specified values in Table 2.

Table 2 — Mechanical properties

Tensile strength R_m min. MPa	Proof stress of non-proportional elongation $R_{p0,2}$ min. MPa	Percentage elongation after fracture[a] A min.
665	450	8

[a] Gauge length = 5,65 $\sqrt{S_o}$ mm or 50 mm, where S_o is the original cross-sectional area, in square millimetres.

Should any of the test pieces not meet the specified requirements, or should they break outside the gauge limits, two further test pieces representative of the same batch shall be tested in the same manner. The alloy shall be deemed to comply only if both additional test pieces meet the specified requirements.

However, the manufacturer can re-heat treat the material and resubmit it for testing in accordance with this part of ISO 5832. In this case, all parts should be heat-treated in the same fashion.

5 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 ISO 6892-1.

Table 3 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures (International Standards where these exist)
Mechanical properties	4	
— Tensile strength		ISO 6892-1
— Proof stress of non-proportional elongation		ISO 6892-1
— Percentage elongation		ISO 6892-1