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Fourth edition
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Implants for surgery — Metallic materials —

Part 4: Cobalt-chromium-molybdenum casting alloy

Implants chirurgicaux — Matériaux métalliques —

Partie 4: Alliage de fonderie en cobalt, chrome et molybdène

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Foreword

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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 document 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).

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This fourth edition cancels and replaces the third edition (ISO 5832-4:2014), which has been technically revised.

The main changes are as follows:

— the introduction has been updated;

— Clause 4 on chemical composition has been updated;

— the mechanical testing language has been updated;

— this document has been harmonized with the ISO 5832 series.

A list of all parts in the ISO 5832 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

While no known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body, long-term clinical experience with the material referred to in this document has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications. However, this document covers the raw material and not finished medical devices, where the design and fabrication of the device can impact biological response.

Implants for surgery — Metallic materials —

Part 4: Cobalt-chromium-molybdenum casting alloy

1 Scope

This document 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 can differ from those given in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 6892-1 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 Chemical composition

The heat analysis of a representative sample of the alloy when determined in accordance with Clause 6 shall be in accordance 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	Mass fraction of compositional limits %
Chromium	27,0 to 30,0
Molybdenum	5,0 to 7,0
Nickel	0,50 max.
Iron	0,75 max.
Carbon	0,35 max.
Manganese	1,0 max.
Silicon	1,0 max.
Tungsten	0,20 max.
Phosphorus	0,020 max.
Sulfur	0,010 max.
Nitrogen	0,25 max.
Aluminium	0,10 max.
Titanium	0,10 max.
Boron	0,010 max.
Cobalt	Balance
Values adjusted to ASTM F75-18, Reprinted with permission from ASTM F75-18, copyright ASTM International. A copy of the complete standard may be obtained from www.astm.org	

5 Mechanical properties

The tensile properties of the alloy, when tested in accordance with Clause 6, shall be in accordance with the specified values in Table 2.

If any of the test pieces fail within the gauge limits and do not meet specified requirements, two retest pieces shall be tested in the same manner, for each failed test piece. The alloy shall be deemed to conform only if both additional test pieces meet the specified requirements.

If a test piece fails outside the gauge limits, the test is acceptable if it meets the specified requirements. If it does not meet specified requirements the test shall be discarded and a retest shall be performed.

If any of the retests fails to meet the appropriate requirements, the product represented shall be deemed not to conform to this document. However, the manufacturer can, if desired, subject the material to heat treatment again and resubmit it for testing in accordance with this document.

Table 2 — Mechanical properties

Minimum tensile strength $R_{m,min}$ MPa	Minimum proof strength or yield strength $R_{p0,2,min}$ MPa	Minimum percentage elongation after fracture[a] A_{min} %
665	450	8
[a] Gauge length is equal to 5,65 S_o mm or 50 mm, where S_o is the original cross-sectional area, in square millimetres.		

6 Test methods

The test methods used to determine conformity to this document 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	Clause	Test method
Chemical composition	Clause 4	Recognized analytical procedures (ISO methods where these exist)
Mechanical properties — Tensile strength — Proof strength or yield strength — Percentage elongation after fracture	Clause 5	ISO 6892-1