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Implants for surgery — Metallic materials —

Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy

Implants chirurgicaux — Matériaux métalliques —

Partie 6: Alliage corroyé à base de cobalt, de nickel, 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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 5832-6:1997) which has been technically revised.

The main changes compared to the previous edition are as follows:

— the introduction has been updated;

— requirements for boron in Table 1 has been added;

— information on grain size in 5.2 has been added;

— requirements for tensile properties in Table 2 have been updated and 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 the biological response.

Implants for surgery — Metallic materials —

Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy

1 Scope

This document specifies the characteristics of, and corresponding test methods for, wrought cobalt-nickel chromium-molybdenum alloy for use in the manufacture of surgical implants.

NOTE The tensile properties of a sample obtained from a finished product made of this alloy do not necessarily comply with those specified 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 643, *Steels — Micrographic determination of the apparent grain size*

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

3 Terms and definitions

No terms and definitions are listed in this document.

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 the alloy, when determined as specified in Clause 7, shall conform to the relevant chemical composition specified in Table 1.

Table 1 — Chemical composition

Element	Mass fraction %
Nickel	33,0 to 37,0
Chromium	19,0 to 21,0
Molybdenum	9,0 to 10,5
Iron	1,0 max.
Titanium	1,0 max.
Manganese	0,15 max.
Silicon	0,15 max.
Carbon	0,025 max.
Phosphorus	0,015 max.
Sulfur	0,010 max.
Boron	0,015 max.
Cobalt	Balance

5 Microstructure

5.1 General

The microstructure of the alloy shall be uniform.

5.2 Grain size index

The grain size in the annealed condition, as determined in accordance with Clause 7, shall not be coarser than grain size No. 4. The grain size in other conditions may be determined as agreed upon between the manufacturer and the user.

6 Tensile properties

The tensile properties of the alloy, when tested in accordance with Clause 7, shall be in accordance with the values specified in Table 2.

NOTE The tensile properties of this material can be altered by cold-working and cold-working plus ageing processes.

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 may, if desired, subject the material to heat treatment again and resubmit it for testing in accordance with this document.

Table 2 — Tensile properties

Condition	Tensile strength R_m min. MPa	Yield strength or proof strength $R_{p0,2}$ min. MPa	Percentage elongation after fracture[a] A min. %
Annealed	793	300	50,0
Medium hard	1 000	655	20,0
Hard	1 207	1 000	10,0

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

7 Test methods

The test methods used to determine conformity to the requirements of this document shall be those given in Table 3.

The representative test pieces for the determination of tensile properties shall be prepared in accordance with ISO 6892-1.

Table 3 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	4	Recognized analytical procedures (refer to the international standards where they exist)
Grain size	5	ISO 643
Tensile properties	6	ISO 6892-1

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