SLOVENSKI STANDARD
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Vsadki (implantati) za kirurgijo - Kovinski materiali - 7. del: Kovne in hladno oblikovane kobalt-krom-nikelj-molibden-železove zlitine (ISO/DIS 5832-7:2023)

Implants for surgery - Metallic materials - Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy (ISO/DIS 5832-7:2023)

Chirurgische Implantate - Metallische Werkstoffe - Teil 7: Schmiedbare und kaltumformbare Cobalt-Chrom-Nickel-Molybdän-Eisenlegierung (ISO/DIS 5832-7:2023)

Implants chirurgicaux - Matériaux métalliques - Partie 7: Alliage à forger mis en forme à froid à base de cobalt, de chrome, de nickel, de molybdène et de fer (ISO/DIS 5832-7:2023)

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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

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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*.

This fourth edition cancels and replaces the third (ISO 5832-7:2016), which has been technically revised.

The main changes are as follows:

— introduction has been updated;

— mechanical testing language has been updated;

— document harmonised to 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 part of ISO 5832 has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications. However, this standard 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 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

1 Scope

This document 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 The mechanical 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 4967, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams*

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 the alloy when determined as specified in Clause 7 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	Element compositional limits, % (*m*/*m*)
Cobalt	39,0 to 42,0
Chromium	18,5 to 21,5
Nickel	14,0 to 18,0

Table 1 *(continued)*

Element	Element compositional limits, % (*m*/*m*)
Molybdenum	6,5 to 8,0
Manganese	1,0 to 2,5
Silicon	1,0 max.
Carbon	0,15 max.
Phosphorus	0,015 max.
Sulfur	0,015 max.
Beryllium	0,001 max.
Iron	Balance

5 Microstructure

5.1 Grain size

The microscopic structure shall be uniform. The grain size, determined as specified in Clause 7, shall be no coarser than grain size No. 5.

5.2 Inclusion content

The non-metallic inclusion content of the alloy, determined as specified in Clause 7, shall not exceed the limits given in Table 2.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content thin[a]
A – Sulfides	1
B – Aluminates	3
C – Silicates	1
D – Oxides, globular	3

[a] There shall be no thick inclusions.

6 Mechanical properties

The mechanical properties, determined as specified in Clause 7, shall be in accordance with the requirements of Table 3.

Table 3 — Mechanical properties

Condition	Tensile strength min. MPa	Proof strength or yield strength min. MPa	Percentage elongation after fracture min. %
Annealed	950	450	65
Hot worked	950	600	20
30 % cold-worked	1 450	1 300	8
Spring temper[a]	1 650	1 400	1

[a] For specific applications.