# SLOVENSKI STANDARD
# oSIST prEN ISO 5832-7:2018

**01-november-2018**

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**Vsadki (implantati) za kirurgijo - Kovinski materiali - 7. del: Kovne in hladno oblikovane kobalt-krom-nikelj-molibden-železove zlitine (ISO 5832-7:2016)**

Implants for surgery - Metallic materials - Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy (ISO 5832-7:2016)

Chirurgische Implantate - Metallische Werkstoffe - Teil 7: Schmiedbare und kaltumformbare Cobalt-Chrom-Nickel-Molybdän-Eisenlegierung (ISO 5832-7:2016)

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 (ISO 5832-7:2016)



**Ta slovenski standard je istoveten z:** **prEN ISO 5832-7**

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**ICS:**

| | | |
|---|---|---|
| 11.040.40 | Implantanti za kirurgijo, protetiko in ortetiko | Implants for surgery, prosthetics and orthotics |

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INTERNATIONAL STANDARD

**ISO 5832-7**

Third edition
2016-11-15

# 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 on 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 the following URL: www.iso.org/iso/foreword.html.

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 5832-7:1994), which has been technically revised.

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



 

# Introduction

No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience of the use of 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 conditions.

# 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

No terms and definitions are listed in this document.

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

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

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

## 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 to 42 |
| Chromium | 18,5 to 21,5 |
| Nickel | 14 to 18 |
| Molybdenum | 6,5 to 8,0 |
| Manganese | 1,0 to 2,5 |
| Silicon | 1 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.