

SLOVENSKI STANDARD
oSIST prEN ISO 5832-6:2018
01-november-2018

Vsadki (implantati) za kirurgijo - Kovinski materiali - 6. del: Kobalt-nikelj-krom-molibdenova kovana zlitina (ISO 5832-6:1997)

Implants for surgery - Metallic materials - Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy (ISO 5832-6:1997)

Chirurgische Implantate - Metallische Werkstoffe - Teil 6: Kobalt-Nickel-Chrom-Molybdän Schmiedelegierung (ISO 5832-6:1997)

Implants chirurgicaux - Produits à base de métaux - Partie 6: Alliage corroyé à base de cobalt, de nickel, de chrome et de molybdène (ISO 5832-6:1997)

Ta slovenski standard je istoveten z: prEN ISO 5832-6

ICS:

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

INTERNATIONAL STANDARD

ISO
5832-6

Second edition
1997-07-15

Implants for surgery — Metallic materials —

Part 6:

**Wrought cobalt-nickel-chromium-molybdenum
alloy**

Implants chirurgicaux — Produits à base de métaux —

*Partie 6: Alliage corroyé à base de cobalt, de nickel, de chrome et
de molybdène*

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Reference number
ISO 5832-6:1997(E)

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5832-6 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This second edition cancels and replaces the first edition (ISO 5832-6:1980), 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 10: Wrought titanium 5-aluminium 2,5-iron alloy
- Part 11: Wrought titanium 6-aluminium 7-niobium alloy
- Part 12: Wrought cobalt-chromium-molybdenum 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.

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Implants for surgery — Metallic materials —

Part 6:

Wrought cobalt-nickel-chromium-molybdenum alloy

1 Scope

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

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5832. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5832 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 643:1983, *Steels — Micrographic determination of the ferritic or austenitic grain size*.

ISO 6892:—¹⁾, *Metallic materials — Tensile testing at ambient temperatures*.

3 Chemical composition

The heat analysis of a representative sample of the alloy when determined in accordance with clause 6 shall comply with the chemical composition specified in table 1.

Table 1 — Chemical composition

| Element | Compositional limits, % (m/m) |
|------------|-------------------------------|
| 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. |
| Cobalt | Balance |

1) To be published. (Revision of ISO 6892:1984)