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

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 5832-6:2019 sisaldab Euroopa standardi EN ISO 5832-6:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 5832-6:2019 consists of the English text of the European standard EN ISO 5832-6:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 02.10.2019.	Date of Availability of the European standard is 02.10.2019.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.40

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5832-6

October 2019

ICS 11.040.40

English Version

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

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

This European Standard was approved by CEN on 2 September 2019.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 5832-6:2019 E

European foreword

The text of ISO 5832-6:1997 has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 5832-6:2019 by Technical Committee CEN/TC 285 "Non-active surgical implants" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 5832-6:1997 has been approved by CEN as EN ISO 5832-6:2019 without any modification.

Contents

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

Printed in Switzerland

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.

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)