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



#### EESTI STANDARDI EESSÕNA

#### 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 <u>standardiosakond@evs.ee</u>.

#### ICS 11.040.40

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega: Koduleht <a href="mailto:www.evs.ee">www.evs.ee</a>; telefon 605 5050; e-post <a href="mailto:info@evs.ee">info@evs.ee</a>

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

## EUROPEAN STANDARD

NORME EUROPÉENNE

#### **EN ISO 5832-6**

# EUROPÄISCHE NORM

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

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

#### **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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

#### **Endorsement notice**

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

Contents		Page
1	Scope	1
2	Normative references	
3	Chemical composition	1
4	Microstructure	
5	Mechanical properties	
6	Test methods	
		is publication may be
	ISO 1997	
repr	rights reserved. Unless otherwise specified, no part of the roduced or utilized in any form or by any means, electronic or	r mechanical, including
	tocopying and microfilm, without permission in writing from the pu	blisher.
(	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	

#### © ISO 1997

Printed in Switzerland

#### Introduction

No known surgical implant material has ever been shown to cause ne hu e mate, able level u d in appropria. 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.

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	

Table 1 — Chemical composition

<sup>1)</sup> To be published. (Revision of ISO 6892:1984)