



International
Standard

ISO 5832-7

Implants for surgery — Metallic materials —

Part 7:

Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

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

Fourth edition
2024-04

STANDARDSISO.COM : Click to view the full PDF of ISO 5832-7:2024



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents		Page
Foreword.....		iv
Introduction.....		v
1	Scope.....	1
2	Normative references.....	1
3	Terms and definitions.....	1
4	Chemical composition.....	1
5	Microstructure.....	2
5.1	Grain size.....	2
5.2	Inclusion content.....	2
6	Mechanical properties.....	2
7	Test methods.....	3

STANDARDSISO.COM : Click to view the full PDF of ISO 5832-7:2024

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (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;
- this document has been harmonized with the 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 document has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications. However, this document covers the raw material and not finished medical devices, where the design and fabrication of the device can impact biological response.

STANDARDSISO.COM : Click to view the full PDF of ISO 5832-7:2024

STANDARDSISO.COM : Click to view the full PDF of ISO 5832-7:2024

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 can differ from 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	Mass fraction of compositional limits %
Cobalt	39,0 to 42,0
Chromium	18,5 to 21,5
Nickel	14,0 to 18,0
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 microstructure 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](#).