BS ISO 5832-7:2016

BSI Standards Publication

Implants for surgery — Metallic materials

Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

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National foreword

This British Standard is the UK implementation of ISO 5832-7:2016. It supersedes BS 7252-7:1994 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/1, Materials for surgical implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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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

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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.

INTERNATIONAL STANDARD ISO 5832-7:2016(E)

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.

Table 3 — Mechanical properties

Condition	Tensile strength min. MPa	Proof stress of non-proportional elongation min. MPa	Percentage elongation min. %
Annealed	950	450	65
Hot worked	950	600	20
30 % cold-worked	1 450	1 300	8
Spring temper[a]	1 650	1 400	1

[a] For specific applications.

7 Test methods

The test methods to be used in determining compliance with the requirements of this document shall be those given in Table 4.

Table 4 — Test methods

Requirement	Relevant clause or subclause	Test method
Chemical composition	Clause 4	Recognized analytical procedures (ISO methods where these exist)
Inclusion content	5.2	ISO 4967
Grain size	5.1	ISO 643
Mechanical properties Tensile strength Percentage elongation Proof stress of non-proportional elongation	Clause 6	ISO 6892-1

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