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Implants for surgery — Metallic materials —

Part 5: Wrought cobalt-chromium-tungsten-nickel

Implants chirurgicaux — Produits à base de métaux —

Partie 5: Alliage corroyé à base de cobalt, de chrome, de tungstène et de nickel

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Contents

Page

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 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 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*.

This fourth edition cancels and replaces the third edition (ISO 5832-5:2005) which has been technically revised. The main changes are as follows:

— the introduction has been updated;

— limits for carbon, silicon, and manganese in Table 1 have been updated;

— requirements of inclusion content in Table 2 have been updated;

— tensile properties Clause 6 and Table 3 have been updated and harmonized to the ISO 5832 series;

— material conditions for grain size measurement in 5.1 have been updated.

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 the finished medical devices, where the design and fabrication of the device can impact biological response.

Implants for surgery — Metallic materials —

Part 5: Wrought cobalt-chromium-tungsten-nickel

1 Scope

This document specifies the characteristics of, and corresponding test methods for, wrought cobalt-chromium-tungsten-nickel alloy for use in the manufacture of surgical implants.

NOTE The tensile 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 4967:2013, *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 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 a representative sample of the alloy, when determined as specified in Clause 7, shall comply with the chemical composition specified in Table 1.

Table 1 — Chemical composition

Element	Compositional limits mass fraction %
Chromium	19,00 to 21,00
Tungsten	14,00 to 16,00
Nickel	9,00 to 11,00
Iron	3,00 max.
Carbon	0,05 to 0,15
Silicon	0,40 max.
Manganese	1,00 to 2,00
Sulfur	0,030 max.
Phosphorus	0,040 max.
Cobalt	Balance

5 Microstructure

5.1 Grain size index

Samples shall be prepared and etched for examination by any recognized technique. The grain size in the annealed condition measured in accordance with ISO 643 shall be 5 or finer. The grain size in other conditions may be determined as specified in the purchase order.

NOTE ISO 643 is given as a reference even though the material dealt with in this document is not iron-based.

5.2 Inclusion content

A longitudinal sample suitably polished shall be examined in accordance with ISO 4967:2013, Method A, and shall not exhibit inclusions in excess of those specified in Table 2.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content: thin[a]
A — Sulfides	1,5
B — Aluminates	1,5
C — Silicates	1,5
D — Oxides (globular)	1,5
[a] Thick inclusions are allowed until 1,0.	

6 Tensile properties

The tensile properties of the alloy, determined as specified in Clause 7, shall be in accordance with the requirements of Table 3.

If any of the test pieces fail within the gauge limits and do not meet specified requirements, two retest pieces shall be tested in the same manner, for each failed test piece. The alloy shall be deemed to conform only if both additional test pieces meet the specified requirements.