

INTERNATIONAL STANDARD

ISO
5832-8

Second edition
1997-07-15

Implants for surgery — Metallic materials —

Part 8:

**Wrought cobalt-nickel-chromium-molybdenum-
tungsten-iron alloy**

Implants chirurgicaux — Produits à base de métaux —

Partie 8: Alliage corroyé à base de cobalt, de nickel, de chrome, de molybdène, de tungstène et de fer



Reference number
ISO 5832-8:1997(E)

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Printed in Switzerland

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5832-8 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This second edition cancels and replaces the first edition (ISO 5832-8:1987), which has been technically revised.

ISO 5832 consists of the following parts, under the general title *Implants for surgery — Metallic materials*:

- Part 1: *Wrought stainless steel*
- Part 2: *Unalloyed titanium*
- Part 3: *Wrought titanium 6-aluminium 4-vanadium alloy*
- Part 4: *Cobalt-chromium-molybdenum casting alloy*
- Part 5: *Wrought cobalt-chromium-tungsten-nickel alloy*
- Part 6: *Wrought cobalt-nickel-chromium-molybdenum alloy*
- Part 7: *Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy*
- Part 8: *Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy*
- Part 9: *Wrought high nitrogen stainless steel*
- Part 10: *Wrought titanium 5-aluminium 2,5-iron alloy*
- Part 11: *Wrought titanium 6-aluminium 7-niobium alloy*
- Part 12: *Wrought cobalt-chromium-molybdenum alloy*

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.

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Implants for surgery — Metallic materials —

Part 8:

Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and the corresponding test methods for, wrought cobalt-nickel-chromium-molybdenum-tungsten-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 depend on the treatment undergone, and 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 643:1983¹⁾, *Steels — Micrographic determination of the ferritic or austenitic grain size.*

ISO 6892:—²⁾, *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.

4 Microstructure

The microstructure³⁾ shall be uniform and single-phased in the annealed condition. The grain size in the annealed condition, determined in accordance with clause 6, shall not be coarser than grain size No. 5.

1) ISO 643 is given as a reference, even though the material dealt with in this part of ISO 5832 is not iron-based.

2) To be published. (Revision of ISO 6892:1984)

3) For determination of the microstructure, the following etching reagent may be used: 10 ml of nitric acid ($\rho_{20} = 1,4$ kg/l) plus 100 ml of hydrochloric acid ($\rho_{20} = 1,19$ kg/l) plus 0,3 ml of Vogel's Sparbeize plus 100 ml of distilled water.

5 Mechanical properties

The tensile properties of the alloy, when tested in accordance with clause 6, shall comply with the values specified in table 2.

NOTE — The mechanical properties of this material can be altered by cold-working and cold-working plus ageing processes.

6 Test methods

The test methods to be used in determining compliance with this part of ISO 5832 shall be those given in table 3.

Representative test pieces for the determination of mechanical properties shall be prepared in accordance with ISO 6892.

Table 1 — Chemical composition

| Element | Compositional limits, % (m/m) |
|------------|-------------------------------|
| Cobalt | Balance |
| Nickel | 15,0 to 25,0 |
| Chromium | 18,0 to 22,0 |
| Molybdenum | 3,0 to 4,0 |
| Tungsten | 3,0 to 4,0 |
| Iron | 4,0 to 6,0 |
| Titanium | 0,5 to 3,50 |
| Carbon | 0,05 max. |
| Manganese | 1,00 max. |
| Silicon | 0,50 max. |
| Sulfur | 0,010 max. |

Table 2 — Mechanical properties

| Condition | Tensile strength R_m min. MPa | Proof stress of non-proportional elongation $R_p 0,2$ min. MPa | Percentage elongation after fracture ¹⁾ A min. % |
|-------------------------------------|--|---|--|
| Fully annealed | 600 | 275 | 50 |
| Cold-worked or cold-worked and aged | | | |
| Medium hard | 1 000 | 830 | 18 |
| Hard | 1 310 | 1 170 | 12 |
| Extra hard | 1 580 | 1 310 | 5 |

1) Gauge length = $5,65\sqrt{S_0}$ or 50 mm, where S_0 is the original cross-sectional area, in square millimetres.

Table 3 — Test methods

| Parameter | Relevant clause | Test method |
|-----------------------|-----------------|--|
| Chemical composition | 3 | Recognized analytical procedures (ISO methods where these exist) |
| Grain size | 4 | ISO 643 |
| Mechanical properties | 5 | ISO 6892 |