

INTERNATIONAL STANDARD

ISO
5832-8

First edition
1987-08-01



INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Implants for surgery — Metallic materials —

Part 8 :

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

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Implants chirurgicaux — Produits à base de métaux —

ISO 5832-8:1987

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

.0a500576ec8a/iso-5832-8-1987

Reference number
ISO 5832-8: 1987 (E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

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

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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1 Scope and field of application

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 may not necessarily comply with those specified in this part of ISO 5832.

2 References

ISO 643, *Steels — Micrographic determination of the ferritic or austenitic grain size*.¹⁾

ISO 6892, *Metallic materials — Tensile testing*.

3 Chemical composition

When tested in accordance with the methods specified in clause 6, the heat analysis of the alloy 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	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.

4 Microstructure

The microstructure²⁾ shall be uniform and single-phased in the annealed condition. The grain size in the annealed condition, determined as specified in clause 6, shall be no 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) For the determination of the microstructure, the following etching reagent may be used : 10 ml of nitric acid (ρ_{20} 1,4 kg/l) plus 100 ml of hydrochloric acid (ρ_{20} 1,19 kg/l) plus 0,3 ml of Vogel's Sparbeize plus 100 ml of distilled water.

5 Mechanical properties

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

The tensile properties of the alloy, determined as specified in clause 6, shall be in accordance with the requirements of table 2.

6 Test methods

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

Table 2 — Mechanical properties

Conditions	Tensile strength R_m min.	Proof stress of non-proportional elongation $R_{p0,2}$ min.	Percentage elongation after fracture** A min.	Percentage reduction of area Z min.
	N/mm ² *	N/mm ² *	%	%
Fully annealed	600	276	50	65
Cold worked or cold worked and aged				
Medium hard	1 000	827	18	50
Hard	1 310	1 172	12	45
Extra hard	1 580	1 310	5	35

* 1 N/mm² = 1 MPa

** 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

Requirement	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Grain size	4	ISO 643
Mechanical properties Tensile strength Proof stress of non-proportional elongation Percentage elongation after fracture Percentage reduction of area	5	ISO 6892

UDC 615.465 : 669.255.24.26.28.27.15.295

Descriptors : medical equipment, surgical implants, metal products, wrought products, nickel molybdenum chromium alloys, specifications, tests.

Price based on 2 pages