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International Standard



5832/6

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

**Implants for surgery — Metallic materials —
Part 6 : Wrought cobalt-nickel-chromium-molybdenum
alloy**

Implants chirurgicaux — Produits à base de métaux — Partie 6 : Alliage à forger à base de cobalt, de nickel, de chrome et de molybdène.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up 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.

International Standard ISO 5832/6 was developed by Technical Committee ISO/TC 150, *Implants for surgery*, and was circulated to the member bodies in August 1979.

It has been approved by the member bodies of the following countries :

Australia	Germany, F. R.	Romania
Austria	India	Spain
Belgium	Italy	Switzerland
Canada	Libyan Arab Jamahiriya	United Kingdom
Denmark	New Zealand	USA
France	Poland	USSR

No member body expressed disapproval of the document.

Implants for surgery — Metallic materials — Part 6 : Wrought cobalt-nickel-chromium-molybdenum alloy

1 Scope and field of application

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

NOTE — The mechanical properties of a sample obtained from finished products made of this alloy may not necessarily comply with those specified in this International Standard.

2 References

ASTM E8, *Methods of tension testing of metallic materials*.

ASTM E112, *Standard methods for estimating the average grain size of metals*.

NOTE — The above references will be replaced by references to appropriate International Standards when the latter become available.

3 Chemical composition

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 (for test methods, see clause 6).

Table 1 — Chemical composition

Element	Compositional limits % (m/m)
Nickel	33,0 to 37,0
Chromium	19,0 to 21,0
Molybdenum	9,0 to 10,5
Iron	1,0 max.
Titanium	1,0 max.
Manganese	0,15 max.
Silicon	0,15 max.
Carbon	0,025 max.
Phosphorus	0,015 max.
Sulphur	0,010 max.
Cobalt	Balance

4 Microstructure

The microscopic structure of the alloy shall be uniform, and the grain size, determined as specified in clause 6, shall be no coarser than grain size No. 4.

5 Mechanical properties

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

5.1 Test pieces

Representative test pieces for the determination of mechanical properties shall be prepared in accordance with the provisions of ASTM E8.

5.2 Tensile test

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

Table 2 — Mechanical properties

Condition	Ultimate tensile strength min.	Yield strength (0,2 % offset) min.	Elongation ¹⁾ min.
	MPa	MPa	%
Annealed	800	300	40
Medium hard	1 000	650	20
Hard	1 200	1 000	10

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

6 Methods of test

The methods of test to be used in determining compliance with the requirements of this International Standard shall be those given in table 3.

Table 3 — Methods of test

Requirement	Relevant clause	Method of test
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Grain size	4	ASTM E112
Mechanical properties	5	
Ultimate tensile strength		ASTM E8
Yield strength		ASTM E8
Elongation		ASTM E8