

International Standard



5832/7

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

Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

Implants pour la chirurgie — Produits à base de métaux — Partie 7: Alliage à forger mis en forme à froid à base de cobalt-chrome-nickel-molybdène-fer

First edition — 1984-03-15

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UDC 615.465 : 669.255.26.24.28.15

Ref. No. ISO 5832/7-1984 (E)

Descriptors : surgical implants, cold formed products, alloys, cobalt containing alloys, chromium containing alloys, molybdenum containing alloys, nickel containing alloys, iron alloy, material specifications, chemical composition, microstructure, mechanical properties, tests.

Price based on 2 pages

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (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 authorized 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 5832/7 was developed by Technical Committee ISO/TC 150, *Implants for surgery*, and was circulated to the member bodies in March 1983.

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

Australia	India	Spain
Belgium	Mexico	Switzerland
France	Poland	USSR
Germany, F.R.	Romania	

No member body expressed disapproval of the document.

Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

1 Scope and field of application

This International Standard 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 may not necessarily comply with those specified in this International Standard.

2 References*

ISO 82, *Steel — Tensile testing.*

ISO 86, *Steel — Tensile testing of sheet and strip less than 3 mm and not less than 0,5 mm thick.*

ISO 89, *Steel — Tensile testing of wire.*

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

ISO 4967, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams.*

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	Composition limits, % (m/m)
Cobalt	39,0 to 42,0
Chromium	18,5 to 21,5
Nickel	15,0 to 18,0
Molybdenum	6,5 to 7,5
Manganese	1,0 to 2,0
Carbon	0,15 max.
Beryllium	0,001 max.
Iron	Balance

4 Microstructure

4.1 Inclusion content

The non-metallic inclusion content of the alloy, determined as specified in clause 6, shall not exceed the limits given in table 2.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content Thin
A — Sulphides	1
B — Aluminates	3
C — Silicates	1
D — Oxides, globular	3

There shall be no thick inclusions.

4.2 Grain size

The microscopic structure shall be uniform. The grain size, determined as specified in clause 6, shall be no coarser than grain size No. 5.

* International Standards concerning steel are referenced although this material is not iron based.