

INTERNATIONAL STANDARD ISO 5832/IV



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

Implants for surgery — Metallic materials — Part IV : Cobalt-chromium-molybdenum casting alloy

*Implants chirurgicaux — Produits à base de métaux —
Partie IV . Alliage à couler à base de cobalt, de chrome, et de molybdène*

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Descriptors: surgical implants, products made with metal, cobalt alloys, chromium-containing alloys, molybdenum-containing alloys, materials specifications, chemical composition, mechanical properties, tests, tension tests, marking, user-supplier relations.

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/IV was developed by Technical Committee ISO/TC 150, *Implants for surgery*, and was circulated to the member bodies in January 1977.

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

Australia	France	Romania
Austria	Germany	South Africa, Rep. of
Belgium	India	Spain
Canada	Italy	Switzerland
Czechoslovakia	Mexico	Turkey
Denmark	New Zealand	U.S.S.R.

The member bodies of the following countries expressed disapproval of the document on technical grounds :

United Kingdom
U.S.A.

Implants for surgery – Metallic materials –

Part IV : Cobalt-chromium-molybdenum casting alloy

1 SCOPE AND FIELD OF APPLICATION

This International Standard specifies the characteristics of, and corresponding test methods for, cobalt-chromium-molybdenum casting 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 REFERENCE

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

NOTE – The above reference will be replaced by a reference to the appropriate International Standard when the latter becomes available.

3 CHEMICAL COMPOSITION

The analysis of a representative sample of the alloy shall comply with the chemical composition specified in table 1 (for test methods, see clause 5).

TABLE 1 – Chemical composition

Element	Compositional limits % (m/m)
Chromium	26,5 to 30,0
Molybdenum	4,5 to 7,0
Nickel	2,5 max.
Iron	1,0 max.
Carbon	0,35 max.
Manganese	1,0 max.
Silicon	1,0 max.
Cobalt	Balance

4 MECHANICAL PROPERTIES

4.1 Test pieces

At least four test pieces for the determination of tensile properties shall be prepared by melting representative test samples of the alloy and casting the melt in accordance with the manufacturer's instructions to form test pieces not less than 4 mm in diameter.

4.2 Tensile test

The tensile properties of two test pieces, determined as specified in clause 5, shall be in accordance with the requirements of table 2.

TABLE 2 – Mechanical properties

Ultimate tensile strength min.	Yield strength (0,2 % offset) min.	Elongation ¹⁾ min.	Reduction of area min.
MPa	MPa	%	%
665	450	8	8

1) Gauge length = $5,65 \sqrt{S_0}$ or 4 to 5 times the original diameter, where S_0 is the original cross-sectional area in square millimetres.

Should either of the test pieces not meet the specified requirements, or should they break outside the gauge limits, two further test pieces representative of the same batch shall be tested in the same manner. The alloy shall be deemed to comply only if both additional test pieces meet the specified requirements.

5 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)
Mechanical properties	4	ASTM E8