INTERNATIONAL STANDARD

ISO 5832-6

> Second edition 1997-07-15

Implants for surgery — Metallic materials —

Part 6:

Wrought cobalt-nickel-chromium-molybdenum

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(standards.iteh.ai) Implants chirurgicaux — Produits à base de métaux —

Partie 6: Alliage corroyé à base de cobalt, de nickel, de chrome et https://standard.demolybdeneandards/sist/5fla594c-6b0f-4a6e-9955-5e9115db7c50/iso-5832-6-1997



Contents

Page

1	Scope	1
2	Normative references	1
3	Chemical composition	1
4	Microstructure	2
5	Mechanical properties	2
6	Test methods	2

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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 nongovernmental, 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.

iTeh Sinternational Standard ISO 5832-6 was prepared by Technical Committee ISO/TC 150, Implants for surgery, Subcommittee SC 1, Materials.

(standards.iteh.ai) This second edition cancels

This second edition cancels and replaces the first edition (ISO 5832-6:1980), which has been technically revised.

https://standards.ijSOⁱ5832ⁱconsists of the following parts, under the general title *Implants for surgerly*^{-db} Metallic materials.⁷

- 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-nickelmolybdenum-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 6: Wrought cobalt-nickel-chromium-molybdenum alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, wrought cobalt-nickelchromium-molybdenum 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 the specifications given in this part of ISO 5832.

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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 643:1983, Steels — Micrographic determination of the ferritic or austenitic grain size.

ISO 6892:—1), 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.

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.
Sulfur	0,010 max.
Cobalt	Balance

Table 1 — Chemical composition	Table	1 —	- Chemical	composition
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1) To be published. (Revision of ISO 6892:1984)

4 Microstructure

The microstructure of the alloy shall be uniform. The grain size, determined in accordance with clause 6, shall not be coarser than grain size No. 4.

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

Should any 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.

NOTE 2 However, the manufacturer may re-heat-treat the material and resubmit it for testing in accordance with the requirements of this part of ISO 5832.

Condition	Tensile strength	Proof stress of non- proportional elongation	Percentage elongation after fracture ¹⁾	
	<i>R</i> m	R _p 0,2	A	
	iTeh STANDA	ARD PrinceVIE	win.	
	MPa	MPa	%	
Annealed	800 (standai	ds.iteboal)	40	
Medium				
Hard	1000	<u>832-6:1997</u> 650	20	
Hard	https://standards.iteh.ai/catalog/star 1 200 5e9115db7c5	1dards/sist/511a594c-6601-4a66 0/iso-5832-6-19997	-9955-	
1) Gauge length = 5,65 $\sqrt{S_o}$ or 50 mm, where S_o is the original cross-sectional area, in square millimetres.				

Table 2 — Mechanical properties

6 Test methods

The test methods to be used in determining compliance with the requirements of 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 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

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