INTERNATIONAL STANDARD

ISO 5832-12

Second edition
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Implants for surgery — Metallic materials —

Part 12: Wrought cobalt-chromium-molybdenum alloy

Implants chirurgicaux — Matériaux métalliques —

Partie 12: Alliage corroyé à base de cobalt, de chrome et de molybdène

Reference number
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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 5832-12 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This second edition cancels and replaces the first edition (ISO 5832-12:1996), which has been technically revised.

ISO 5832 consists of the following parts, under the general title *Implants for surgery — Metallic materials*:

— *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-nickel-molybdenum-iron alloy*

— *Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy*

— *Part 9: Wrought high nitrogen stainless steel*

— *Part 11: Wrought titanium 6-aluminium 7-niobium alloy*

— *Part 12: Wrought cobalt-chromium-molybdenum alloy*

— *Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium 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.

Implants for surgery — Metallic materials —

Part 12: Wrought cobalt-chromium-molybdenum alloy

1 Scope

This part of ISO 5832 covers the requirements for two wrought cobalt 28-chromium 6-molybdenum alloys used for surgical implants. The properties apply specifically to wrought bar, rod and wire.

NOTE 1 The mechanical properties of a sample obtained from a finished product made of this alloy can differ from those specified in this part of ISO 5832.

NOTE 2 The high carbon content of this alloy produces a structure containing a significant carbide distribution. This can be adjusted either in the production of the bar or in subsequent thermomechanical processing to produce the final device. Carbide distribution in the final device is not included as part of this document.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 643, *Steels — Micrographic determination of the apparent grain size*

ISO 6892, *Metallic materials — Tensile testing at ambient temperature*

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.

Table 1 — Chemical composition

Element	Mass fraction %	
	Alloy 1 Low carbon	Alloy 2 High carbon
Chromium	26,0 to 30,0	26,0 to 30,0
Molybdenum	5,0 to 7,0	5,0 to 7,0
Iron	0,75 max.	0,75 max.
Manganese	1,0 max.	1,0 max.
Silicon	1,0 max.	1,0 max.
Carbon	0,14 max.	0,15 to 0,35
Nickel	1,0 max.	1,0 max.
Nitrogen	0,25 max.	0,25 max.
Cobalt	Balance	Balance

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 5.

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.

If any of the test pieces break outside the gauge length or fail to meet the specified requirements, two further test pieces representative of the same batch shall be tested in the same manner. The alloy shall be deemed to comply only when both additional test pieces meet the specified requirements.

Table 2 — Mechanical properties

Condition	Tensile strength $R_{m,min}$ MPa	Proof stress $R_{p0,2min}$ MPa	Percentage elongation A_{min} %
Annealed	897	517	20
Hot worked	1 000	700	12
Warm worked	1 192	827	12

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.

Table 3 — Test Methods

Parameter	Relevant clause	Test method
Chemical composition	3	Recognised analytical procedures (ISO methods, where these exist)
Grain size	4	ISO 643
Mechanical properties	5	ISO 6892

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