

शल्य चिकित्सा के लिए प्रत्यारोपण — धातु सामग्री

भाग 5 पिटवॉ कोबाल्ट-क्रोमियम-टंगस्टन-निकल मिश्रधातु

Implants for Surgery — Metallic Materials

Part 5 Wrought Cobalt-Chromium-Tungsten-Nickel Alloy

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IMPLANTS FOR SURGERY — METALLIC MATERIALS

PART 5 WROUGHT COBALT-CHROMIUM-TUNGSTEN-NICKEL ALLOY

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, wrought cobalt-chromium-tungsten-nickel alloy for use in the manufacture of surgical implants.

NOTE The tensile properties of a sample obtained from a finished product made of this alloy might not necessarily comply with those specified in this part of ISO 5832.

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 4967:1998, Steel — Determination of content of nonmetallic inclusions — Micrographic method using standard diagrams

ISO 6892, Metallic materials — Tensile testing at ambient temperature

3 Chemical composition

The analysis of a representative sample of the alloy when determined as specified in Clause 6 shall comply with the chemical composition specified in Table 1.

Table 1 — Chemical composition

Element	Compositional limits mass fraction %
Chromium	19 to 21
Tungsten	14 to 16
Nickel	9 to 11
Iron	≤ 3
Carbon	≤ 0,15
Silicon	≤ 1
Manganese	≤ 2
Sulfur	0,03
Phosphorus	0,04
Cobalt	Balance

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4 Microstructure

4.1 Grain size index

Samples shall be prepared and etched for examination by any recognized technique. The grain size measured in accordance with ISO 643 shall be 5 or finer.

NOTE ISO 643 is given as a reference even though the material dealt with in this part of ISO 5832 is not iron-based.

4.2 Inclusion content

A longitudinal sample suitably polished shall be examined in accordance with ISO 4967, Method A, and shall not exhibit inclusions in excess of those specified in Table 2.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content: thin a
A — Sulfides	1
B — Aluminates	3
C — Silicates	1
D — Oxides (globular)	3
a Thick inclusions are allowed unti	10,5.

5 Tensile properties

The tensile properties of the alloy, determined as specified in Clause 6, shall be in accordance with the requirements of Table 3.

The level of mechanical properties for material in other than the annealed condition shall be specified in the purchase order.

Table 3 — Tensile properties

Condition	Tensile strength MPa	0,2 % offset proof stress MPa	Percentage elongation %
Annealed	≥ 860	≥ 310	≥ 30

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 4.

Representative test pieces for the determination of tensile properties shall be prepared in accordance with ISO 6892.

Table 4 — Test methods

Requirement	Relevant clause or subclause	Test methods	
Chemical composition	Clause 3	Recognized analytical procedures (ISO methods where these exist)	
Tensile properties	Clause 5	ISO 6892	Mais
Grain size	4.1	ISO 643	
Inclusion content	4.2	ISO 4967	

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