
INTERNATIONAL STANDARD



5832 / II

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Implants for surgery — Metallic materials — Part II : Unalloyed titanium

*Implants chirurgicaux — Produits à base de métaux —
Partie II : Titane non allié*

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

The member body of the following country expressed disapproval of the document on technical grounds :

U.S.A.

Implants for surgery — Metallic materials — Part II : Unalloyed titanium

1 SCOPE AND FIELD OF APPLICATION

This International Standard specifies the characteristics of, and corresponding test methods for, unalloyed titanium for use in the manufacture of surgical implants.

Provision is made for five grades of titanium based on tensile strength (see table 2).

NOTE — The mechanical properties of a sample obtained from a finished product made of this metal may not necessarily comply with those specified in this International Standard.

2 REFERENCES

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

ASTM E112, *Standard methods for estimating the average grain size of metals*.

NOTE — The above references will be replaced by references to appropriate International Standards when the latter become available.

3 CHEMICAL COMPOSITION

The heat analysis of the titanium shall comply with the relevant chemical composition specified in table 1 (for test methods, see clause 6).

4 MICROSTRUCTURE

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

5 MECHANICAL PROPERTIES

5.1 Test pieces

Representative test pieces for the determination of mechanical properties shall be prepared in accordance with the provisions of ASTM E8.

TABLE 1 — Chemical composition

Element	Compositional limits, % (m/m), max.			
	Grade 1	Grade 2	Grade 3	Grades 4A and 4B
Nitrogen	0,03	0,03	0,05	0,05
Carbon	0,10	0,10	0,10	0,10
Hydrogen	0,015 ¹⁾	0,015 ¹⁾	0,015 ¹⁾	0,015 ¹⁾
Iron	0,20	0,30	0,30	0,50
Oxygen	0,18	0,25	0,35	0,50
Titanium	Balance	Balance	Balance	Balance

1) Except for billets, for which the maximum hydrogen content shall be 0,0100 % (m/m).