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

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FOREWORD

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

U.S.A.

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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*).

5.2 Tensile test

The tensile properties of the titanium, determined as specified in clause 6, shall be in accordance with the requirements of table 2.

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 titanium shall be deemed to comply only if both additional test pieces meet the specified requirements.

If any of the retests fails to meet the appropriate requirements, the product represented shall be deemed not to comply with this International Standard. However, the manufacturer may, if he so desires, re-heat treat the material and resubmit it for testing in accordance with the requirements of this International Standard.

5.3 Bend test

Titanium sheet and strip, when tested as specified in clause 6, shall not show any cracking on the outside surface of the test piece.

6 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 2 – **Mechanical properties**

Grade	Condition	Ultimate tensile strength[1] min. MPa	Yield strength (0,2 % offset)[1] min. MPa	Elongation[2] min. %	Reduction of area (bars and billets only) min. %	Mandrel diameter for bend test for sheet and strip[3] where $t \leqslant 2$ mm	Mandrel diameter for bend test for sheet and strip[3] where t is 2 to 5 mm
1	Annealed	240	170	24	30	3 t	4 t
2	Annealed	345	230	20	30	4 t	5 t
3	Annealed	450	300	18	30	4 t	5 t
4A	Annealed	550	440	15	25	5 t	6 t
4B	Cold-worked	680	520	10	18	6 t	7 t

1) Tensile and yield requirements apply to material taken both parallel and perpendicular to the direction of rolling.

2) Gauge length = 5,65 $\sqrt{S_o}$ or 50 mm, where S_o is the original cross-sectional area in square millimetres.

3) t = thickness of the sheet or strip.

TABLE 3 – **Methods of test**

Requirement	Relevant clause	Method of test
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Grain size	4	ASTM E112
Mechanical properties	5	
Ultimate tensile strength		ASTM E8
Yield strength		ASTM E8
Elongation		ASTM E8
Reduction of area		ASTM E8
Bend test		Bend the sheet or strip through 180° around a mandrel of the appropriate diameter specified in table 2