BS EN ISO 5832-2:2018

BSI Standards Publication

Implants for surgery - Metallic materials

Part 2: Unalloyed titanium

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National foreword

This British Standard is the UK implementation of EN ISO 5832-2:2018. It is identical to ISO 5832-2:2018. It supersedes BS EN ISO 5832-2:2012, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/1, Materials for surgical implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2018

ISBN 978 0 580 94255 6

ICS 77.120.50; 11.040.40

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 May 2018.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5832-2

May 2018

ICS 11.040.40

Supersedes EN ISO 5832-2:2012

English Version

Implants for surgery - Metallic materials - Part 2: Unalloyed titanium (ISO 5832-2:2018)

Implants chirurgicaux - Produits à base de métaux - Partie 2: Titane non allié (ISO 5832-2:2018)

Chirurgische Implantate - Metallische Werkstoffe - Teil 2: Unlegiertes Titan (ISO 5832-2:2018)

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 5832-2:2018) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

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

This document supersedes EN ISO 5832-2:2012.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 5832-2:2018 has been approved by CEN as EN ISO 5832-2:2018 without any modification.

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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 non-governmental, 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, SC 1, *Materials*.

This fourth edition cancels and replaces the third edition (ISO 5832-2:1999), which has been technically revised.

A list of all parts in the ISO 5832 series can be found on the ISO website.

Introduction

No known surgical implant material has ever been shown to cause absolutely no adverse reaction in the human body. However, long-term clinical experience of the use of the material referred to in this document has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications.

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INTERNATIONAL STANDARD ISO 5832-2:2018

Implants for surgery - Metallic materials —

Part 2:
Unalloyed titanium

1 Scope

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

Six grades of titanium based on tensile strength are listed in Table 2.

NOTE The mechanical properties of a sample obtained from a finished product made of this metal do not necessarily comply with those specified in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 7438, *Metallic materials — Bend test*

ASTM E112, *Standard test methods for determining average grain size*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

4 Chemical composition

The heat analysis when determined as specified in Clause 7 shall conform to the requirements as to chemical composition specified in Table 1. Ingot analysis may be used for reporting all chemical requirements except hydrogen, which shall be determined after the last heat treatment and pickling procedure.

Table 1 — Chemical composition

Element	Maximum compositional limits percent mass fraction				
	Grade 1 ELI	**Grade 1**	**Grade 2**	**Grade 3**	**Grades 4A and 4B**
Nitrogen	0,012	0,03	0,03	0,05	0,05
Carbon	0,03	0,08	0,08	0,08	0,08
Hydrogen	0,012 5[a]	0,012 5[a]	0,012 5[a]	0,012 5[a]	0,012 5[a]
Iron	0,10	0,20	0,30	0,30	0,50
Oxygen	0,10	0,18	0,25	0,35	0,40
Titanium	Balance	Balance	Balance	Balance	Balance

[a] Except for billets, for which the maximum hydrogen content shall be 0,010 0 % (mass fraction) and for flat products for which the maximum hydrogen content shall be 0,015 % (mass fraction).

5 Microstructure

The microscopic structure of the titanium in the annealed condition shall be uniform. The grain size, determined as specified in Clause 7, shall be no coarser than grain size No. 5.

At a magnification of ×100, no inclusions or foreign phases shall be visible. Iron is a beta phase stabilizer and the allowable iron limits might be sufficient to retain beta phase which is not considered a foreign phase in the microstructure.

6 Mechanical properties

6.1 Tensile properties

The tensile properties of the titanium, determined as specified in Clause 7, shall be in accordance with the requirements of Table 2.

If any of the test pieces fail within the gauge limits and do not meet specified requirements, two retest pieces shall be tested in the same manner, for each failed test piece. The alloy shall be deemed to comply only if both additional test pieces meet the specified requirements.

If a test piece fails outside the gauge limits, the test is acceptable if the percentage elongation after fracture meets the requirements. If the percentage elongation after fracture does not meet requirements the test shall be discarded and a retest shall be performed.

If any of the retests fails to meet the appropriate requirements, the product represented shall be deemed not to comply with this document. However, the manufacturer may, if desired, subject the material to heat treatment again and resubmit it for testing in accordance with this document.

6.2 Bending properties

Titanium sheet and strip, when tested as specified in Clause 7, shall not show any cracking on the outside surface of the test piece.

Table 2 — Mechanical properties

Grade	Condition[a]	Tensile strength[b]	Yield strength	Elongation after fracture[c]	Reduction of Area[d]	Mandrel diameter for bend test for sheet and strip[e]	
		R_m	$R_{p0,2}$	A	Z	where t < 2 mm	where 2 mm ≤ t < 5 mm
		MPa minimum	MPa minimum	% minimum	% minimum	mm	
1 ELI	Annealed	200	140	30	—	3 t	4 t
1	Annealed	240	170	24	30	3 t	4 t
2	Annealed	345	275	20	30	4 t	5 t
3	Annealed	450	380	18	30	4 t	5 t
4A	Annealed	550	483	15	25	5 t	6 t
4B	Cold-worked	680	520	10	—	6 t	6 t

[a] Maximum diameter or thickness equal to 75 mm.

[b] Tensile, yield and bending requirements of sheet shall apply to material taken both parallel and perpendicular to the direction of rolling.

[c] Gauge length = 5,65 $\sqrt{S_0}$ or 50 mm, where S_0 is the original cross-sectional area, in square millimetres.

[d] Reduction of area values have been extracted from ASTM F67-13 Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700), with permission from ASTM International. ASTM International owns the copyright of ASTM F67-13. A copy of the complete standard can be obtained from ASTM, https://www.astm.org/.

[e] t = thickness of the sheet or strip.

7 Test methods

The test methods to be used in determining conformity to the requirements of this document shall be those given in Table 3.

Representative test pieces for the determination of mechanical properties shall be prepared in accordance with the provisions of ISO 6892-1.

Table 3 — Methods of test

Requirement	Relevant clause	Method of test
Chemical composition	4	Recognized analytical procedures
Grain size	5	ISO 643 or ASTM E 112
Mechanical properties	6	ISO 6892-1
Tensile strength		ISO 6892-1
Yield strength		ISO 6892-1
Elongation after fracture		ISO 6892-1
Reduction of area		ISO 6892-1
Bend test		ISO 7438 Bend the sheet or strip through an angle of at least 105° around a mandrel of the diameter specified in Table 2