Implants for surgery - Metallic materials - Part 2: Unalloyed titanium (ISO 5832-2:1999)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 5832-2:2012 sisaldab Euroopa standardi EN ISO 5832-2:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 5832-2:2012 consists of the English text of the European standard EN ISO 5832-2:2012.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 23.05.2012.	Date of Availability of the European standard is 23.05.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.40

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5832-2

May 2012

ICS 11.040.40

English Version

Implants for surgery - Metallic materials - Part 2: Unalloyed titanium (ISO 5832-2:1999)

Implants chirurgicaux - Produits à base de métaux - Partie 2: Titane non allié (ISO 5832-2:1999)

Chirurgische Implantate - Metallische Werkstoffe - Teil 2: Unlegiertes Titan (ISO 5832-2:1999)

This European Standard was approved by CEN on 28 April 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 5832-2:2012: E

Foreword

The text of ISO 5832-2:1999 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 5832-2:2012 by 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 2012, and conflicting national standards shall be withdrawn at the latest by November 2012.

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

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 5832-2:1999 has been approved by CEN as a EN ISO 5832-2:2012 without any modification.

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 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 — Metalic materials —

Part 2:
Unalloyed titanium

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, unalloyed titanium for use in the manufacture of surgical implants.

Provision is made for six 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 part of ISO 5832.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 6892:1998*, Metallic materials — Tensile testing at ambient temperature.*

ISO 7438:1995*, Metallic materials — Bend test.*

ASTM E 112:1988*, Standard Test Methods for Determining Average Grain Size.*

3 Chemical composition

The heat analysis when determined as specified in clause 6 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.

4 Microstructure

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

At a magnification of 100×, no inclusions or foreign phases shall be visible.