SLOVENSKI STANDARD
SIST EN ISO 5832-2:2012

01-oktober-2012

Vsadki (implantati) za kirurgijo - Kovinski materiali - 2. del: Nelegirani titan (ISO 5832-2:1999)

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

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

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

Ta slovenski standard je istoveten z: EN ISO 5832-2:2012

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
77.120.50	Titan in titanove zlitine	Titanium and titanium alloys

SIST EN ISO 5832-2:2012 **en**

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)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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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of an identical text or by endorsement, at the latest by November 2012, and conflicting national standards shall be withdrawn at the latest by November 2012.

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Endorsement notice

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

INTERNATIONAL STANDARD

ISO 5832-2

First edition
1999-07-15

Implants for surgery — Metallic materials —

Part 2:
Unalloyed titanium

Implants chirurgicaux — Produits à base de métaux —

Partie 2: Titane non allié

Reference number
ISO 5832-2:1999(E)

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5832-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials.*

This third edition cancels and replaces the second edition (ISO 5832-2:1993), which has been technically revised.

ISO 5832 consists of the following parts, under the general title *Implants for surgery — Metallic materials*:

— *Part 1: Wrought stainless steel*

— *Part 2: Unalloyed titanium*

— *Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

— *Part 4: Cobalt-chromium-molybdenum casting alloy*

— *Part 5: Wrought cobalt-chromium-tungsten-nickel alloy*

— *Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*

— *Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy*

— *Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy*

— *Part 9: Wrought high nitrogen stainless steel*

— *Part 10: Wrought titanium 5-aluminium 2,5-iron alloy*

— *Part 11: Wrought titanium 6-aluminium 7-niobium alloy*

— *Part 12: Wrought cobalt-chromium-molybdenum alloy*

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

Printed in Switzerland

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.