Neurokirurgilised implantaadid. Isesulguvad intrakraniaalsed aneurüsmiklambrid

Neurosurgical implants - Self-closing intracranial aneurysm clips

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 9713:2004 sisaldab Euroopa standardi EN ISO 9713:2004 ingliskeelset teksti. Käesolev dokument on jõustatud 18.05.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 9713:2004 consists of the English text of the European standard EN ISO 9713:2004. This document is endorsed on 18.05.2004 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This International Standard describes characteristics of self-closing aneurysm clips intended for permanent intracranial implantation and specifies requirements for their marking, packaging, sterilization and for labelling and accompanying documentation.	**Scope:** This International Standard describes characteristics of self-closing aneurysm clips intended for permanent intracranial implantation and specifies requirements for their marking, packaging, sterilization and for labelling and accompanying documentation.

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Võtmesõnad:

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Neurosurgical implants

Self-closing intracranial aneurysm clips

(ISO 9713 : 2002)

Implants neurochirurgicaux – Clips intracrâniens pour anévrisme à autofermeture (ISO 9713 : 2002)

Neurochirurgische Implantate – Selbstschließende intrakranielle Aneurysmen-Clips (ISO 9713 : 2002)

This European Standard was approved by CEN on 2004-01-02.

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 Management Centre or to any CEN member.

The European Standards exist 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 Management Centre has the same status as the official versions.

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

CEN

European Committee for Standardization
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Europäisches Komitee für Normung

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Foreword

International Standard

ISO 9713 : 2002 Neurosurgical implants – Self-closing intracranial aneurysm clips,

which was prepared by ISO/TC 150 'Implants for surgery' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 285 'Non-active surgical implants', the Secretariat of which is held by NEN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by August 2004 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 9713 : 2004 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

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Introduction

Magnetic fields of considerable strength [e.g. 0,2 T to 2,0 T (tesla) or more] are used in medicine with increasing frequency as part of diagnostic techniques such as magnetic resonance imaging (MRI). Exposure to electromagnetic radiation may pose a hazard to patients who have intracranial aneurysm clips. Clips with magnetic properties (dia-, para-, antiferro-, ferro- and/or ferrimagnetic) become magnetized when subjected to a magnetic field and under this condition are liable to directing forces. These forces may result in the clip being removed from the aneurysm that it was intended to occlude and even being moved through the tissues. Because of the very high field strengths, even materials normally regarded as non-magnetic may exhibit some response to the magnetic field, such as minimal deflection or rotation. It is therefore essential that aneurysm clips have weakly or non-magnetic properties.

Compounds of certain non-magnetic elements may, when processed, have strong magnetic properties. The opposite also occurs. The work done at manufacture may have an additional effect. However, material normally regarded as non-magnetic may exhibit some response when subjected to MRI levels of field strength.

A secondary effect is that the presence of a metallic clip may interfere with the MRI process, resulting in deterioration of the quality of the scanning image.

One of the main intentions of this International Standard is to help to ensure that appropriate and comparable information is supplied for each clip in order to facilitate the choice of the correct clip by the surgeon. The closing force of the clip is an important factor in the selection process, and this International Standard requires that the manufacturers determine the closing force in a uniform manner and state this value on the labelling. The actuation of some types of clip can unduly result in a reduction of the closing force.

1 Scope

This International Standard describes characteristics of self-closing aneurysm clips intended for permanent intracranial implantation and specifies requirements for their marking, packaging, sterilization and for labelling and accompanying documentation. In addition it gives a method for the measurement of closing force.

This International Standard is not applicable to malleable clips, or clips intended to be used during the course of surgery and removed before wound closure (temporary clips).

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 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

ISO 5832-5, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy*

ISO 5832-6, *Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*

ISO 5832-7, *Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy*

ISO 5832-8, *Implants for surgery — Metallic materials — Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy*

ISO 14630:1997, *Non-active surgical implants — General requirements*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 16061, *Instrumentation for use in association with non-active surgical implants — General requirements*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.