

**Neurokirurgilised implantaadid. Ilesulguvad
intrakraniaalsed aneurüsmiklambrid**

Neurosurgical implants - Self-closing intracranial aneurysm
clips

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 9713:2009 sisaldab Euroopa standardi EN ISO 9713:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 13.05.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 9713:2009 consists of the English text of the European standard EN ISO 9713:2009.

This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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ICS 11.040.40

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EUROPEAN STANDARD

EN ISO 9713

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Supersedes EN ISO 9713:2004

English Version

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 19 April 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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 and United Kingdom.



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of ISO 9713:2002 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 9713:2009 by Technical Committee CEN/TC 285 "Non-active surgical implants" 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 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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.

This document supersedes EN ISO 9713:2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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, 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 and the United Kingdom.

Endorsement notice

The text of ISO 9713:2002 has been approved by CEN as a EN ISO 9713:2009 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5	1, 2, 3, 9.2	Part of ER 1 relating to risk of use error is not addressed in this European Standard.
6	1, 2, 7.1, 7.3, 9.2	Part of ER 1 relating to risk of use error is not addressed in this European Standard. Part of ER 7.1 relating to the result of biophysical or modelling research is not addressed in this European Standard.
7	6, 9.2	
8	3, 4,	
9	13.1, 13.3	Part of ER 13.3.f relating to single use is not addressed in this European Standard.
10	1, 5, 7.2, 8.1, 8.3, 8.4, 8.5	Part of ER 1 relating to risk of use error is not addressed in this European Standard.
11	5, 8.6, 8.7, 13.1	

12	8.7, 13.1, 13.2, 13.3, 13.4,13.6	<p>The part of ER 13.3.a) concerning the information on the authorized representative is not addressed in this European Standard.</p> <p>Part of ER 13.3.f relating to safety issues of single use is not addressed in this European Standard.</p> <p>Part of ER 13.6.h relating to single use is not addressed in this European Standard.</p> <p>Part of ER 13.6.q) relating to date of issue is not addressed in this European Standard.</p>
		ER 6.a) is not addressed in this European Standard.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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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.

Neurosurgical implants — Self-closing intracranial aneurysm clips

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.