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Neurokirurgiska implantat – Självstängande intrakraniella aneurysmklämmor (ISO 9713:2002)

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

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Europastandarden EN ISO 9713:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 9713:2009.

Denna standard ersätter SS-EN ISO 9713:2004, utgåva 1.

The European Standard EN ISO 9713:2009 has the status of a Swedish Standard. This document contains the official English version of EN ISO 9713:2009.

This standard supersedes the Swedish Standard SS-EN ISO 9713:2004, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00.
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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 9713

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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.

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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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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.

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.

3.1
accuracy
ability of a measuring instrument to give responses close to a true value

NOTE "Accuracy" is a qualitative concept.

3.2
aneurysm clip
device primarily intended for the permanent occlusion of the neck or sac of an intracranial aneurysm

3.3
closing force
force produced between the blades of the clip

3.3.1
nominal closing force
closing force defined by the manufacturer for each type of clip

3.3.2
actual closing force
closing force measured on each clip by the manufacturer before packaging

3.4
image artifact
inappropriate image signal in an MR image

NOTE Image artifact may be characterized as decreased signal intensity (voids) where signal should be produced, with or without geometric image distortion, but can also include abnormally increased signal intensity.

3.5
magnetic properties
property of a material to become magnetized when subjected to a magnetic field

NOTE 1 Materials which are ferro- or antiferrimagnetic are strongly magnetic. Dia- and paramagnetic materials are weakly magnetic.

NOTE 2 Materials which can exhibit strongly magnetic properties are not suitable for the manufacturer of aneurysm clips.

3.6
magnetic induction
B
vector indicating both direction and magnitude of a magnetic field induced by an electric current flowing through conducting wire or wires

NOTE 1 It is expressed in teslas (T) or volt seconds per square metre.

NOTE 2 Values of magnetic inductance up to 2 T are used at the time of publication of this International Standard.

3.7
MRI safe
⟨of a device⟩ demonstrated to present no additional risk to the patient when used in the MRI environment, but may affect the quality of the diagnostic information

NOTE MRI safe does not imply MRI compatibility in terms of magnetism.

3.8
repeatability
ability of a measuring instrument to provide closely similar indications for repeated applications of the same measurand under the same conditions

NOTE These conditions include

— reduction to a minimum of the variations due to the observer,

— the same measurement procedure,

— the same observer,

— the same measurement equipment, used under the same conditions,

— the same location,

— repetition over a short period of time.

4 Description of aneurysm clips

4.1 Mechanism of action

The description of certain clip mechanisms and their gripping action is shown in Figure 1.

4.2 Geometry

Diagrammatic representation (not to scale) of a some examples of clip forms is indicated in Figure 2.

5 Indication of dimensions

The following dimensions of clips and components shall be indicated:

a) the overall length;

b) the length of the blades;

c) the width of the blades giving, as appropriate, the width (disregarding any radius or taper at the tip) of blades of uniform width, the minimum and maximum widths of non-uniform blades, and the overall width of fenestrated blades;

d) the internal diameter of any encircling or encompassing portions of the clip.

The variety of designs of clip does not make it feasible to specify the points between which the blade length should be measured. Manufacturers should indicate these points clearly on all diagrams. Examples of indication of dimensions are given in Figure 3. The diagrams are for illustration only and do not indicate a definitive requirement.

NOTE It is suggested that the blade length be indicated as that portion of the jaw which comes into contact with the other jaw when the clip is closed without a vessel in place or, for encircling clips, the longitudinal internal dimension of the clip when closed.

6 Materials

The materials shall comply with the requirements of ISO 5832-2, ISO 5832-3, ISO 5832-5, ISO 5832-6, ISO 5832-7 or ISO 5832-8.

Stainless steel is excluded as a material for aneurysm clips.