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Neurosurgical implants — Self-closing intracranial aneurysm clips

Implants neurochirurgicaux — Clips intracrâniens pour anévrisme à autofermeture

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for Surgery.*

This third edition cancels and replaces the second edition (ISO 9713:2002), which has been technically revised.

The main changes compared to the previous edition are as follows:

— terms and definitions have been revised to more accurately define the information contained within the document;

— Clause 7 "MRI safety" has been revised as to better align with the recommendations provided in the most recent ASTM standard related to MRI;

— in Clause 8 the closing force assessment was edited to better clarify the procedures;

— Clause 9 "Supplying condition and sterilization" and Clause 10 "Packaging" have been revised as to align with ISO 14630 and to reduce the likelihood of future conflicts between the two documents.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

One of the main intentions of this document is to help to ensure that appropriate and comparable information is supplied for each clip 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 document requires that the manufacturers determine the actual closing force in a uniform manner and state this value on the labelling. The actuation of some types of clip can result in a reduction of the closing force and should be considered.

Magnetic fields of considerable strength [e.g. 1,5 (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.

Neurosurgical implants — Self-closing intracranial aneurysm clips

1 Scope

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

NOTE In this document when not otherwise established, the term "implant" refers to the self-closing intracranial aneurysm clips.

2 Normative references

The following documents are referred to in the text in such a way that some or all their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 14630:2012, *Non-active surgical implants — General requirements*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

3 Terms and definitions

For the purposes of this document the terms and definitions given in ISO 14630 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
aneurysm clip
device primarily intended for the permanent occlusion of the neck or sac of an intracranial aneurysm

3.2
blade closing surface
blade design intended to contact the vessel

3.3
closing force
force produced between the blades of the clip

3.4
nominal closing force
closing force (3.3) defined by the manufacturer for each clip model

3.5
actual closing force
closing force (3.3) measured on each clip by the manufacturer before packaging

3.6
limit of error
extreme value of measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system.

Note 1 to entry: Usually, the term "maximum permissible errors" or "limits of error" is used where there are two extreme values

Note 2 to entry: The term "tolerance" should not be used to designate 'maximum permissible error'

3.7
image artifact
inappropriate image signal in a magnetic resonance image

Note 1 to entry: 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.

4 Description of aneurysm clips

4.1 Mechanism of action

The mechanism of action for the clip shall be specified.

Illustrations of examples of clip mechanisms of action are shown in Figure 1.

4.2 Geometry

The geometry of the clip, including the blade geometry shall be specified.

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

4.3 Blade closing surface

The design of the blade closing surface shall be specified.

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.

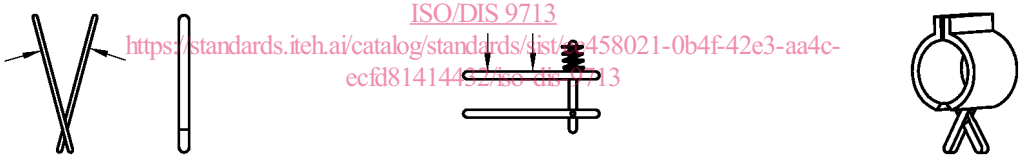
The variety of designs of clip does not make it feasible to specify the points between which the blade length should be measured. Manufacturers should indicate these points clearly on all diagrams. Examples of indication of dimensions are given in Figure 3. The diagrams are for illustration only and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

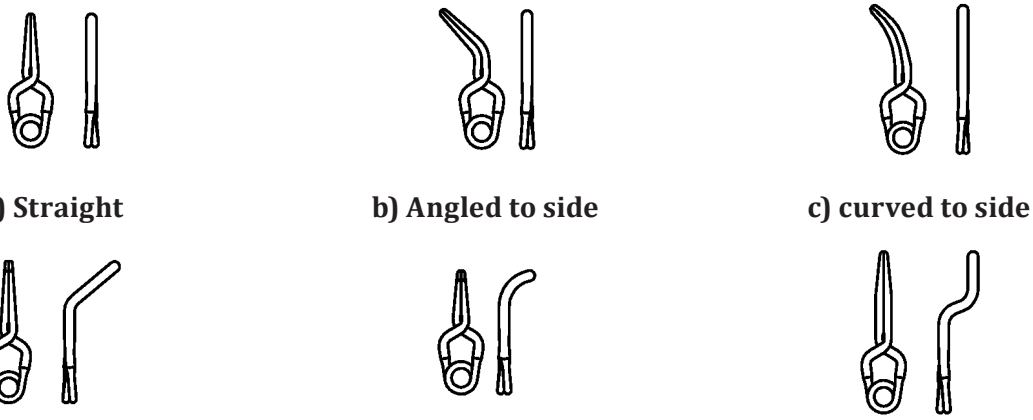
The materials shall comply with the requirements of ISO 5832-2, ISO 5832-3, ISO 5832-5, ISO 5832-6, or ISO 5832-7.

Stainless steel is excluded as a material for aneurysm clips.



a) Alligator action **b) Parallel action** **a) Encircling action**

Figure 1 — Examples of clip mechanisms action



a) Straight **b) Angled to side** **c) curved to side**

d) Angled on flat **e) Curved on flat** **f) Bayonet**