INTERNATIONAL STANDARD

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Neurosurgical implants — Self-closing intracranial aneurysm clips

Implants neurochirurgicaux — Clips intracrâniens pour anévrisme à autofermeture

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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.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9713 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 3, *Neurosurgical implants*.

This second edition cancels and replaces the first edition (ISO 9713:1990), which has been technically revised.

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.

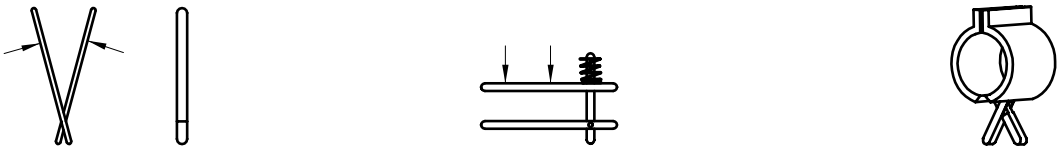
The variety of designs of clip does not make it feasible to specify the points between which the blade length should be measured. Manufacturers should indicate these points clearly on all diagrams. Examples of indication of dimensions are given in Figure 3. The diagrams are for illustration only and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

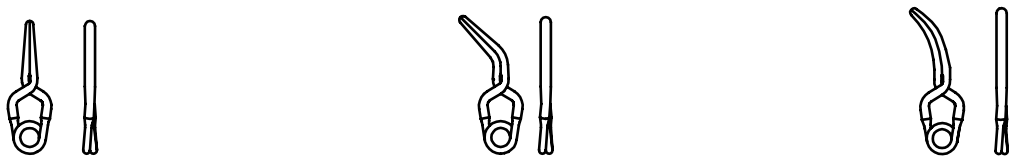
The materials shall comply with the requirements of ISO 5832-2, ISO 5832-3, ISO 5832-5, ISO 5832-6, ISO 5832-7 or ISO 5832-8.

Stainless steel is excluded as a material for aneurysm clips.

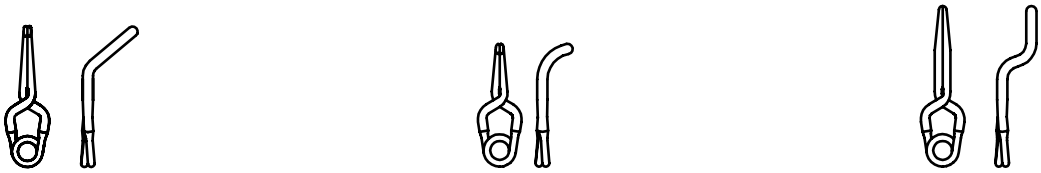


a) Alligator action b) Parallel action c) Encircling action

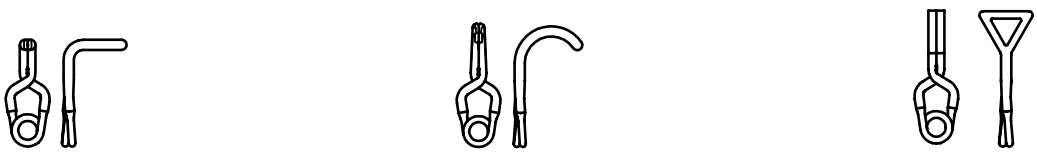
Figure 1 — Examples of clip mechanisms and their gripping action



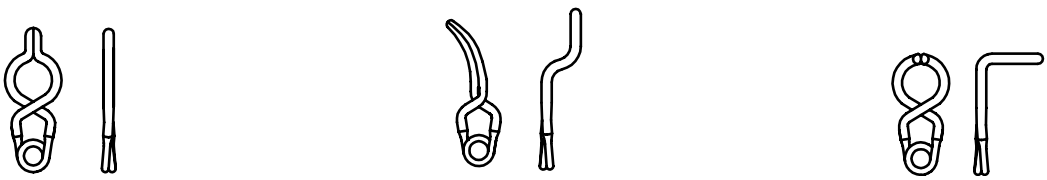
a) Straight b) Angled to side c) Curved to side



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



g) Right-angled h) J-shaped i) Fenestrated (shape may vary)



j) Encompassing k) Combination: curved bayonet l) Encompassing right angle

Figure 2 — Examples of clip forms (not to scale)

Dimensions in millimetres

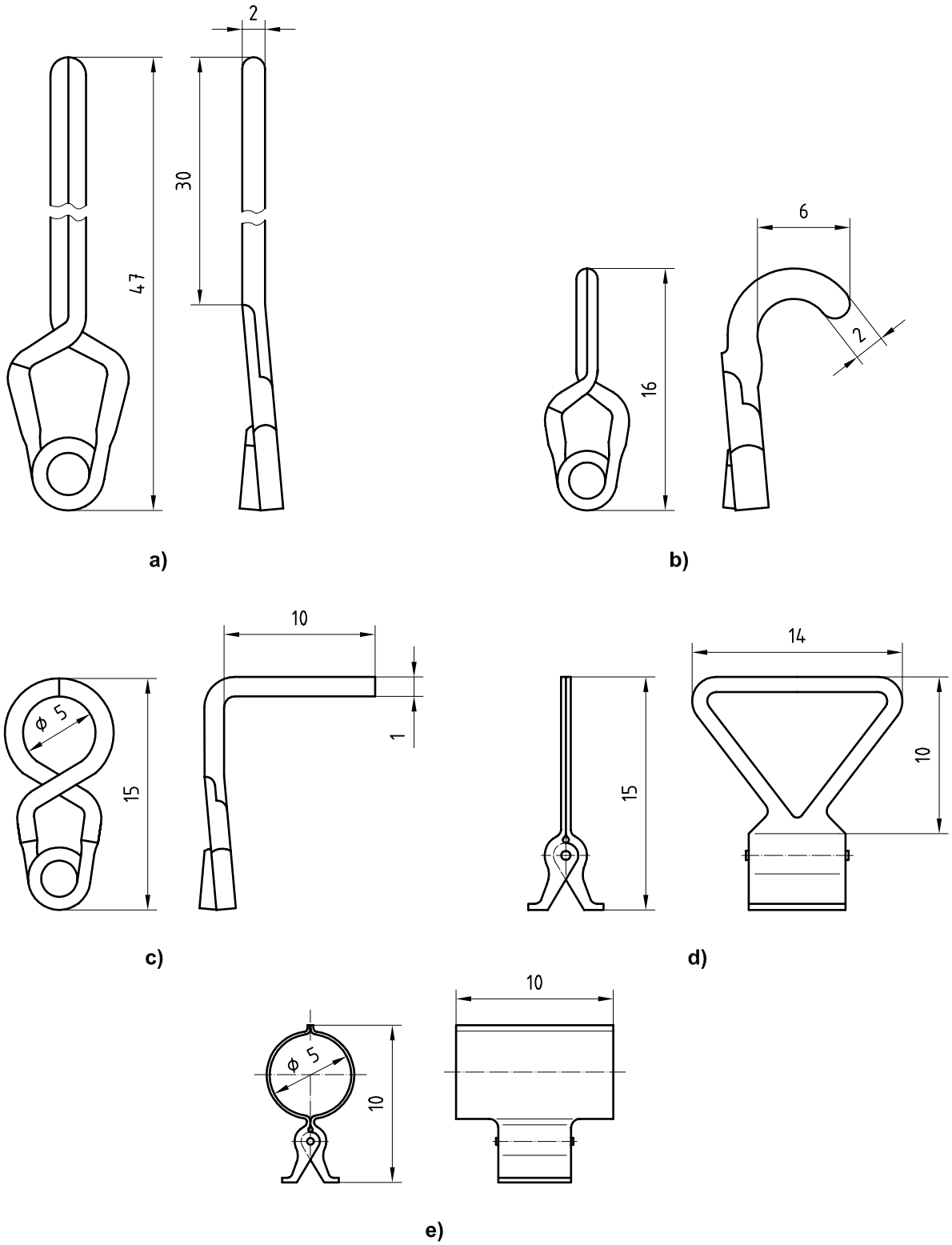


Figure 3 — Examples of dimensioned diagrams of clips

7 Determination of magnetic properties

In order to determine that clips are safe for MR imaging, a performance test for measuring the magnetic properties of finished implants is required. It is insufficient to investigate the magnetic properties of the base material from which the clip is constructed. Testing shall be performed to determine magnetically induced forces and moments on one of each type of clip, selected at random, and to determine the image artifact produced by the clip under worst-case MR scanning conditions. The worst-case scanning conditions shall be given in the labelling as indicated in clause 12, item p).

8 Closing force

8.1 Measurement of closing force of clips

8.1.1 Apparatus

8.1.1.1 Apparatus, capable of measuring the closing force of the clip, having an accuracy of 2 % and a repeatability of 1 %.

A number of designs of apparatus exist. No single design has been specified, as this would be unduly restrictive. It is recommended that the apparatus be calibrated routinely to ensure its accuracy and repeatability.

8.1.2 Procedure

Measure and record the actual closing force of each clip, in millinewtons, using the apparatus specified in 8.1.1, at the point on the clip specified in either a) or b), and with an opening of 1 mm at the point where the measurement is made:

a) at a point one-third along the designated blade length (see clause 5) from the tip; or

b) if the blade is not designed for contact along the entire indicated blade length [e.g. encircling clips, see Figure 2 j) and l)], at a point in the centre of the region of blade contact.

8.1.3 Test report

The test report shall include at least the following information:

a) the identity of the clip;

b) the actual closing force, expressed in millinewtons.

8.2 Tolerance on nominal closing force

When tested as described in 8.1, the closing force of each clip upon the first closing shall be within 7,5 % of the nominal closing force [see clause 12, item k)].

8.3 Degradation of closing force

The closing force on one specimen of each type of clip, selected at random, shall be measured before and after 10 maximal openings of the clip with the recommended applicator. The reduction of the closing force shall be less than 5 % of the nominal closing force.

9 Marking of clips

The clip shall be marked in accordance with ISO 14630.

10 Sterilization

The requirements of clause 9 of ISO 14630:1997 shall apply.

11 Packaging

Packaging shall be in accordance with the requirements of clause 10 of ISO 14630:1997.

In addition, clips shall be packaged singly in a unit pack, which shall be wholly or partially transparent so that the clip is visible. The material of the pack and all protective packaging material shall be lint-free and non-fibrous.

12 Labelling and accompanying documentation

Each unit pack shall be supplied with documentation giving at least the following information:

a) the name and address of the manufacturer or supplier;

b) the design or proprietary identity of the clip;

c) the unique traceability reference;

d) date (year and month) of sterilization, if applicable;

e) the generic names of the construction materials;

f) the mechanism of action (see 4.1);

g) the blade geometry (see 4.2);

h) the maximum blade opening at the tip, expressed in millimetres;

i) the type of serrations, if any, of the blade;

j) the cross-sectional shape of the blades;

k) the actual closing force of each individual clip, in millinewtons (see 8.1.2), and the nominal closing force, in millinewtons, with the nominal tolerance (see 8.2) and a statement that the degradation of closing force after 10 repeated actuations is less that 5 % of the nominal closing force (see 8.3);

l) a diagram of the clip, showing plan and elevation and giving the dimensions as indicated in clause 5; see Figure 3 for example;

NOTE Other dimensions, such as the offset of bayonet designs and of angled or curved clips, may be given.

m) if appropriate, the symbols for “STERILE” or “NON-STERILE” in accordance with ISO 15223;

n) if applicable, instructions for cleaning, sterilization and multiple use of the clip;

o) details and instructions for use of the recommended applicators in accordance with ISO 16061;

p) a card, suitable for retention by the patient, giving details of the clip and a warning against the hazards of exposure to magnetic fields, including information about the magnetic induction and spatial gradients of MRI in which the clip has been tested and for which it is MRI safe.

q) a self-adhesive label, giving at least traceability items a) and c) above of the clip, to be affixed to the patient's clinical notes.

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