INTERNATIONAL STANDARD

ISO 9713

First edition
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Neurosurgical implants — Self-closing intracranial aneurysm clips

Implants neurochirurgicaux — Clips intracraniens pour anévrisme à auto-fermeture

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Reference number
ISO 9713:1990(E)

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.

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.

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International Standard ISO 9713 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

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Introduction

Magnetic fields of considerable strength (e.g. 0,5 to 2,5 tesla) are used in neurology with increasing frequency as part of diagnostic techniques such as magnetic resonance imaging (MRI) [also known as nuclear magnetic resonance (NMR)]. Exposure to electromagnetic radiation may pose a hazard to patients who have intracranial aneurysm clips because of the tendency of metallic clips to move when subjected to a strong magnetic field. This movement may result in the clip being removed from the aneurysm that it was intended to occlude and even to be moved through the tissues. Because of the very high field strengths (which are likely to become even higher as MRI techniques progress), even materials normally regarded as non-magnetic may exhibit some ferromagnetic properties. It is therefore essential that aneurysm clips should not have ferromagnetic properties.

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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.

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At present it has not been found possible to devise a test method to quantify the behaviour of a clip in a magnetic field and therefore to set criteria for the magnetic properties of the clip. However, such work is in progress, and it is expected that requirements will be included when this International Standard is revised.

The main intention of this International Standard is to help 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 manufacturer determine the closing force in a uniform manner and state this value on the labelling. The actuation of some types of clip can result in a change in the closing force, and therefore a tolerance for the closing force is specified. This tolerance, of necessity, only applies to the first actuation of the clip as shipped, and repeated actuation by the surgeon before or during implantation can result in further change in the closing force. When the clip is known to exhibit this type of behaviour, the manufacturer is required to warn against repeated actuation.

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Neurosurgical implants — Self-closing intracranial aneurysm clips

1 Scope

This International Standard specifies requirements for self-closing aneurysm clips intended for permanent intracranial implantation.

It does not cover non-self-closing clips, or clips intended to be used during the course of surgery and removed before wound closure.

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2 Normative references

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The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 5832-1:1987, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel.*

ISO 5832-5:1978, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.*

ISO 5832-6:1980, *Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy.*

ISO 5832-7:1984, *Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy.*

ISO 5832-8:1987, *Implants for surgery — Metallic materials — Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy.*

ISO 6018:1987, *Orthopaedic implants — General requirements for marking, packaging and labelling.*

3 Definitions

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

3.1 aneurysm clip: Device primarily intended for the permanent occlusion of the neck or sac of an intracranial aneurysm.

3.2 closing force: Force produced between the blades of the clip.

4 Nomenclature

The following nomenclature is given in order to facilitate the flow of information and communication between user and manufacturer.

4.1 Mechanism of action

The nomenclature of the mechanism of action of clips is illustrated in figure 1 to figure 3.

4.2 Geometry

The nomenclature of the geometry of typical clips is given in figure 4 to figure 15.

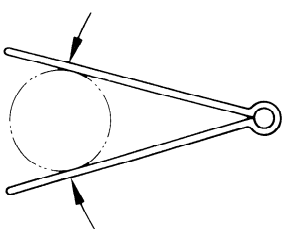

Figure 1 — Clip mechanism — Alligator action

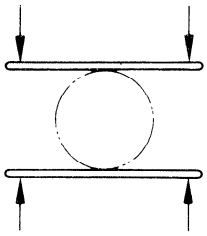

Figure 2 — Clip mechanism — Parallel action

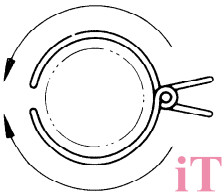

Figure 3 — Clip mechanism — Encircling action

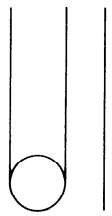

Figure 4 — Straight

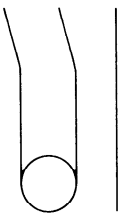

Figure 5 — Angled to side

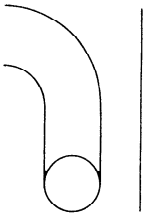

Figure 6 — Curved to side

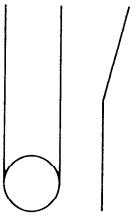

Figure 7 — Angled on flat

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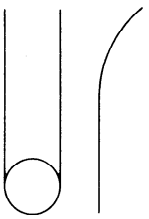

Figure 8 — Curved on flat

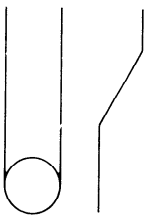

Figure 9 — Bayonet

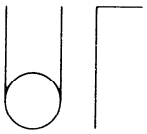

Figure 10 — Right-angled

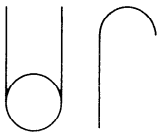

Figure 11 — J-shaped

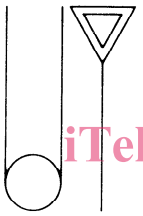

Figure 12 — Fenestrated (shape may vary)

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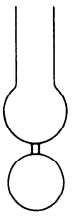

Figure 13 — Encompassing

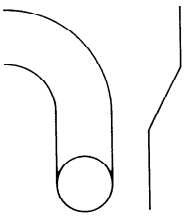

Figure 14 — Combination: curved bayonet

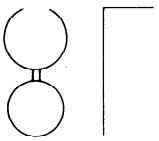

Figure 15 — Encompassing right angle

5 Designation of dimensions

The dimensions of clips and components shall be designated as follows:

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.

NOTES

1 The variety of designs of clip does not make it feasible to specify the points between which the blade length should be designated. Manufacturers should indicate these points clearly on all diagrams. It is suggested that the blade length be designated as that portion of the jaws which come into contact with each other when the clip is closed without a vessel in place or, for encircling clips, the longitudinal internal dimension of the clip when closed.

2 Examples of designation of dimensions are give in figure 16; all dimensions are indicated in millimetres.

6 Materials

The construction materials shall comply with the requirements of ISO 5832, parts 1, 5, 6, 7 and 8.

NOTE 3 The cobalt-based alloy, known as "Elgyloy", which has a composition that differs in minor respects from that alloy specified in ISO 5832-7, is widely used for the manufacture of aneurysm clips and will be included as an additional material as soon as the appropriate ISO specification can be prepared.

7 Tolerance on stated closing force

When tested as described in clause 8, the closing force of the clip upon the first closing shall be within 7,5 % of the value measured and stated by the manufacturer [see clause 11 k)].

8 Method of measuring closing force of clips

8.1 Apparatus

Apparatus capable of measuring the closing force of the clip with an accuracy of 2 % and precision of 1 % or better will be needed.

NOTE 4 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 should be calibrated routinely to ensure its accuracy and precision.

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8.2 Procedure

Measure and record the closing force of the clip, in newtons, using the apparatus specified in 8.1, at the point on the clip specified in either a) or b), and an opening of 1 mm at the point where the measurement is made:

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

b) if the blade is not designed for contact along the entire designated blade length (e.g. encircling clips, see figure 3), at a point in the centre of the region of blade contact.

8.3 Test report

The test report shall include at least the following information:

a) the identity of the clip;

b) the closing force, expressed in newtons.

9 Marking of clips

The clip shall be marked with a traceability reference.

10 Packing

Packaging shall be in accordance with ISO 6018.

In addition, sterile 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.

Non-sterile clips shall be packed singly or in multiples in a pack that is opaque or wholly or partially transparent. If packed in multiples, the clips shall be packaged so as to prevent contact between clips. The material of the pack and all protective packaging material shall be lint-free and non-fibrous.

NOTE 5 Unit packs may be packaged in an outer pack, which may contain one or a number of identical clips or a selection of clips of different designs or sizes.

11 Labelling and accompanying documentation

Each unit pack shall be labelled with, or 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 of the blade;

j) the cross-sectional shape of the blades;

k) the actual closing force of the individual clip expressed in newtons, measured as described in clause 8, and a warning, if appropriate, against repeated actuation of the clip giving an indication of the change in closing force versus number of actuations to the maximum blade opening;

l) the range of closing force, expressed in newtons, for the size and design of clip;

m) an actual-sized diagram of the clip, showing plan and elevation and giving the dimensions as designated in clause 5;

NOTE 6 Other dimensions, such as the offset of bayonet designs and the angle of angled or curved clips, may be given.

n) if appropriate, the word "STERILE";

o) if applicable, instructions for sterilization of the clip and a warning regarding changes in closing force or other mechanical properties that can result from single or repeated sterilization;

p) details and instructions for use of the recommended applicator;

q) a card, suitable for retention by the patient, giving details of the clip and a warning against the hazards of exposure to magnetic fields.

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