Neurosurgical implants - Self-closing intracranial aneurysm clips (ISO 9713:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 9713:2022 sisaldab Euroopa standardi EN ISO 9713:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 9713:2022 consists of the English text of the European standard EN ISO 9713:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 26.01.2022.	Date of Availability of the European standard is 26.01.2022.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.40

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9713

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English Version

Neurosurgical implants - Self-closing intracranial aneurysm clips (ISO 9713:2022)

Implants neurochirurgicaux - Clips intracrâniens pour anévrisme à autofermeture (ISO 9713:2022)

Neurochirurgische Implantate - Selbstschließende intrakranielle Aneurysmen-Clips (ISO 9713:2022)

This European Standard was approved by CEN on 12 December 2021.

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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-CENELEC Management Centre has the same status as the official versions.

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

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Ref. No. EN ISO 9713:2022 E

European foreword

This document (EN ISO 9713:2022) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with 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 July 2022, and conflicting national standards shall be withdrawn at the latest by July 2022.

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

This document supersedes EN ISO 9713:2009.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 9713:2022 has been approved by CEN as EN ISO 9713:2022 without any modification.

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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).

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

For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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:

— the terms and definitions in Clause 3 have been revised to more accurately define the information contained within the document;

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

— the closing force assessments in Clause 8 has been revised to better clarify the procedures;

— the sterilization and packaging clauses (Clauses 9 and 10) have been revised to align with ISO 14630 and to reduce the likelihood of future conflicts.

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

This document is intended 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 field can pose a hazard to patients who have intracranial aneurysm clips. Clips with magnetic properties (either dia-, para-, antiferro-, ferro- or ferrimagnetic, or all) become magnetized when subjected to a magnetic field and under this condition are liable to directing forces. These forces can 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 can, when processed, have strong magnetic properties. The opposite also occurs. The work done during the manufacture can have an additional effect. However, material normally regarded as non-magnetic can exhibit some response when subjected to MRI levels of field strength. A secondary effect is that the presence of a metallic clip can 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 establishes the 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 of 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 information to be supplied by the manufacturer — Part 1: General requirements*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical 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 https://www.electropedia.org/

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