



SLOVENSKI STANDARD SIST EN ISO 9713:2022

01-junij-2022

Nadomešča:
SIST EN ISO 9713:2009

Nevrokirurški vsadki (implantati) - Samozapiralne sponke za uporabo pri intrakranialnih anevrizmah (ISO 9713:2022)

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

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

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

Ta slovenski standard je istoveten z: EN ISO 9713:2022

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ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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EUROPEAN STANDARD

EN ISO 9713

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2022

ICS 11.040.40

Supersedes EN ISO 9713:2009

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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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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.

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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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INTERNATIONAL
STANDARD

ISO
9713

Third edition
2022-01

**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.

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 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.

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