

SLOVENSKI STANDARD
SIST EN ISO 21535:2009/oprA1:2015
01-julij-2015

Neaktivni kirurški vsadki (implantati) - Sklepne proteze - Posebne zahteve za umetni kolk (ISO 21535:2007/DAM 1:2015)

Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants (ISO 21535:2007/DAM 1:2015)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen an Implantate für den Hüftgelenkersatz (ISO 21535:2007/DAM 1:2015)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences spécifiques relatives aux implants de remplacement de l'articulation de la hanche (ISO 21535:2007/DAM 1:2015)

Ta slovenski standard je istoveten z: EN ISO 21535:2009/prA1

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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SIST EN ISO 21535:2009/oprA1:2015 **en**

DRAFT AMENDMENT

ISO 21535:2007/DAM 1

ISO/TC 150/SC 4

Secretariat: BSI

Voting begins on:
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Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants

AMENDMENT 1

Implants chirurgicaux non actifs — Implants de remplacement d'articulation — Exigences spécifiques relatives aux implants de remplacement de l'articulation de la hanche

AMENDEMENT 1

ICS: 11.040.40

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ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.



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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 2.

The main task of technical committees is to prepare International Standards. 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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Amendment 1 to ISO 21535:2007 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

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