

**Mitteaktiivsed kirurgilised implantaadid.
Liigeste asendusimplantaadid.
Erinõuded puusaliigese
asendusimplantaadile**

Non-active surgical implants - Joint replacement
implants - Specific requirements for hip-joint
replacement implants

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 21535:2007 sisaldab Euroopa standardi EN ISO 21535:2007 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 22.11.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 21535:2007 consists of the English text of the European standard EN ISO 21535:2007.</p> <p>This document is endorsed on 22.11.2007 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala:</p> <p>This International Standard provides specific requirements for hip joint replacement implants. With regard to safety, the standard gives requirements for intended performance, design attributes, materials, design valuation, manufacture, sterilization, packaging and information supplied by the manufacturer, and methods of test.</p>	<p>Scope:</p> <p>This International Standard provides specific requirements for hip joint replacement implants. With regard to safety, the standard gives requirements for intended performance, design attributes, materials, design valuation, manufacture, sterilization, packaging and information supplied by the manufacturer, and methods of test.</p>
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ICS 11.040.40

Võtmesõnad: definitions, design, dimensional tolerances, dimensions, hips, information, materials, mechanical strength, medical equipment, prosthetic devices, specifications, surface condition, surgical implants, tests

English Version

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

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)

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

This European Standard was approved by CEN on 16 August 2007.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 21535:2007) 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 March 2008, and conflicting national standards shall be withdrawn at the latest by March 2008.

This document supersedes EN 12563:1998.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA which is an integral part of this document.

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

Endorsement notice

The text of ISO 21535:2007 has been approved by CEN as a EN ISO 21535:2007 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this International Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 3, 4, 5, 7.1, 7.2, 9.2	
5	1, 2, 3, 4, 5, 6, 7.1, 9.1, 9.2	
6	1, 2, 3, 4, 7.1, 7.2, 7.3, 7.4, 8.2, 9.1, 9.2	
7	1, 2, 3, 4, 5, 6, 7.1, 7.2, 7.3, 14	
8	1, 2, 3, 4, 5, 7.1, 7.2, 7.3	
9	3, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7, 13.3	Via ISO 14630
10	3, 5, 7.2, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7	Via ISO 14630
11	9.1, 13	
NOTE Clauses 4, 5, 6, 7, 8 and subclause 11.5 supplement and are dependent on the corresponding clauses of ISO 21534.		

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

**Non-active surgical implants — Joint
replacement implants — Specific
requirements for hip-joint replacement
implants**

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



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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.

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.

ISO 21535 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 21535:2002), which has been technically revised.

Introduction

There are three levels of International Standard dealing with non-active surgical implants. These are as follows, with level 1 being the highest:

- level 1: general requirements for non-active surgical implants and instrumentation used in association with implants;
- level 2: particular requirements for families of non-active surgical implants;
- level 3: specific requirements for types of non-active surgical implant.

This International Standard is a level 3 standard and contains requirements applying specifically to hip joint replacements.

The level 1 International Standard, ISO 14630, contains requirements that apply to all non-active surgical implants. It also indicates that there are additional requirements in the level 2 and level 3 standards. The level 2 standards apply to more restricted sets or families of implants such as those designed for use in osteosynthesis, cardiovascular surgery or joint replacement.

To address all requirements, it is recommended that a standard of the lowest available level be consulted first.

Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants

1 Scope

This International Standard provides specific requirements for hip joint replacement implants. With regard to safety, this International Standard specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, information supplied by the manufacturer, and methods of test.

2 Normative references

The following referenced documents are indispensable for the application 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 7206-1, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions*

ISO 7206-2:1996, *Implants for surgery — Partial and total hip joint prostheses — Part 2: Articulating surfaces made of metallic, ceramic and plastics materials*

ISO 7206-4, *Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties of stemmed femoral components*

ISO 7206-6:1992, *Implants for surgery — Partial and total hip joint prostheses — Part 6: Determination of endurance properties of head and neck region of stemmed femoral components*

ISO 7206-10, *Implants for surgery — Partial and total hip joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads*

ISO 14630:—¹⁾, *Non-active surgical implants — General requirements*

ISO 21534:2007, *Non-active surgical implants — Joint replacement implants — Particular requirements*

3 Terms and definitions

For the purposes of this document the terms and definitions in ISO 21534 and ISO 7206-1 together with the following apply.

3.1

acetabular component

implant intended to be fixed to the prepared biological acetabulum

NOTE The component can be of monobloc or modular construction.

1) To be published. (Revision of ISO 14630:2005)