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

Käesolev Eesti standard EVS-EN ISO 21535:2009 sisaldab Euroopa standardi EN ISO 21535:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21535:2009 consists of the English text of the European standard EN ISO 21535:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.10.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.10.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 06.05.2009.	Date of Availability of the European standard text 06.05.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.40

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21535

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Supersedes EN ISO 21535:2007

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 12 April 2009.

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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 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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of ISO 21535:2007 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21535:2009 by 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 November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 21535:2007.

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 EU Directive.

For relationship with EU Directive, 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 21535:2009 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 on medical devices.

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 European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 3, 4, 5, 7.1, 7.2, 9.2	The part of ER 1 relating to the risk of use error is not addressed in this European Standard. The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard.
5	1, 2, 3, 4, 5, 6, 7.1, 9.1, 9.2	The part of ER 1 relating to the risk of use error is not addressed in this European Standard .The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard.
6	1, 2, 3, 4, 7.1, 7.2, 7.3, 7.4, 8.2, 9.1, 9.2	The part of ER 1 relating to the risk of use error is not addressed in this European Standard .The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard.The part of ER 7.4 relating to the regulatory provision for the verification of the medicinal product is not addressed in this European Standard.
7	1, 2, 3, 4, 5, 6, 6a., 7.1, 7.2, 7.3,	The part of ER 1 relating to the risk of use error is not addressed in this European Standard. The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard.

8	1, 2, 3, 4, 5, 7.1, 7.2, 7.3	The part of ER 1 relating to the risk of use error is not addressed in this European Standard. The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard.
9	3, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7, 13.3	Via ISO 14630 The modification of ER 13.3 f is not addressed in this European Standard.
10	3, 5, 7.2, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7	Via ISO 14630
11	9.1, 13	The part of ER 13.3.a concerning the information on the authorized representative is not addressed in this European Standard. ER 13.3 f is only partly addressed in this European Standard: safety issue of single use. ER 13.6 q is not addressed by this International Standard.
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.

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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)