Mitteaktiivsed kirurgilised implantaadid. Liigest asendavad implantaadid. Erinõuded

Non-active surgical implants - Joint replacement implants - Particular requirements

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 21534:2009 sisaldab Euroopa standardi EN ISO 21534:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21534:2009 consists of the English text of the European standard EN ISO 21534:2009.
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.

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 21534

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English Version

Non-active surgical implants - Joint replacement implants - Particular requirements (ISO 21534:2007)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences particulières (ISO 21534:2007)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen (ISO 21534:2007)

This European Standard was approved by CEN on 12 April 2009.

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.

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

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Ref. No. EN ISO 21534:2009: E

Foreword

The text of ISO 21534:2007 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 21534:2009 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 21534:2007.

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 21534:2007 has been approved by CEN as a EN ISO 21534:2009 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.
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.
9	3, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7, 13.3	The part 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	
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. The ER 13.3 f is only partly addressed in this European Standard: safety issue of single use. The part of ER 13.6.h) relating to single use is not addressed in this European Standard. ER 13.6 q is not addressed in this European Standard.
NOTE All clauses supplement and are dependent on the corresponding clauses of EN 14630		

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 2 standard and contains requirements that apply to all non-active surgical implants in the family of joint replacement implants.

The level 1 standard 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 1 standard has been published as ISO 14630.

Level 3 standards apply to specific types of implants within a family, such as knee and hip joints. 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 — Particular requirements

1 Scope

This International Standard specifies particular requirements for total and partial joint replacement implants, artificial ligaments and bone cement, hereafter referred to as implants. For the purposes of this International Standard, artificial ligaments and their associated fixing devices are included in the term "implant".

It specifies requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information to be supplied by the manufacturer.

Some tests required to demonstrate conformance to this International Standard are contained in or referenced in level 3 standards.

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 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

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

ISO 7206-8, *Implants for surgery — Partial and total hip joint prostheses — Part 8: Methods of determining endurance performance of stemmed femoral components*

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14242-1, *Implants for surgery — Wear of total hip-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for tests*

ISO 14242-2, *Implants for surgery — Wear of total hip joint prostheses — Part 2: Methods of measurement*

ISO 14243-2, *Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement*

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

ISO 14879-1, *Implants for surgery — Total knee-joint prostheses — Part 1: Determination of endurance properties of knee tibial trays*

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