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 21534:2007 sisaldab Euroopa standardi EN ISO 21534:2007 ingliskeelset teksti. Käesolev dokument on jõustatud 22.11.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 21534:2007 consists of the English text of the European standard EN ISO 21534:2007. This document is endorsed on 22.11.2007 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Käesolev standard esitab erinõuded liigest asendavatele täis- ja osaimplantaatidele, tehisligamentidele ja luutsemendile, millele siit alates viidatakse kui lihtsalt "implantaatidele". Käesoleva standardi tarvis on tehisligamendid ja nendega seotud kinnitusvahendid mahutatud terminisse implantaadid ning siit alates on neile viidatud kui lihtsalt "implantaatidele".	**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

ICS 11.040.40

Võtmesõnad: kirurgilised implantaadid, konstruktsioon, kontrollimine, materjalid, meditsiiniaparatuur, nõutavad välispinna omadused, pakkimine, proteesimisseadmed, sildiga märgistamine, steriliseerimine, teave, tehnilised andmed, tootmine

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21534

September 2007

ICS 11.040.40

Supersedes EN 12010:1998

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 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.

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

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Foreword

This document (EN ISO 21534:2007) 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 12010:1998.

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 21534:2007 has been approved by CEN as a EN ISO 21534:2007 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 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.1 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	
10	3, 5, 7.2, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7	
11	9.1, 13	
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.

INTERNATIONAL STANDARD

ISO 21534

Second edition
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Non-active surgical implants — Joint replacement implants — Particular requirements

Implants chirurgicaux non actifs — Implants de remplacement d'articulation — Exigences particulières

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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 21534 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 21534:2002), 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 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)