

MITTEAKTIIVSED KIRURGILISED IMPLANTAADID.
LIIGESTE ENDOPROTEESID. ERINÕUDED PÕLVELIIGESE
ENDOPROTEESIDELE

Non-active surgical implants - Joint replacement
implants - Specific requirements for knee-joint
replacement implants (ISO 21536:2023)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN ISO 21536:2024 sisaldab Euroopa standardi EN ISO 21536:2024 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 24.07.2024.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN ISO 21536:2024 consists of the English text of the European standard EN ISO 21536:2024.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 24.07.2024.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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EUROPEAN STANDARD

EN ISO 21536

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English Version

**Non-active surgical implants - Joint replacement implants -
Specific requirements for knee-joint replacement implants
(ISO 21536:2023)**

Implants chirurgicaux non actifs - Implants de
remplacement d'articulation - Exigences spécifiques
relatives aux implants de remplacement de
l'articulation du genou (ISO 21536:2023)

Nichtaktive chirurgische Implantate - Implantate zum
Gelenkersatz - Spezielle Anforderungen an Implantate
für den Kniegelenkersatz (ISO 21536:2023)

This European Standard was approved by CEN on 4 June 2023.

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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-CENELEC 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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 21536:2024) 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 January 2025, and conflicting national standards shall be withdrawn at the latest by January 2025.

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

This document supersedes EN ISO 21536:2009, EN ISO 21536:2009/A1:2014.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO 21536:2023 has been approved by CEN as EN ISO 21536:2024 without any modification.

Contents

Page

Foreword.....	iv
Introduction.....	vi
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	2
4 Intended performance.....	6
5 Design attributes.....	6
5.1 General.....	6
5.2 Tolerances and dimensions.....	7
5.2.1 Tolerances and dimensions of taper connections.....	7
5.2.2 Surface finish of non-articulating regions of knee joint components.....	8
5.2.3 Surface finish of articulating surfaces of knee joint components.....	8
5.3 Thickness of knee joint components.....	8
5.3.1 General.....	8
5.3.2 Thickness of UHMWPE in tibial inserts, monobloc tibial components, mobile-bearing components, patella inserts and monobloc patellar components.....	8
5.3.3 Thickness of metal and ceramic in femoral components, tibial trays and patellar trays.....	9
6 Materials.....	10
7 Design evaluation.....	10
7.1 General.....	10
7.2 Pre-clinical evaluation.....	10
7.2.1 General.....	10
7.2.2 Test methods and performance requirements.....	12
7.3 Clinical investigation.....	18
7.4 Post market surveillance.....	19
8 Manufacture.....	19
9 Sterilization.....	19
10 Packaging.....	19
11 Information to be supplied by the manufacturer.....	19
11.1 General.....	19
11.2 Product type and dimensions.....	19
11.3 Constructional and functional compatibility of components.....	20
11.4 Marking.....	20
11.5 Information for the patient.....	20
11.6 Electronic instructions for use.....	20
Annex A (informative) Evaluation of the range of relative angular motion of components of fully constrained total knee joint replacement implants.....	21
Bibliography.....	22

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 21536:2007), which has been technically revised. It also incorporates the Amendment ISO 21536:2007/Amd 1:2014.

The main changes are as follows:

- The scope has been expanded to specify more precisely the knee joint replacement types which are the subject of this document. Also, the scope now clarifies the requirements for implants which have been legally marketed and for which there is a history of sufficient and safe clinical use.
- The number of normative references has been expanded, including the addition of several ASTM standards.
- Several new definitions have been added, including: maximum claimed flexion, mobile-bearing component, mobile-bearing knee joint prosthesis, partial knee joint prosthesis and partial knee joint replacement, posterior stabilized tibial insert, reference implant, sufficient and safe clinical use, tibial insert, total knee joint prosthesis and total knee joint replacement, ultra-high molecular weight polyethylene and UHMWPE, uni-compartmental knee joint replacement and UKR, and worst case.
- The design attributes to be taken into account have been specified in [Clause 5](#). The requirements for the thickness of various knee joint components made from plastic, metal and ceramic have been expanded.
- Several new general requirements have been added in [7.2.1](#), which specify

- a) the circumstances when a test can be omitted,
 - b) the testing of the worst case,
 - c) the processes to be followed when no performance requirement has been specified, and
 - d) the processes to be followed when a performance requirement has been specified but has not been met.
- The number of pre-clinical evaluations (bench tests) to be performed has been greatly increased in [7.2.2](#). For some of the tests, a performance requirement has been specified. For some of the tests, no performance requirement has been specified and, in these cases, a new requirement has been added, namely the requirement to demonstrate that the performance of the implant under evaluation is the same or better than that of a reference implant. If no reference implant exists, a sequence of alternative options has been specified. These alternative options are also available in the case where there is a performance requirement, which is not met by the implant being tested.
 - A new clinical investigation subclause has been added in [7.3](#), with several requirements which specify the circumstances in which a clinical investigation can be required.
 - A new post-market surveillance subclause has been added in [7.4](#), which references the requirements in ISO 21534:2007, 7.4.
 - Several new marking requirements have been specified in [11.4](#).
 - A note has been added in [11.6](#) which states that in some jurisdictions there is the option to provide the instructions for use in electronic instead of paper format.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

There are three levels of standards 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 document is a level 3 standard and contains requirements applying specifically to knee joint replacements.

The level 1 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. For joint replacement implants, the level 2 standard is ISO 21534.

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 knee-joint replacement implants

1 Scope

This document specifies requirements for knee-joint replacement implants. Regarding safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, information supplied by the manufacturer and methods of test.

This document applies to both total and partial knee joint replacement implants. It applies to these replacements both with and without the replacement of the patella-femoral joint. It applies to components made of metallic and non-metallic materials.

This document applies to a wide variety of knee replacement implants, but for some specific knee replacement implant types, some considerations, not specifically covered in this document, can be applicable. Further details are given in [7.2.1.2](#).

The requirements which are specified in this document are not intended to require the re-design or re-testing of implants which have been legally marketed and for which there is a history of sufficient and safe clinical use. For such implants, compliance with this document can be demonstrated by providing evidence of the implant's sufficient and safe clinical use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 5834-1, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form*

ISO 7207-1:2007, *Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions*

ISO 7207-2, *Implants for surgery — Components for partial and total knee joint prostheses — Part 2: Articulating surfaces made of metal, ceramic and plastics materials*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14243-1, *Implants for surgery — Wear of total knee-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test*

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

ISO 14243-3, *Implants for surgery — Wear of total knee-joint prostheses — Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test*

ISO 14243-5, *Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint*

ISO 14630, *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*

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

ASTM F648, *Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants*

ASTM F1223, *Standard Test Method for Determination of Total Knee Replacement Constraint*

ASTM F2722, *Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops*

ASTM F2723, *Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation*

ASTM F2724, *Standard Test Method for Evaluating Mobile Bearing Knee Dislocation*

ASTM F2777, *Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion*

ASTM F3210, *Standard Test Method for Fatigue Testing of Total Knee Femoral Components under Closing Conditions*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7207-1, ISO 14630, ISO 21534 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 femoral component

component of a *total knee joint prosthesis* (3.14), *patella-femoral knee joint prosthesis* or *uni-compartmental knee joint prosthesis* (3.16) intended to be secured to the femur to replace its articulating surface(s)

3.2 maximum claimed flexion

highest amount of flexion the *total knee joint prosthesis* (3.14) or *uni-compartmental knee joint prosthesis* (3.16) can achieve as claimed by the manufacturer based on the requirements defined in 7.2.2.11

Note 1 to entry: A higher amount of flexion than the maximum claimed flexion can exist based on computer aided design (CAD) or implant shape considerations.

3.3 mobile-bearing component

component of a total or uni-compartmental *mobile-bearing knee joint prosthesis* (3.4) which articulates with both the *femoral component* (3.1) and the *tibial tray* (3.13)

Note 1 to entry: The mobile-bearing component can be manufactured as one component or a set of components, in both cases intended to be assembled in the *mobile-bearing knee joint prosthesis* (3.4) by the user.

Note 2 to entry: The mobile-bearing component is usually a sub-component of the *tibial component* (3.11), supported by the *tibial tray* (3.13).

Note 3 to entry: The mobile-bearing component can also be referred to as the meniscal component.