MITTEAKTIIVSED KIRURGILISED IMPLANTAADID. LIIGESTE ENDOPROTEESID. ERINÕUDED PUUSALIIGESE ENDOPROTEESIDELE

Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants (ISO 21535:2023)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 21535:2024 sisaldab Euroopa standardi EN ISO 21535:2024 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21535:2024 consists of the English text of the European standard EN ISO 21535:2024.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 24.07.2024.	Date of Availability of the European standard is 24.07.2024.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.40

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21535

July 2024

ICS 11.040.40

Supersedes EN ISO 21535:2009, EN ISO 21535:2009/A1:2016

English Version

Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants (ISO 21535:2023)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences spécifiques relatives aux implants de remplacement de l'articulation de la hanche (ISO 21535:2023)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Spezielle Anforderungen an Implantate für den Hüftgelenkersatz (ISO 21535:2023)

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

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

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

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

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

Ref. No. EN ISO 21535:2024 E

European foreword

This document (EN ISO 21535:2024) 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 21535:2009, EN ISO 21535:2009/A1:2016.

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.

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

Endorsement notice

The text of ISO 21535:2023 has been approved by CEN as EN ISO 21535:2024 without any modification.

Contents

Page

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 21535:2007), which has been technically revised. It also incorporates the Amendment ISO 21535:2007/Amd 1:2016.

The main changes are as follows:

— The scope has been expanded to specify more precisely the hip 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: bipolar femoral hip and bipolar femoral hip joint replacement, bipolar femoral component, constrained hip and constrained hip joint replacement, dual mobility head and dual mobility femoral component, dual mobility hip and dual mobility hip joint replacement, femoral head, reference implant, resurfacing hip joint replacement, sufficient and safe clinical use, ultra-high molecular weight polyethylene and UHMWPE, and worst case.

— The design attributes to be taken into account have been specified in Clause 5. The requirements for tolerances, dimensions and thickness of various hip 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.

— A warning for the surgeon about the consequences of component malposition or the use of specific components which can decrease joint range of motion has been added in 11.6.

— A note has been added in 11.7 which states that in some jurisdictions there is the option to provide the instructions for use in electronic instead of paper format.

— All the figures have been revised.

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 hip 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 hip-joint replacement implants

1 Scope

This document specifies requirements for hip-joint replacement implants. With regard to 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 hip joint replacement implants. It applies to components made of metallic and non-metallic materials.

This document applies to a wide variety of hip replacement implants, but for some specific hip 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 6475, *Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods*

ISO 7206-1:2008, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions*

ISO 7206-2, *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 and performance of stemmed femoral components*

ISO 7206-6, *Implants for surgery — Partial and total hip joint prostheses — Part 6: Endurance properties testing and performance requirements of 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 7206-12, *Implants for surgery — Partial and total hip joint prostheses — Part 12: Deformation test method for acetabular shells*

ISO 7206-13, *Implants for surgery — Partial and total hip joint prostheses — Part 13: Determination of resistance to torque of head fixation of stemmed femoral components*

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

ISO 11491, *Implants for surgery — Determination of impact resistance of ceramic femoral heads for hip joint prostheses*

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 test*

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

ISO 14242-3, *Implants for surgery — Wear of total hip-joint prostheses — Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test*

ISO 14242-4, *Implants for surgery — Wear of total hip-joint prostheses — Part 4: Testing hip prostheses under variations in component positioning which results in direct edge loading*

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

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

ASTM F543, *Standard Specification and Test Methods for Metallic Medical Bone Screws*

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

ASTM F1820, *Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices*

ASTM F1875, *Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface*

ASTM F2009, *Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses*

ASTM F2033, *Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials*

ASTM F2345, *Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads*

ASTM F2580, *Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis*

ASTM F2582, *Standard Test Method for Impingement of Acetabular Prostheses*

ASTM F3018, *Standard Guide for Assessment of Hard-on-Hard Articulation Total Hip Replacement and Hip Resurfacing Arthroplasty Devices*

ASTM F3047M, *Standard Guide for High Demand Hip Simulator Wear Testing of Hard-on-hard Articulations*

ASTM F3090, *Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement*

ASTM F3143, *Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Replacement Bearings Under Standard Conditions Using a Reciprocal Friction Simulator*

ASTM F3446, *Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Implants Using an Anatomical Motion Hip Simulator*