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Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants

Implants chirurgicaux non actifs — Implants de remplacement d'articulation — Exigences spécifiques relatives aux implants de remplacement de l'articulation du genou

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Foreword

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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*