
**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

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 21536 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 21536:2002), which has been technically revised.

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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 3 standard and contains requirements applying specifically to knee joint replacements. 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 2 standards apply to more restricted sets or families of implants such as those designed for use in osteosynthesis, cardiovascular surgery or joint replacement.

To address all requirements, it is recommended that a standard of the lowest available level be consulted first.

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

1 Scope

This International Standard provides specific requirements for knee joint replacement implants. With regard to safety, this International Standard specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, information supplied by the manufacturer and methods of test.

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

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 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*

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

3 Terms and definitions

For the purposes of this document the terms and definitions of ISO 21534 and ISO 7207-1 together with the following apply.

3.1

femoral component

component of a total knee joint replacement intended to be secured to the femur to replace its articulating surfaces

NOTE These implants can be manufactured as one component or a set of components to be assembled by the user.

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