INTERNATIONAL STANDARD

ISO 14879-1

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Implants for surgery — Total knee-joint prostheses

Part 1: Determination of endurance properties of knee tibial trays

Implants chirurgicaux — Prothèses totales de l'articulation du genou

Partie 1: Détermination des propriétés d'endurance des tablettes tibiales du genou

Reference number
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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 3.

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 part of ISO 14879 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14879-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

ISO 14879 consists of the following part, under the general title *Implants for surgery — Total knee-joint prostheses*:

— *Part 1: Determination of endurance properties of knee tibial trays*

Implants for surgery — Total knee-joint prostheses —

Part 1:
Determination of endurance properties of knee tibial trays

1 Scope

This part of ISO 14879 specifies a test method for determining the endurance properties, under specified laboratory conditions, of tibial trays used in knee-joint prostheses to support and secure the plastics articulating surface. It applies to tibial trays which cover both the medial and lateral plateaux of the tibia.

The test method does not apply to tibial components manufactured solely from plastics materials.

This part of ISO 14879 does not cover methods of examining and reporting the final condition of the test specimen; these may be the subject of agreement between the test laboratory and the parties submitting the specimen for test.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 14879. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14879 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 4965:1979, *Axial load fatigue testing machines — Dynamic force calibration — Strain gauge technique.*

ISO 7207-1:1994, *Implants for surgery — Components for partial and total knee-joint prostheses — Part 1: Classification, definitions and designation of dimensions.*

3 Terms and definitions

For the purposes of this part of ISO 14879, the terms and definitions given in ISO 7207-1 apply, together with the following.

3.1
anteroposterior centreline
line which passes through the centre of the tibial tray, parallel to the sagittal

3.3
mediolateral centreline
line which passes through the centre of the tibial tray, parallel to the coronal, or frontal, plane