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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 embases tibiales

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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.

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 documents 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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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, S*ubcommittee SC 4, *Bone and joint replacement.*

This second edition cancels and replaces the first edition (ISO 14879-1:2000), which has been technically revised. The main changes compared to the previous edition are as follows:

— in Clause 2, dynamic force calibration according to ISO 4965-1 was excluded and ISO 7500-1 was included;

— in 3.1 and 3.2, the centreline was defined considering stem as a reference;

— in 5.3, was included the possibility to glue the spacer;

— in 7.7, the test frequency was limited up to 10 Hz but higher test frequencies may be used if evidence (dynamic calibration) is provided.

A list of all parts in the ISO 14879 series can be found on the ISO website.

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.

Implants for surgery — Total knee-joint prostheses —

Part 1:
Determination of endurance properties of knee tibial trays

1 Scope

This document 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 plastic 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 plastic materials.

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

NOTE Correlation of test results with in vivo performance has not been established.

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

ISO 7500-1:2018, *Metallic materials — Calibration and verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Calibration and verification of the force-measuring system*

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
anteroposterior centreline
line which passes through the centre of the tibial tray stem, parallel to the sagittal plane and perpendicular to the line of force application

Note 1 to entry: The central stem or other prominence on the inferior surface of the tibial tray may also be named as keel.

3.2
mediolateral centreline
line which passes through the centre of the tibial tray stem, parallel to the coronal, or frontal plane and perpendicular to the line of force application

Note 1 to entry: The central stem or other prominence on the inferior surface of the tibial tray may also be named as keel.

3.3
ML moment arm
d_{ml}
perpendicular distance between the *anteroposterior centreline* (3.1) of the tibial component and the line of force application

Note 1 to entry: The distance is positive if the loading point is medial to the anteroposterior centreline.

3.4
AP moment arm
d_{ap}
perpendicular distance between the *mediolateral centreline* (3.2) of the tibial component and the line of force application

Note 1 to entry: The distance is positive if the loading point is posterior to the mediolateral centreline.

4 Principle

The test specimen is placed in a test rig and fixed so that one condyle of the tray extends as a cantilever. A cyclic force is applied to the unsupported condyle through a spacer. The cyclic force is applied until the test specimen exhibits failure or until the chosen number of cycles has been attained. The specimen is examined for defects caused by the loading.

5 Apparatus

5.1 Testing machine, with the following characteristics:

a) a sinusodial dynamic-loading waveform at the primary frequency;

b) an error in applied force not greater than ±2 % at the maximum force (in accordance with ISO 7500-1);

c) instrumentation to record the number of cycles.

5.2 Means of fixing the test specimen, to allow:

a) the test specimen to be held as a cantilever beam;

b) fixing the inferior surface or clamping the superior surface of the unsupported test specimen tray away from the mid-line. If necessary, both fixation methods may be used. Epoxy resin or bone cement (see ISO 5833) may be used as an embedding material for the inferior surface;

c) the tibial tray to be supported up to the anteroposterior centreline (see Figures 1 and 2), within tolerances for linear displacement of ±1 mm and for angular displacement of ±2º between the tibial anteroposterior centreline and the fixture support line. If the tray includes a central stem or other prominence on the inferior surface, these shall be supported only up to the anteroposterior centreline in the same manner;

d) the load axis to be perpendicular to the undeflected superior surface of the test specimen.