FINAL DRAFT

INTERNATIONAL STANDARD

ISO/FDIS 14879-1

ISO/TC **150**/SC **4**

Secretariat: BSI

Voting begins on:
2020-04-14

Voting terminates on:
2020-06-09

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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Reference number
ISO/FDIS 14879-1:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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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).

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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.

ISO 14879-1 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 10Hz but higher test frequencies may be used if evidence (dynamic calibration) is provided.

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 4965-1, *Metallic materials — Dynamic force calibration for uniaxial fatigue testing — Part 1: Testing systems*

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 4965-1);

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.

5.3 Spacer, to be placed between the test specimen and the load applicator to distribute the loading and reduce fretting.

Ultra-high molecular weight polyethylene, acetal co-polymer or acetal homopolymer may be used as plastic spacer. Metal might be used as spacer material if the plastic spacer is not capable to transfer the test force. The spacer can be glued to the tray to prevent translation during testing.

It is recommended that the diameter of the spacer is 13,0 mm ± 0,5 mm and a minimum thickness at the point of the force application shall be 6,0 mm ± 0,5 mm (See Figure 3). The spacer diameter and/or shape may be modified to accommodate the tibial tray design being tested, but any deviations from these specified dimensions shall be included in the test report. The spacer shall contain a spherical indentation (or recess) in order to accommodate the load applicator. This recess shall be greater to or equal than the diameter of the load applicator and is included to minimize the chance of spacer fracture under load.

NOTE Material in accordance with type 1 or type 2 of ISO 5834-2 has been found suitable

5.4 Load applicator, a rod with a spherical indentor with a radius of 16 mm at its end. It is recommended that the indentor be manufactured from metallic material. The load applicator shall be free to move in the transverse direction of force application.

The load applicator may be modified to accommodate aspects of the tray design, such as a rim around the periphery.

6 Sample size and test conditions

The sample size and the test conditions shall be defined by the party submitting the specimens for test.

Test conditions shall include:

a) loading waveform;

b) maximum and minimum test force;

c) limit number of cycles for test duration (runout);

d) test frequency;

e) test environment;

f) spacer material;

g) location of anteroposterior and mediolateral centrelines (for asymmetric tibial trays)

The test shall be conducted under force control using a minimum force corresponding to 10 % of the maximum force in terms of absolute values.

NOTE 1 ISO 21536 establishes an endurance requirement considering a minimum of five specimens passing 10 million cycles at maximum force of 900 N.

NOTE 2 It is recognized that for some materials the environment can affect the fatigue performance.

7 Testing procedure

7.1 Determine the tibial width and tibial depth in accordance with Figures 3 and 5 of ISO 7207-1:2007, for establishing the mediolateral and anteroposterior centrelines.

7.2 Fix the test specimen in the test rig in accordance with 5.2 c). If the test specimen is asymmetrical, ensure that it is fixed so that the worst-case testing condition is applied. Ensure that there is a clearance

of at least 5 mm between the undersurface of the loaded compartment on the tibial tray and any part of the fixture. Ensure that the loaded part of the tibial tray does not make contact with any part of the fixture during testing.

7.3 Position the test specimen so that the load axis is orthogonal to the undeflected superior surface of the tray within a tolerance of 2°. The loading point shall be located in order to assure the ML moment arm and AP moment arm are applied on the tibial tray and corresponding to the position where it is expected to be loaded in vivo at 0° flexion.

NOTE 1 The tray surface will not remain perpendicular to the load axis during loading.

7.4 Use one of the following methods to determine the position of the loading point.

a) **For biconcave tibial designs**, the loading point shall be at the intersection with the tray of a line drawn normal to the tray which intersects the deepest part of the recess in the articular surface.

b) **For other tibial components**, the femoral component, the tibial articulating surface component and the tibial tray shall be assembled at 0° flexion and the position of the centre of pressure determined. The centre of pressure shall be on the line perpendicular to the tray which passes through the loading point.

The position of the centre of pressure may be determined using pressure-sensitive film, removable dye, a 3-D CAD system or component drawings.

7.5 Measure the dimensions d_{ap} and d_{ml} (3.3, 3.4 and Figures 1 and 2).

7.6 Place the spacer (5.3) between the test specimen and the load applicator (Figure 1 or 2). The spacer shall be replaced if, during testing, its thickness is reduced to 3 mm or if it fragments.

7.7 With the spherical indentor in place, start the testing machine and adjust it so that it applies the maximum force F_{max}, at a frequency not greater than 10 Hz. Visually inspect the tray under normal or corrected vision every 5×10^5 cycles (see 7.9) without removing the tray from the testing machine.

Higher test frequencies may be used if evidence (dynamic calibration) is provided that the test results are identical to those obtained at 10Hz or less.

7.8 Measure the vertical deflection of the tibial tray using adequate instrumentation.

7.9 Continue the test until one of the following occurs:

a) the spacer thickness is reduced to 3 mm or it fragments;

In this case, note the occurrence and fit a new spacer before continuing the test;

b) the specimen fractures;

c) cracks are observed when the specimen is inspected under normal or corrected vision or other non-destructive means;

d) exceed a predetermined deflection limit

e) the limit cycles test duration (runout) is achieved;

NOTE ISO 21536 establishes a runout of 10×10^6 cycles.

f) the test machine fails to maintain the specified force range [5.1 b].

7.10 At the end of the test:

a) record the total number of cycles of loading applied when the test was terminated;

b) report the reason for termination of the test;

c) examine the test specimens using the methods requested by the party that submitted the specimen for testing.

8 Test report

The test report shall include the following information:

a) a reference to this document (including its year of publication);

b) sample size submitted for testing;

c) the identity of the test specimens, as stated by the party submitting the specimens for test, including tibial tray thickness, size, *d* and *w,* as defined in ISO 7207-1, and materials of construction;

d) details of the test conditions, maximum compressive force, limit number of cycles for test duration (runout); test frequency; rationale if test frequency higher than 10 Hz was used, rationale for the waveform other than sinusoidal, spacer material, diameter and thickness (including any deviations in diameter or shape), indenter diameter, location of anteroposterior and mediolateral centrelines (for asymmetric tibial trays), rationale, if available, for the side (medial or lateral) chosen for testing (i.e., worst-case), side of load application (medial or lateral for asymmetric tibial trays), ML moment arm (d_{ml}), AP moment arm (d_{ap}), and fixation method;

e) whether one or more replacement spacers was used;

f) a statement of results including number of cycles applied and mode of failure, location of fracture (if fractured), description of test specimens at the end of the test, and the results of examination requested by the party submitting the specimen for test;

g) if necessary, report the deflection limit, method of measurement and the point at which the deflection is measured;

h) test environment.

9 Disposal of test specimens

Test prostheses shall not be used for clinical purposes after testing. Care should be exercised in the use of the specimens for further mechanical tests, because the loading regime may have altered the mechanical properties.