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**Implants for surgery — Wear of total ankle-joint prostheses — Loading and displacement parameters for wear-testing machines with load or displacement control and corresponding environmental conditions for test**

*Implants chirurgicaux — Usure des prothèses totales de l'articulation de la cheville — Paramètres de charge et de déplacement pour machines d'essai d'usure avec contrôle de la charge ou du déplacement et conditions environnementales correspondantes d'essai*



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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](http://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](http://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*.

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](http://www.iso.org/members.html).

# Implants for surgery — Wear of total ankle-joint prostheses — Loading and displacement parameters for wear-testing machines with load or displacement control and corresponding environmental conditions for test

## 1 Scope

This document specifies the relative angular movement between articulating components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the wear testing of total ankle-joint prostheses in wear-testing machines with load or displacement control.

NOTE This document is based on the method described by ISO 14243-1 and ISO 14243-3 and allows for the use of the same test equipment as for total knee replacement wear testing.

## 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 14243-2, *Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions 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

#### **talar component**

total ankle-joint prosthesis component attached to the talus

Note 1 to entry: Component that articulates against the bearing (see [Figure 1](#)).

### 3.2

#### **tibial component**

total ankle-joint prosthesis component attached to the tibia

### 3.3

#### **bearing**

total ankle-joint prosthesis component intended for articulating with both tibial component and talar component surfaces

Note 1 to entry: The superior bearing surface supports the tibial internal/external rotation, and the inferior bearing surface supports the talar plantar/dorsiflexion (see [Figure 1](#)).