BS ISO 14242-1:2014

BSI Standards Publication

Implants for surgery — Wear of total hip-joint prostheses

Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

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This British Standard is the UK implementation of ISO 14242-1:2014. It supersedes BS ISO 14242-1:2002 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/4, Surgical Implants - Bone and Joint Replacements.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Implants for surgery — Wear of total hip-joint prostheses —

Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

Implants chirurgicaux — Usure des prothèses totales de l'articulation de la hanche —

Partie 1: Paramètres de charge et de déplacement pour machines d'essai d'usure et conditions environnementales correspondantes d'essai

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Contents

Page

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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This third edition cancels and replaces the second edition (ISO 14242-1:2012), which has been technically revised.

ISO 14242 consists of the following parts, under the general title *Implants for surgery — Wear of total hip-joint prostheses*:

— *Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test*

— *Part 2: Methods of measurement*

— *Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test*

INTERNATIONAL STANDARD ISO 14242-1:2014(E)

Implants for surgery — Wear of total hip-joint prostheses —

Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

1 Scope

This part of ISO 14242 specifies the relative angular movement between articulating components, the pattern of the applied force, the speed and duration of testing, the sample configuration, and the test environment to be used for the wear testing of total hip-joint prostheses.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7206-1, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions*

ISO 14242-2, *Implants for surgery — Wear of total hip-joint prostheses — Part 2: Methods of measurement*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7206-1 and the following apply.

3.1
abduction/adduction
angular movement shown in Figure 1 a)

3.2
flexion/extension
angular movement shown in Figure 1 b)

3.3
inward/outward rotation
angular movement shown in Figure 1 c)

3.4
polar axis
axis of the acetabular component which intersects the centre of the spherical articulating surface and is perpendicular to the plane of the flange or, if no flange is present, perpendicular to the plane of the entry diameter