INTERNATIONAL STANDARD

ISO 11491

First edition
2017-07

Implants for surgery — Determination of impact resistance of ceramic femoral heads for hip joint prostheses

Implants chirurgicaux — Détermination de la résistance à l'impact des têtes de fémur en céramique pour les prothèses de la hanche

Reference number
ISO 11491:2017(E)

© ISO 2017



COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Principle **2**
5 Apparatus and equipment **2**
6 Procedure **5**
6.1 General 5
6.2 Test method for impact resistance (cyclic strength) 6
6.2.1 Setting the test specimen 6
6.2.2 Applying an impact 6
6.2.3 Load cell data sampling 6
6.3 Test method for the cyclic load-release burst test 6
6.3.1 Setting the test specimen 6
6.3.2 Loading of the specimen 6
6.3.3 Termination of the load-release cycles 7
6.3.4 Examination of the specimen 7
7 Impact test: Calculation of an impact energy **7**
8 Test report **7**
Bibliography **9**

© ISO 2017 – All rights reserved

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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bones and joint replacements*.

© ISO 2017 – All rights reserved

Introduction

Partial and total hip joint prostheses are designed to transmit load and allow movement under high stress conditions. They are intended to replace anatomical structures and to provide function as closely as possible to the attributes of the normal natural joint. Some designs of femoral components of total hip joint prostheses comprise a ceramic femoral head and a metal femoral stem. It is important, therefore, that the ceramic femoral head is of sufficient strength to withstand the static loads as well as the dynamic impact loads likely to be exerted on the prostheses during use. It has been found that the ISO 7206-10 test did not produce the same type of fracture for zirconia heads that were similar to fractures produced clinically, while the test fractures produced on alumina heads were similar to clinical fractures. It is important, specifically in cases of a new ceramic material and/or new taper configurations, to know the behaviour after impact loading such as delayed fracture that may not be detected by a purely static burst test. Hence, this document specifies two alternative test methods to determine the impact strength of ceramic femoral heads.

The fracture mechanisms of ceramic ball heads occurring after an impact load may be either an immediate overload breakage or subcritical crack growth. Subcritical crack growth may then lead to failure at forces lower than the initial static burst load. In ceramic ball heads loaded via the interface between the metal trunnion (neck unit) and the ball head, subcritical crack growth may either be induced by impaction or by incremental load-release cycles with quasi-static forces.

© ISO 2017 – All rights reserved

Implants for surgery — Determination of impact resistance of ceramic femoral heads for hip joint prostheses

1 Scope

This document specifies two alternative test methods for determining the impact resistance of ceramic femoral heads for hip joint prostheses.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 197-1, *Copper and copper alloys — Terms and definitions — Part 1: Materials*

ISO 4288, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture*

ISO 7206-10, *Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7206-10 and the following apply.

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

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

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

3.1
impact energy
potential mechanical energy of the falling/drop weight used for applying the impact

3.2
cyclic impact resistance
maximum impact energy without failure of the test specimen, when consecutively increased impacts are applied

3.3
impact load
peak measured force before fracture when impact energy or quasi-static load-release cycles are applied

3.4
impact velocity
falling weight velocity immediately prior to impact

3.5
quasi-static force
force that changes slowly with time so that any mass inertia influence can be neglected

© ISO 2017 – All rights reserved