

This is a preview of "ISO 6474-2:2019". [Click here to purchase the full version from the ANSI store.](#)

Second edition
2019-03

Implants for surgery — Ceramic materials —

Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement

Implants chirurgicaux — Produits céramiques —

Partie 2: Matériaux composites à matrice alumine de haute pureté renforcée par des grains de zirconie



Reference number
ISO 6474-2:2019(E)

© ISO 2019

This is a preview of "ISO 6474-2:2019". Click here to purchase the full version from the ANSI store.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, 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
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

This is a preview of "ISO 6474-2:2019". [Click here to purchase the full version from the ANSI store.](#)

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and Definitions	3
4 Classification	3
4.1 Material types.....	3
4.2 Test categories.....	3
4.2.1 General.....	3
4.2.2 Category 1: required tests representative for periodical production control.....	3
4.2.3 Category 2: required tests representative for the general material specification...	3
4.3 Material properties.....	4
5 Preparation of specimens	5
6 Test methods	6
6.1 Bulk density.....	6
6.1.1 General.....	6
6.1.2 Calculation of ultimate density.....	6
6.1.3 Empirical determination of the ultimate density.....	6
6.2 Chemical composition.....	7
6.3 Microstructure.....	7
6.4 Strength properties.....	8
6.4.1 General.....	8
6.4.2 Biaxial flexural strength.....	8
6.4.3 4-point flexural strength.....	8
6.4.4 Weibull modulus.....	9
6.5 Radioactivity.....	9
6.6 Fracture toughness.....	9
6.6.1 General.....	9
6.6.2 SEVNB.....	9
6.6.3 SEPB.....	9
6.6.4 SCF.....	9
6.7 Hardness.....	10
6.8 Young's modulus.....	10
6.9 Cyclic fatigue.....	10
6.10 Accelerated ageing.....	10
6.10.1 General.....	10
6.10.2 Strength.....	11
6.10.3 Cyclic fatigue.....	11
6.10.4 Wear.....	11
Bibliography	12

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*, Subcommittee SC 1, *Materials*.

This second edition cancels and replaces the first edition (ISO 6474-2:2012) which has been technically revised.

A list of all parts in the ISO 6474 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.

This is a preview of "ISO 6474-2:2019". [Click here to purchase the full version from the ANSI store.](#)

Introduction

No known surgical implant material has ever been found to be completely free of adverse reactions in the human body. However, long-term clinical experience of use of alumina and zirconia (the main components of the material referred to in this document) as biomaterials has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications.