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First edition
2010-02-15

Implants for surgery — Ceramic materials —

Part 1: Ceramic materials based on high purity alumina

Implants chirurgicaux — Produits céramiques —

Partie 1: Produits céramiques à base d'alumine de haute pureté



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 6474-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This first edition, together with ISO 6474-2, cancels and replaces ISO 6474:1994, which has been technically revised.

ISO 6474 consists of the following parts, under the general title *Implants for surgery — Ceramic materials*:

- *Part 1: Ceramic materials based on high purity alumina*
- *Part 2: Composite materials based on a high purity alumina matrix with zirconia reinforcement*

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Introduction

No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience of use of the material referred to in ISO 6474 has shown that an acceptable level of biological response can be expected, when the material is used in appropriate applications.