TECHNICAL REPORT

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Implants for surgery — Fundamental principles

Implants chirurgicaux — Principes fondamentaux

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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.

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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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/TR 14283 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This second edition cancels and replaces the first edition (ISO/TR 14283:1995), the annex of which has been updated.

Introduction

Requirements on the design, manufacture and performance of implantable medical devices are developing in various ways in different countries and international regions. As the medical device industry is already active on a global basis, and is becoming more so, concern is growing as to the need for international and mutually recognized standards for the design and performance of such devices.

In order for standards and legal or regulatory requirements to be compatible, they both need to be based on an understanding of the fundamental principles applicable to the implants. This Technical Report presents a compilation of these principles. The structure of this report is derived and adapted from the Essential Requirements given in the European Council Medical Device Directives.

This Technical Report is, by its nature, purely informative.

When balancing risk and benefit to the patients, it is good practice to subject implants to a risk analysis and this is implicit in this Technical Report. However, risk analysis cannot always identify all risks. Such uncertainty may be acceptable in the light of perceived benefits to the patient. Follow-up performance review can provide information to confirm the acceptability of the risk.

The correspondence of the fundamental principles contained in this Technical Report with pre-existing national and/or regional requirements is contained in Annex A. The bibliography provides a list of standards that may be used to link these fundamental principles to standards giving product related requirements and guidance on the analysis of risks associated with the use of implants.

NOTE 1 This report is intended to be a basis for harmonized standards, but it is recognized that specific wording may be at variance with wording or definitions used in existing national documents, particularly in areas related to “lifetime”, “intended use”, “normal conditions of use”, etc.

NOTE 2 Should standards based on this Technical Report be recognized by national authorities having responsibility for approval for commercialization of such devices in their respective countries, the opportunity exists for the rationalization and harmonization of such approval activities. The consequent overall cost reduction is to the benefit of all parties, particularly patients, health care providers, insurers and industry.

Implants for surgery — Fundamental principles

1 Scope

This Technical Report provides fundamental principles for the design and manufacture of active or non-active implants in order to achieve the intended purpose.

2 Terms and definitions

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

2.1
accessory
article which, while not being a medical device, is intended specifically by its manufacturer to be used together with a device to enable the device to be used as intended by its manufacturer

2.2
active medical device
any medical device whose operation depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy

NOTE Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

2.3
intended purpose
use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials

2.4
labelling
all written, printed or graphic matter

— affixed to a medical device or any of its containers or wrappers, or

— accompanying a medical device

relating to identification, technical description, and use of the medical device, but excluding shipping documents

NOTE Some regional and national regulations refer to “labelling” as “information supplied by the manufacturer”.

[ISO 13485:2003]

2.5
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his/her own name, regardless of whether these operations are carried out by that person him-/herself or on his/her behalf by a third party

