TECHNICAL REPORT

ISO/TR 14283

Second edition
2004-07-15

Implants for surgery — Fundamental principles

Implants chirurgicaux — Principes fondamentaux

Reference number
ISO/TR 14283:2004(E)

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Published in Switzerland

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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.

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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

2.6
medical device
any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

NOTE Adapted from ISO 13485:2003.

2.7
medicinal product
any substance or combination of substances presented for treating or preventing disease in human beings or animals with a view to making a medical diagnosis, or for restoring, correcting or modifying physiological functions in human beings or in animals

2.8
surgical implant
device which is intended

— to be totally introduced into the human body, or

— to replace an epithelial surface or the surface of the eye

by surgical intervention, and which is intended to remain in place after the procedure

NOTE Any medical device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered a surgical implant.

3 General principles

3.1 The implants should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

3.2 The solutions adopted by the manufacturer for the design and construction of the implants should conform to safety principles, taking into account the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order:

a) eliminate or reduce risks as far as possible (inherently safe design and construction);

b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated;

c) inform users of the residual risks due to any shortcomings of the protection measures adopted.

3.3 The implants should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in 3.1, as specified by the manufacturer.

3.4 When the implant is subjected to stresses which can occur during normal conditions of use, the characteristics and performances referred to in 3.1, 3.2 and 3.3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the implant as indicated by the manufacturer.

3.5 The implants should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage when taking into account the instructions and information provided by the manufacturer.

3.6 Any undesirable side-effect should constitute an acceptable risk when weighed against the performances intended.

4 Specific principles regarding design and construction

4.1 Chemical, physical and biological properties

4.1.1 The implants should be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Clause 3 on general principles. Particular attention should be paid to

a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,

b) the compatibility between the materials used and biological tissues, cells and body fluids, taking into account the intended purpose of the implant.

4.1.2 The implants should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the implants and to the patients, taking into account the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.

4.1.3 The implants should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures. If the implants are intended to administer medicinal products, they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned, according to the provisions and restrictions governing these products, and such that their performance is maintained in accordance with the intended use.

4.1.4 If an implant incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in 2.7 and which is liable to act upon the body with action ancillary to that of the implant, the safety, quality and usefulness of the substance should be verified, taking into account the intended purpose of the implant.

4.1.5 The implants should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the implant.

4.1.6 Implants should be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the implant, taking into account the implant and the nature of the environment in which it is intended to be used.

4.1.7 Implants should be designed and manufactured in such a way as to minimize the risks to the patient or user by the programming and control systems, including software.

4.2 Infection and microbial contamination

4.2.1 The implants and manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design should allow easy handling and, where necessary, minimize contamination of the implant by the patient, or vice versa, during use.

4.2.2 Tissues of animal origin should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.

Information on the geographical origin of the animals should be retained by the manufacturer.

Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal security. In particular, safety with regard to viruses and other transferable agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.

4.2.3 Implants delivered in a sterile state should be designed, manufactured and packed in protective packaging which provides a microbial barrier to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions stipulated by the manufacturer, until the protective packaging is damaged or opened.

4.2.4 Implants delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.

4.2.5 Implants intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

4.2.6 Packaging systems for non-sterile implants should keep the product without deterioration at the level of cleanliness stipulated and, if the implants are to be sterilized prior to use, minimize the risk of microbial contamination. The packaging system should be suitable, taking into account the method of sterilization indicated by the manufacturer.

4.2.7 The packaging and/or label of the implant should distinguish between identical or similar products sold in both sterile and non-sterile conditions.

4.3 Construction and environmental properties

4.3.1 If the implant is intended for use in combination with other devices or equipment, the whole combination, including the connection system, should be safe and should not impair the specified performances of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.

4.3.2 Implants should be designed and manufactured in such a way as to remove or minimize, as far as possible, the following:

a) risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,

b) risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,

c) risks of reciprocal interference with other devices (such as defibrillators or high-frequency surgical equipment) normally used in the investigations or for the treatment given,

d) risks which may arise where maintenance and calibration are impossible, including (if applicable)

   — excessive increase of leakage currents,

— ageing of materials used,

— excess heat generated by the implant,

— decreased accuracy of any measuring or control mechanism.

4.3.3 Implants should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal conditions and fault conditions. By “risks during normal conditions and fault conditions” are meant those risks which have been determined by a risk analysis. Particular attention should be paid to implants whose intended use includes exposure to flammable substances or to substances which could cause combustion.

4.4 Implants with a measuring function

4.4.1 Implants with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy and stability, within appropriate limits of accuracy and taking into account the intended purpose of the implant. The limits of accuracy should be indicated by the manufacturer.

4.4.1.1 The measurements, monitoring and display scale should be designed in accordance with ergonomic principles, taking into account the intended purpose of the implant.

4.4.1.2 If an implant or its accessories bears instructions required for the operation of the implant or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

4.4.2 The measurements made by implants with a measuring function should be expressed in units conforming to the provisions of the ISO 31 series.

4.5 Protection against radiation

4.5.1 General

Implants should be designed and manufactured in such a way that exposure of patients, users and other persons to radiation is reduced as low as possible, compatible with the intended purpose, while not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

4.5.2 Intended radiation

4.5.2.1 If implants are designed to emit hazardous levels of radiation necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission, the implants should be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.

4.5.2.2 If implants are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

4.5.3 Unintended radiation

Implants should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.

4.5.4 Instructions

The operating instructions for implants emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user, and ways to avoid misuse and eliminate the risks inherent in use.