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Implants for surgery — Fundamental principles

Implants chirurgicaux — Principes fondamentaux

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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.

The main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

— type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;

— type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;

— type 3, 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).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 14283, which is a Technical Report of type 3, was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This document is being issued as a type 3 Technical Report providing a compilation of the principles of the implants for surgery: see the Introduction.

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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/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 laid down in the EC medical device Directives.

This Technical Report was prepared in Working Group 7 of ISO/TC 150 by experts from the following P-members: Australia, Canada, China, France, Germany, Japan, Netherlands, Switzerland, UK and USA.

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 correspondance of the fundamental principles contained in this Technical Report with pre-existing national and/or regional requirements is contained in Annex A. Other annexes cover standards that may be used to link these fundamental principles to standards giving product related requirements (Annex B.1) and guidance on the analysis of risks associated with the use of implants (Annex B.2).

NOTE 1: This report is intended to be a base for harmonised 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.

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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 Definitions

For the purposes of this Technical Report, the following definitions apply:

2.1 Medical device

Medical device means 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.

2.2 Active medical device

Any medical device operation of which 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. 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 Implant

Any medical device which is intended:

- to be totally or partially introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,

by an invasive procedure and which is intended to remain in place.

2.4 Medicinal product

Any substance or combination of substances presented for treating or preventing disease in human beings or animals.

Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.

2.5 Intended purpose

Intended purpose means the 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.

2.6 Manufacturer

Manufacturer means the 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 own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

2.7 Accessory

Accessory means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

2.8 Label

All written, printed or graphic matter

a) on a medical device or any of its containers or wrappers or

b) accompanying a medical device

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

NOTE 3: This definition is as given in ISO/DIS 13485 "Quality system - Medical devices - Particular requirements for the application of EN 29001 (ISO 9001).

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 account of 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 sub-clause 2.1, as specified by the manufacturer.

3.4 The characteristics and performances referred to in sub-clauses 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 if indicated by the manufacturer, when the implant is subjected to the stresses which can occur during normal conditions of use.

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 taking account of 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 the "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 account of 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 account of 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 that their performance is maintained in accordance with the intended use.

4.1.4 Where an implant incorporates, as an integral part, a substance which, if used separately, may be considered to be medicinal product as defined in sub-clause 2.4 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 account of 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, miminize 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 account of 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 condition.

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 is possible:

(a) the 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) the 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. With the 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 account of 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 line with ergonomic principles, taking account of the intended purpose of the implant.

4.4.1.2 When an implant or its accessories bear instructions required for the operation of the implant or indicate 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 be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

4.5.2 Intended radiation

4.5.2.1 Where 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 Where 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.