INTERNATIONAL STANDARD

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Implants for surgery — Minimum data sets for surgical implants

Implants chirurgicaux — Ensembles minimaux de données relatives aux implants chirurgicaux

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 16054 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Annex A of this International Standard is for information only.

Introduction

The importance and utility of registry, tracking and retrieval analysis systems in understanding long term clinical performance of implant devices and in patient follow up in the event of unforeseen device malfunction is understood. This International Standard addresses the minimum information concerning the patient, the device manufacturer and the clinical and surgical procedures which needs to be collected to ensure efficient and rapid international patient follow up should it be required. It also provides the core data set to allow linkage of different registries for the purposes of retrieval analysis.

Medical device regulators should consider inclusion of these minimum data requirements in the distribution chain to the end user as a progression of the requirements of ISO 13485.

Users of this International Standard are advised that it is possible to collect all the data items specified in this International Standard and, if desired, to transfer them to third party registers using automated methods. An informative annex to this International Standard provides references to technical standards which define mechanisms for automation of both data collection and transmission.

Implants for surgery — Minimum data sets for surgical implants

1 Scope

This International Standard defines minimum data sets for surgical implants to facilitate recording and international exchange of data for the purposes of implant registry and tracking systems and for retrieval analysis. Minimum data collection requirements are specified for the purpose of implant tracking to allow recall for product correction or patient follow up in the event of unforeseen device malfunction. The minimum data set also fulfils the core data requirements to allow cross referencing between extended data sets for the purposes of retrieval analysis and research.

This International Standard is applicable to the manufacturers and distributors of medical devices intended for permanent implant, i.e. more than 30 days and to those hospitals and other medical facilities which carry out implant procedures. It specifies requirements for data items to be recorded by the manufacturers and distributors of permanently implantable medical devices and by hospitals and other medical facilities at both the time of implant and at the time of any subsequent explant procedure.

This International Standard is intended to define a minimum data set to be recorded for all implant and explant events, as well as providing for the timely retrieval of minimum implant data related to specific subsets of patients who have received specific identified devices or devices within a specified range of lot, batch or serial numbers, for the purpose of patient follow up.

It is not the intent of this International Standard to provide a means of data recovery which is related to specific medical practitioners, medical facilities or manufacturers for purposes other than patient follow up.

NOTE Users of this International Standard should ensure compliance with appropriate national standards or regulations concerning data protection and handling.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 13485, *Quality systems — Medical devices — Particular requirements for the application of ISO 9001*.

ISO 8402, *Quality management and quality assurance — Vocabulary*.

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 13485 and ISO 8402 (but see 3.1) and the following apply.

3.1
implantable medical device
any medical device or active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, or to replace an epithelial surface or the surface of the eye, and which is intended to remain after the procedure for at least 30 days and which can only be removed by surgical or medical intervention

