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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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

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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

NOTE ISO 13485 gives a separate definition for **active implantable medical devices** and specifically excludes these from the definition for **implantable medical devices**. The above definition differs from that given in ISO 13485 in that the separate definitions for **implantable medical devices** and **active implantable medical devices** are combined into one.

3.2
implant event
the act of surgical intervention by which an implantable medical device is

— totally introduced into the human body, or

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

— partially introduced into the human body,

and which is intended to remain in place after the procedure for at least 30 days and which can only be removed by medical or surgical intervention

3.3
explant event
the act of surgical intervention by which an implantable medical device is removed from a patient

3.4
medical facility
the person or organization responsible for maintaining the patient record

NOTE 1 The medical facility is also, by definition, the final **customer** (see ISO 8402) in the distribution chain.

NOTE 2 In some cases hospitals may be considered suppliers, for example where patient records are the sole responsibility of individual surgeons practising within the hospital.

4 Data sets

4.1 General

For modular implantable medical devices which are supplied either separately or as kits, each separately supplied component or each separate item of a kit shall be considered to be a unique and separate implantable medical device subject to recording as unique and separate implant and explant events. Examples of separate modular components are:

— the pulse generator and electrode lead(s) of an implantable cardiac pacemaker or defibrillator, and

— the cement and each of the separate components of a modular hip prosthesis.

4.2 Supplier data

The data items a) to d) shall be recorded and retained by each supplier in the distribution chain as follows:

a) the identity of the previous supplier in the distribution chain;

b) customer identity;

c) the device name or description and catalogue number as given in the product information of the previous supplier which uniquely identifies the type of device;

d) serial number or lot or batch number sufficient to identify the device to a level of the unique lot or batch or device.

Where a supplier allocates new product catalogue numbers, device names or descriptions, or serial, lot or batch numbers, that supplier shall maintain records which link the new identifiers with those provided by the previous supplier in the distribution chain.

Independent records of each separate supplier in a distribution chain shall, where known, include the identity of the original producer of the implantable medical device and those known to be in the supply chain.

Supplier data records shall be maintained in such a way as to allow timely traceability of the implantable medical devices through the distribution chain.

The data may be transmitted to a third party registry for archiving purposes. Users of this International Standard should ensure that any such transmission complies with relevant national standards or regulations concerning data protection and handling.

4.3 Medical facility data

The data items a) to j) defined as follows shall be recorded and retained by the medical facility for each separate implant event.

For explant events, as many of the data items from a) to j) shall be recorded as are available to the medical facility.

These data should be maintained in such a way as to allow timely retrieval of the following data items for a set of patients who have been implanted with a specific device type or a specific range of lot, batch or serial numbers:

a) place of implant event and/or explant event;

b) date of implant event and/or explant event;

c) identity of the responsible clinician;

d) patient identity;

e) supplier identity and address;

f) the device name or description and catalogue number as given in the supplier's product information which uniquely identifies the type of device;

g) serial number or lot or batch number sufficient to identify the device to a level of the unique lot or batch or device;

h) primary clinical indication for implant or explant, which may be selected from a predefined list;

i) anatomical location of implant, including side where applicable;

j) disposition (location or storage) of the explanted device.

Medical facility records shall, where known, include the identity of the original producer of the implantable medical device and those suppliers known to be in the supply chain.

Medical facility data shall be maintained in such a way as to allow expeditious traceability of the implantable medical devices. Data shall be maintained for a period appropriate to the device taking into consideration the expected performance lifetime of the device.

The data may be transmitted to a third party registry for archiving purposes. Users of this International Standard should ensure that any such transmission complies with relevant national standards or regulations concerning data protection and handling.

Annex A
(informative)

Automated device labelling and data capture

Users of this International Standard are advised that the collection of the data items specified in this International Standard and, if required, the transmission of these data to third party registers may be achieved by automated methods. This annex provides reference to other publications which provide specifications for automated data collection methods and for formats for electronic data interchange.

— NP 15418, *EAN/UPC Application Identifiers and FACT Data identifiers*.

— NP 15420, *Bar coding — Symbology Specification — EAN/UPC*.

— NP 15417, *Bar coding — Symbology Specification — Code 128*.

— *The Health Industry Bar Code (HIBC) supplier labelling standard*.

— *HL7: Application Protocol for Electronic Data Exchange in Healthcare Environments*.

— *HL7's Implementation Support Guide*.

— *Appropriate standards under development by ISO/IEC JTC 1/SC 31*.

— EN 800, *Bar Coding — Symbology Specification — Code 39*.