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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery.*

This second edition cancels and replaces the first edition (ISO 16054:2000), which has been technically revised. The main changes compared to the previous edition are as follows:

— clarification to definitions with the provision of specific examples of the defined terms;

— updated general requirements for data sets with direction on what constitutes an individual implant;

— inclusion of GTIN and UDI as options for implant identification in data items lists;

— inclusion of expiry date and date of acquisition in supplier data items list;

— defined requirements for data maintenance for medical facilities;

— separated data item lists for medical facilities concerning implant and explant events and identified items specific to each type of event;

— included cause and situation in the data item list of an explant event;

— updated reference list in Annex A.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The importance and utility of registry, tracking and retrieval analysis systems in understanding long term clinical performance of implants and in patient follow up in the event of unforeseen implant malfunction is understood.

This document specifies the minimum data collection requirements 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.

It is possible to collect all the data items specified in this document and, if desired, to transfer them to third party registers using automated methods. Annex A and the Bibliography provide references to technical standards which define mechanisms for automation of both data collection and transmission. Annex A is for information only.

Implants for surgery — Minimum data sets for surgical implants

1 Scope

This document defines minimum data sets for implants to facilitate recording and international exchange of data for the purposes of implant tracking systems. This data can also be used to support retrieval analysis and implant registry.

This document is applicable to the manufacturers and distributors of medical devices intended for implant via a surgical procedure and to those hospitals and other medical facilities which carry out implant or explant procedures. It specifies requirements for data items to be recorded by the manufacturers and distributors of implants and by hospitals and other medical facilities at both the time of implant event and at the time of any subsequent explant event.

This document 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 codes, for the purpose of patient follow up.

It is not the intent of this document 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 or product recall in the event of unforeseen device malfunction.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
implant
device that is intended to be totally introduced into the human body, or to replace an epithelial surface or the surface of the eye, by means of surgical intervention and that is intended to remain in place after the procedure, or any medical device that is intended to be partially introduced into the human body by means of surgical intervention and that is intended to remain in place after the procedure for at least 30 days

Note 1 to entry: Note to entry: In this document, the term "implant" refers to each individual component of a system or a modular implant, provided separately or as a kit, as well as all ancillary implants or associated implants required for the implant event.

[SOURCE: ISO 14630:2012, 3.8, modified — The words "surgical implant" have been changed to "implant". Note to entry added.]

3.2
kit
set of components provided together and designed to be implanted as a system

EXAMPLE Pulse generator and lead(s) of an implantable cardiac pacemaker or defibrillator.

3.3
modular implant
implant which is supplied as a number of components and which is intended to be assembled by the user

EXAMPLE Femoral stem, modular femoral head, acetabular cup and liner are each separate modular components of a modular hip prosthesis.

3.4
ancillary implant
an implantable device, not included as a component of an implant system, but without which the system cannot be surgically inserted

EXAMPLE Cement for cemented stem of a hip joint replacement, or screws for orthopaedic plates.

3.5
associated implant
an implantable device, included as a component of a modular implant or supplied separately, that is surgically inserted for the specific clinical condition to facilitate the use of the primary implant

EXAMPLE An augmentation device used to stabilise the tibial tray of a knee joint replacement or the acetabular cup of a hip joint replacement; sleeves applied to the stem of a hip or knee joint prosthesis to fill canal defects and prevent rotation; a cement restrictor used in hip joint replacement to occlude the intramedullary canal.

3.6
implant event
act of surgical intervention by which an implant is

— totally introduced into the human body;

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

— partially introduced into the human body

3.7
explant event
act of surgical intervention by which an implant is removed from a patient

3.8
medical facility
person or organization responsible for maintaining the patient record

Note 1 to entry: The medical facility is typically the final customer in the distribution chain.

Note 2 to entry: In some cases, medical facilities can be considered suppliers, for example where patient records are the sole responsibility of individual surgeons practising within the medical facility.

Note 3 to entry: Medical facility can, for example, refer to hospitals and clinics.

3.9
expiry date
date on the implant packaging that defines the last possible date on which the device can be implanted

EXAMPLE Shelf life.

4 Data sets

4.1 General

It is noted that the challenge in the creation of cross referenceable datasets lies with the definition and consistent application of a basic dataset. This document can provide the initial list for tracking implants. However, in order to support, for instance, retrieval analysis, a more extensive dataset might be required.

Each implant, including ancillary and associated implants, shall be recorded separately.

For modular implants, each implanted component shall be considered a unique and separate implant.

For both implant and explant events each unique and separate implant shall be subject to recording.

4.2 Supplier data

The following data items a) to f) shall be recorded and retained by each supplier (which includes but is not limited to manufacturers, distributors and medical facilities) in the distribution chain:

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

b) customer identity;

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

d) serial code or lot or batch code, unique device identifier (UDI) or Global Trade Item Number (GTIN) sufficient to identify the device to a level of the unique lot or batch or device;

e) implant expiry date;

f) date on which the supplier acquired the implant from the manufacturer.

If a supplier in the distribution chain allocates new product catalogue codes, device names or descriptions, or serial, lot or batch codes, 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 implant 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 implants through the distribution chain.

4.3 Medical facility data

4.3.1 General

Medical facility data shall be maintained in such a way as to allow expeditious traceability of the implants. Data shall be maintained for a period appropriate to the implant(s) taking into consideration the expected performance lifetime of the implant(s).

Medical facility records shall, where known, include the identity of the implant manufacturer and those suppliers known to be in the supply chain.

4.3.2 Implant event

The implant event data shall 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 codes.

The following data items shall be recorded and retained by the medical facility for each separate implant in every implant event:

a) place (e.g. hospital) at which the implant event occurred;

b) date of implant event;

c) identity of the responsible clinician;

d) patient identity;

e) supplier and/or manufacturer identity and address;

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

g) lot, batch or serial code, whichever is sufficient to identify the implant(s) to a level of the unique lot, batch or implant respectively. Wherever possible, the UDI and/or GTIN should be recorded;

h) primary clinical indication for implant event;

i) uniquely identifiable anatomical location of implant(s), including side/position where applicable;

j) expiry date;

k) any observations relating to the implant event, provided they do not infringe patient privacy.

4.3.3 Explant event

The following data shall be recorded and retained by the medical facility for each implant retrieved during each explant event:

a) place (e.g. hospital) at which the explant event occurred;

b) date of explant event;

c) identity of the responsible clinician;

d) patient identity;

e) primary clinical indication for explant event. In addition, if the clinical indication for the explant event can be attributed to the implant, record the implant-related attribute and, if applicable, the part of the implant, that has failed;

NOTE The clinical indication can be selected from a predefined list if one exists at the medical facility.

f) uniquely identifiable anatomical location of the retrieved implant(s), including side where applicable;

g) disposition (location or storage) of the explanted implant(s). In the case where the implant(s) is sent for retrieval analysis, recorded data shall include the detail regarding the centre responsible for managing the analysis or the clinical study;

h) any observations relating to the explant event, provided they do not infringe patient privacy.

Where available, the following information shall also be included:

i) supplier and/or manufacturer identity and address;

j) traceability marks available from the retrieved implant(s) or implantation records i.e. serial code, lot or batch code or UDI.

Annex A
(informative)

Automated device labelling and data capture

The collection of the data items specified in this document and, if required, the transmission of these data to third party registers can be achieved by automated methods. Publications which provide specifications for automated data collection methods and for formats for electronic data interchange can be found in the Bibliography.