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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).

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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.

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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.

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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.]

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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.

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