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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
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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.

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.