Implants for surgery - Minimum data sets for surgical implants

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 16054:2002 sisaldab Euroopa standardi EN ISO 16054:2002 ingliskeelset teksti. Käesolev dokument on jõustatud 12.07.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 16054:2002 consists of the English text of the European standard EN ISO 16054:2002. This document is endorsed on 12.07.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This International Standard defines minimum data sets for surgial implants to facilitate recording and international exchange of data for the purposes of implant registry and tracking to allow recall for product correction or patient follow cross referencing between extended data sets for the purposes of retrieval analysis and research.	**Scope:** This International Standard defines minimum data sets for surgial implants to facilitate recording and international exchange of data for the purposes of implant registry and tracking to allow recall for product correction or patient follow cross referencing between extended data sets for the purposes of retrieval analysis and research.

ICS 11.040.40

Võtmesõnad: ceramic, ceramics, data records, definition, definitions, fine mechanics, implants (surgical), information exchange, international, medical sciences, medicine, sintered, specification (approval), specifications, surgery, surgical implants

EUROPEAN STANDARD
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EN ISO 16054

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English version

Implants for surgery

Minimum data sets for surgical implants

(ISO 16054 : 2000)

Implants chirurgicaux – Ensembles minimaux de données relatives aux implants chirurgicaux (ISO 16054 : 2000)

Chirurgische Implantate – Mindestdatensätze für chirurgische Implantate (ISO 16054:2000)

This European Standard was approved by CEN on 2002-04-11.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Management Centre: rue de Stassart 36, B-1050 Brussels

Ref. No. EN ISO 16054 : 2002 E

Foreword

International Standard

ISO 16054 : 2000 Implants for surgery – Minimum data sets for surgical implants,

which was prepared by ISO/TC 150 'Implants for surgery, has been adopted by Technical Committee CEN/TC 285 'Non-active surgical implants', the Secretariat of which is held by NEN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by November 2002 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 16054 : 2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative.)

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.

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