INTERNATIONAL STANDARD

ISO 12891-1

Third edition
2015-07-01

Retrieval and analysis of surgical implants —

Part 1: Retrieval and handling

Retrait et analyse des implants chirurgicaux —

Partie 1: Retrait et manipulation

Reference number
ISO 12891-1:2015(E)

© ISO 2015



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Terms and definitions ... **1**

3 Method ... **2**

3.1 Obtaining the clinical history of the implant and patient ... 2
3.2 Pre-explantation checks and examinations ... 2
3.3 Collecting the surgical implant ... 2
3.4 Collecting the tissue and fluid samples ... 3
3.5 Photographic record of the explantation ... 3
3.6 Containing and labelling the retrieved surgical implant, tissues, and fluids for future identification ... 4
3.7 Cleaning the retrieved surgical implant ... 4
3.8 Decontaminating the retrieved surgical implant ... 6
3.9 Packaging the retrieved surgical implant, tissues, and fluids for shipment ... 7
3.10 Use of coolant materials ... 8
3.11 Labelling of the packing materials ... 8
3.12 Documentation to be supplied with retrieved surgical implants ... 8
3.13 Unpacking following shipment ... 9
3.14 Cleaning and decontamination following shipment ... 9
3.15 Documentation to be maintained during examination, analysis, and storage ... 9

4 Analysis of retrieved surrounding tissues and fluids ... **9**

5 Infection control ... **9**

5.1 General ... 9
5.2 Work practices ... 10
5.3 Personal protective equipment ... 10
5.3.1 General ... 10
5.3.2 Gloves ... 10
5.3.3 Masks, eye protection, and face shields ... 10
5.3.4 Gowns, aprons, and other protective body clothing ... 11
5.4 Maintenance of the worksite ... 11
5.4.1 Cleaning and disinfection of worksites ... 11
5.4.2 Protective coverings ... 11
5.4.3 Equipment and tools ... 11
5.4.4 Reusable receptacles ... 12
5.4.5 Contaminated glassware ... 12
5.4.6 Reusable items ... 12
5.4.7 Contaminated materials ... 12
5.5 Human waste disposal ... 12
5.6 Special practices ... 13

Annex A (informative) **Suggested minimum information to be obtained for retrieved surgical implants** ... **14**

Annex B (informative) **Generic procedures for the decontamination of surgical implants** ... **17**

Annex C (informative) **Analyses to be performed on retrieved tissue samples and fluids** ... **23**

Bibliography ... **24**

© ISO 2015 – All rights reserved

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*.

This third edition cancels and replaces the second edition (ISO 12891-1:2011), which has been technically revised.

ISO 12891 consists of the following parts, under the general title *Retrieval and analysis of surgical implants*:

— *Part 1: Retrieval and handling*

— *Part 2: Analysis of retrieved surgical implants*

© ISO 2015 – All rights reserved

Introduction

The investigation of retrieved surgical implants, adjacent tissues, and associated fluids can be undertaken to

— determine the cause of a clinical complication or surgical implant failure,

— improve knowledge of surgical implant performance and safety,

— improve knowledge of the interactions of surgical implants and the human body, and

— develop materials with improved biocompatibility and implants with improved functional longevity.

This International Standard specifies methods for the retrieval, handling, and analysis of surgical implants and associated tissue samples and fluids which are removed from patients during retrieval surgery or post-mortem. ISO 12891-2 specifies methods for the detailed analysis of surgical implants, in which protocols are provided for the collection of data and examinations for surgical implants in relation to their typical applications. For particular investigation programmes, additional, more specific, protocols can be required. If special analytical techniques are employed, the appropriate handling procedures need to be specified.

The purpose of this International Standard is to

— specify a method for the retrieval of surgical implants which is intended to prevent damage to implants, associated tissues, and fluids,

— ensure that retrieved materials are handled safely and decontaminated correctly and that the risk of transmission of infectious diseases is minimized,

— ensure that the retrieval process is properly documented, and

— allow comparisons between investigation results from different sources.

Many variables are involved when undertaking the retrieval of surgical implants. The retrieval can be for the routine replacement of a pacemaker battery or it can be for the revision of a defective surgical implant. The retrieval can be from a living patient or it can be a post-mortem study. The retrieval can involve the removal of a single surgical implant or multiple components as, for example, in the case of hip replacements or certain fracture fixation or spinal devices. In addition to the retrieval of the surgical implant, associated tissues and fluids might also need to be removed. The retrieval can involve a wide variety of personnel such as surgeons, nurses, other hospital staff, surgical implant manufacturer, investigator, and shipping service. Finally, the type of analysis to be performed can vary and can include visual, chemical, histological, and microbiological studies and the eventual analysis can have an impact on the retrieval process. These variables make it impossible to specify a single method which has to be followed in all retrieval cases. For this reason, certain requirements listed in this part of ISO 12891 might only be applicable in certain circumstances and for this reason, some of the requirements are prefaced with statements such as “If applicable” or “Whenever possible”.

This International Standard presents a methodology for the systematic retrieval of surgical implants. It focuses on the practical requirements in particular. In addition to these requirements, there are legal and ethical considerations which might need to be taken into account. These considerations include matters relating to the ownership of the implant, the obtaining of the patient’s consent before the implant is retrieved, the patient’s right to confidentiality, and the need to protect the patient’s safety, health, and litigation rights throughout. For a detailed consideration of these issues, appropriate advice can be sought.

NOTE The methods specified in this International Standard can also be applicable to the retrieval and analysis of surgical implants in animal studies.

© ISO 2015 – All rights reserved

Retrieval and analysis of surgical implants —

Part 1:
Retrieval and handling

1 Scope

This part of ISO 12891 specifies the method to be followed for the retrieval and handling of surgical implants and associated tissues and fluids. In particular, it specifies the essential steps to be followed for the safe and proper obtaining of the clinical history, pre-explantation checks and examinations, collection, labelling, cleaning, decontamination, documentation, packing and shipping. This part of ISO 12891 also provides guidance on infection control.

NOTE National or other regulations, which can be more stringent, can apply.

This part of ISO 12891 does not apply in cases of explantation where there is no intention to collect retrieval data. However, many clauses give useful information which can apply in these cases also.

2 Terms and definitions

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

2.1
absorbent
material capable of absorbing liquids

Note 1 to entry: Absorbent material can either be particulate or non-particulate.

2.2
contamination
unintentional addition or modification, including exposure to a potentially infectious agent

2.3
infectious waste
waste containing or suspected to contain human pathogenic microbiological agents

2.4
outer shipping container
outermost container in which the package is finally shipped

2.5
primary container
tube, envelope, or other impermeable container which holds the retrieved material to be shipped

2.6
secondary container
container into which the primary container is placed

© ISO 2015 – All rights reserved