BS ISO 12891-1:2015

BSI Standards Publication

Retrieval and analysis of surgical implants

Part 1: Retrieval and handling

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National foreword

This British Standard is the UK implementation of ISO 12891-1:2015. It supersedes BS ISO 12891-1:2011 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150, Implants for surgery.

A list of organizations represented on this committee can be obtained on request to its secretary.

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INTERNATIONAL STANDARD

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Retrieval and analysis of surgical implants —

Part 1: Retrieval and handling

Retrait et analyse des implants chirurgicaux —

Partie 1: Retrait et manipulation

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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 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*

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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.

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INTERNATIONAL STANDARD ISO 12891-1:2015(E)

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

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3 Method

3.1 Obtaining the clinical history of the implant and patient

Whenever possible, the clinical history of the patient and the surgical implant shall be obtained and recorded. This clinical history shall include at least the following, if available:

— name or identification number of the patient as permitted by the applicable national regulations;

— original diagnosis which resulted in the use of the surgical implant;

— X-ray of the surgical implant *in situ* taken after the insertion operation;

— patient's activity level including the ability to perform work, sports, and recreational activities;

— patient's medical history relevant to the surgical implant, including the hospital or clinic at which the surgical implant was implanted;

— information on the patient's experience with the surgical implant just before surgical implant retrieval;

— date of retrieval;

— hospital or clinic at which the surgical implant was retrieved.

The information obtained should be treated as confidential.

NOTE 1 Annex A gives an example of the information to be obtained. The annex can be modified as necessary, e.g. for special investigations.

NOTE 2 In any analysis of an explanted surgical implant, it is advantageous to have as much relevant knowledge of the clinical history as possible.

3.2 Pre-explantation checks and examinations

Whenever possible, data which might be lost post-explantation should be collected prior to explantation.

Whenever possible, a functional check of the implant involving an objective measurement shall be performed before explantation surgery.

NOTE A functional check assists in the understanding of the post-explantation behaviour.

If applicable, electronic or other data associated with the surgical implant shall be collected before the implant is explanted. These data should be provided to the evaluator of the surgical implant.

Where appropriate and justifiable, taking into account the need for patient safety, non-invasive examinations of the implantation site with the implant *in situ* shall be performed before the implant is explanted. Such examinations may include X-ray, computed axial tomography scan, or magnetic resonance imaging.

3.3 Collecting the surgical implant

Taking into account the need for patient safety, the surgical implant shall be retrieved in a manner which causes as little damage as possible to both the surgical implant and the surrounding tissues. As far as possible, functional surfaces, e.g. bearing surfaces of joint prostheses, mechanical connections, e.g. hinges, joints, screws, and fracture surfaces of broken surgical implants, shall be protected during and after explantation.

Fragments and debris which can provide valuable information shall also be retrieved.

Retrieved surgical implants should be handled with care either by hand or using appropriate instruments.

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The following shall be documented:

a) position or orientation or state of the retrieved components, if there is more than one retrieved component and if the position or orientation or state is abnormal;

b) location and type of damage, if damage occurs during explantation.

NOTE For proper scientific examination, it is advantageous for the surgical implant to be maintained in a state as close as possible to that in which it existed at the time of retrieval.

3.4 Collecting the tissue and fluid samples

Taking into account the need for patient safety, if tissue and/or fluid samples are to be collected for analysis, then these shall be retrieved in a manner which causes as little damage as possible to both the surgical implant and the tissues.

For microbiological investigation, swabs, tissue, and/or fluid samples shall be taken from a location adjacent to the implant as soon as possible after the surgical implant has been exposed. Where and how the specimens are taken shall be recorded.

NOTE Special culturing techniques can be required to reveal unusual organisms. Sampling for immunological investigations requires expert advice and can call for special procedures.

For histological examination, tissue samples shall be taken from a location adjacent to the implant and/or from other relevant sites (e.g. lymph nodes or any tissue with abnormal appearance).

When possible, tissue samples for histological examination shall include portions extending into the normal tissue.

The site of the tissue excision and the orientation of the tissue relative to the surgical implant shall be indicated and recorded. Where possible, the proximal end of the tissue shall be marked (e.g. with a suture). Where necessary, the original length of the tissue shall be maintained (e.g. with plastic muscle biopsy clamps or by pinning the tissue to a corkboard or by other means, which avoid contact with metal which could corrode).

The tissue samples for histological examination shall be transferred as early as possible to an appropriate fixative or other media. The type of fixative used and the time between excision and placement in the fixative or media shall be documented. The tissue sample shall be treated in a routine manner as required for histological examination, unless a special method is needed for special investigations.

If appropriate, the media used to preserve tissue attached to a retrieved surgical implant shall be selected so as not to affect the surgical implant. When it is not possible to preserve the tissues without affecting the retrieved surgical implant, the portions of the retrieved surgical implant to be analysed should be determined and the tissue preserved accordingly.

Fluids obtained by aspiration shall be appropriately preserved for examination unless a special method is needed for special investigations. The preservation method should be chosen taking into account the intended analysis.

In post-mortem studies, histological examination of remote tissues, e.g. liver and kidney, should also be performed if there is a need to assess toxicity in these locations.

3.5 Photographic record of the explantation

Where appropriate, photographic records shall be made of the surgical implant *in situ* of the surgical site and of the explanted surgical implant and any associated tissue specimens.

Where appropriate, the orientation of all removed surgical implant components in relation to each other and their placement in relation to the body and associated excised material shall be recorded. If not self-explanatory, the proximal end and the orientation in the transverse plane of the implant shall be

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