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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

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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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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*

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.

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

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.

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

marked and documented. Any observed abnormalities in the appearance or condition of the device shall be recorded.

NOTE As appropriate, either the surgical implant and the tissues themselves or the support upon which they are placed (e.g. a corkboard) can be marked.

3.6 Containing and labelling the retrieved surgical implant, tissues, and fluids for future identification

Immediately after collection or photography, all surgical implants, associated tissues, and fluids, which are retrieved for analysis, shall be placed in appropriate containers that can be sealed in such a way that any subsequent opening of the containers can be detected. Suitable containers include envelopes, bags, jars, pots, and boxes.

NOTE Adhesive tape is normally used to seal the containers.

For example, when the container is an envelope, the flap of the envelope shall be taped so that the tape covers both the flap and the envelope itself. When the container is a bag, the opening of the bag shall be sealed with tape. Similarly, when the container is a jar, pot, or box, the juncture of the lid and the container shall be taped. The retriever shall place his initials across the tape. In this way, opening the container tears the tape and disturbs the initials.

Immediately after containing the surgical implants, tissues, and fluids, all containers shall be labelled to ensure their precise identification at some later date. The label shall contain at least the following information:

a) accurate description of the contents of the container (e.g. vascular graft, type XYZ);

b) name or initials of retriever;

c) date, time, and place of retrieval;

d) name or identification number of patient, if available, as permitted by the applicable national regulations;

e) container number or identifier, if there is more than one container;

f) orientation of each component relative to the others, if there is more than one retrieved component and if the orientation is abnormal.

The labels used shall be of a non-removable type (labels that tear when someone tries to remove them).

3.7 Cleaning the retrieved surgical implant

All surgical implants which are retrieved for analysis shall be cleaned before decontamination, unless otherwise specifically instructed. Cleaning can be performed off-site.

Retrieved surgical explants shall be cleaned as follows.

The retrieved surgical implant shall be thoroughly rinsed under running water, but not scrubbed, to remove all biological contaminants, unless such contaminants are important to the analysis. Adherent tissues considered important to the analysis shall be treated as a tissue sample (see 3.4). Loosely adherent material of possible interest should be preserved before the surgical implant is rinsed.

The retrieved surgical implant shall, in addition, be cleaned as recommended by the manufacturer. If the manufacturer cannot be contacted or is unable to supply a means for cleaning the surgical implant, the method chosen shall be that given in Table 1 or any other method which has been shown to be effective while preserving the integrity of the implant, e.g. peracetic acid.

All solutions to be used in the cleaning of retrieved surgical implants shall be prepared at the time of cleaning and shall not be stored in the laboratory for future use. Proteolytic enzyme solutions and

ultrasonic bath solutions shall be disposed of according to the manufacturer's instruction or may be decontaminated using a chemical disinfectant and discarded in the sanitary sewer. Depending on local sewage company requirements and on the recommendation of the manufacturer, chemical cleaning agents might need to be neutralized before discarding into the sanitary sewer.

Any biological debris removed from the surgical implants shall be decontaminated by autoclaving, or disinfected through a chemical disinfectant before disposal (see 5.5).

NOTE Table 1 presents general recommendations and is intended for use only when a manufacturer's recommendations cannot be obtained.

When chemical cleaning agents and/or an ultrasonic bath are used, cleaning should be performed inside a class II, type B (see Reference [2]), biological safety cabinet, which should be exhausted to the outside. In cases where there is tissue in-growth present, a proteolytic enzyme solution may be used in conjunction with ultrasonic cleaning, but only when no histological investigation is planned. Retrieved surgical implants which are too large to be placed in an ultrasonic bath shall be sprayed or surface-wiped with an appropriate chemical cleaning agent or disinfected according to the ultrasonic bath solutions manufacturer. Such surgical implants should be cleaned in a biological safety cabinet of the class and type described above or in an isolated and well-ventilated area in the laboratory. Proper protective precautions, as specified in Clause 5, should be followed. Disposable swabs, brushes, and wipes may be used to remove visible debris from such implants, in conjunction with an appropriate chemical agent.

Table 1 — Generic recommendation for cleaning and decontaminating explanted surgical implants

Device or implant[a] disinfected	Cleaning method[b]	Decontamination method[b,c]
Cardiac pacemaker housing	Proteolytic enzyme solution or 70 % to 80 % isopropanol	Ethylene oxide gas or 70 % to 80 % ethanol or 3 % stabilized hydrogen peroxide
Leads	70 % to 80 % ethanol or 70 % to 80 % isopropanol	70 % to 80 % ethanol or 70 % to 80 % isopropanol
Cardiac valve: Mechanical valves	Proteolytic enzyme solution at or below room temperature with subsequent ultrasonic treatment	Ethylene oxide gas
Xenografts	Proteolytic enzyme solution	Ethylene oxide gas or buffered, alkaline 2 % solution of glutaraldehyde
Allografts	Broad-spectrum antibiotic solution	Ethylene oxide gas or buffered, alkaline 2 % solution of glutaraldehyde
Vascular grafts, biologic	2 % buffered alkaline glutaraldehyde	Buffered, alkaline 2 % glutaraldehyde
Vascular grafts, synthetic	Proteolytic enzyme or 3 % stabilized hydrogen peroxide solution with subsequent ultrasonic treatment	Ethylene oxide gas or buffered, alkaline 2 % solution of glutaraldehyde or 4 % formaldehyde solution
Intra-aortic balloons and other temporary cardiac-assist implants	Peracetic acid[d] with subsequent ultrasonic treatment or solution sodium hypochlorite (500 mg/l to 600 mg/l)	Ethylene oxide gas or 70 % aqueous solutions of ethanol or isopropanol

[a] When tissues are to be preserved, methods such as glutaraldehyde fixation may be used.

[b] Percentages are volume fractions.

[c] For disinfecting, a soaking time of 2 h to 3 h is sufficient. However, a 24 h contact time may be used to provide an extra margin of safety.

[d] **WARNING — Peracetic acid is an explosive; it should be used with caution and stored in an explosion-proof refrigerator.**

[e] KOH (c = 4 mol/l) shall be used for final disposition of central nervous system explants.

Table 1 *(continued)*

Device or implant[a] disinfected	Cleaning method[b]	Decontamination method[b,c]
Breast implants	Intense water rinse, proteolytic enzyme solution with subsequent ultrasonic treatment	2 % glutaraldehyde, 4 % formaldehyde or ethylene oxide gas
Hydrocephalus shunts	Proteolytic enzyme solution at or below room temperature with subsequent ultrasonic treatment	Buffered, alkaline 2 % glutaraldehyde, ethylene oxide gas or 4 % formaldehyde[e]
Vascular port and peritoneal access implants	Sodium hypochlorite solution (50 mg/l to 60 mg/l) or 3% hydrogen peroxide	Buffered, alkaline 2 % solution of glutaraldehyde or 70 % ethanol or isopropanol with 0,2 % glutaraldehyde
Intraocular lenses (HEMA)		Ethylene oxide gas
Silicone elastomeric and polymeric implant components	70 % to 80 % aqueous ethanol or isopropanol with subsequent ultrasonic treatment or sodium hypochlorite solution (50 mg/l to 60 mg/l) or 3 % hydrogen peroxide	Ethylene oxide gas or buffered, alkaline 2% solution of glutaraldehyde
Polymeric implant components (PMMA, PE-UHMW)	Proteolytic enzyme solution, with ultrasonic treatment, or sodium hypochlorite solution (50 mg/l to 60 mg/l) or 3 % hydrogen peroxide	Buffered, alkaline 2 % solution of glutaraldehyde or ethylene oxide gas
Metallic implant components	Intense water rinse, 70 % to 80 % aqueous ethanol or isopropanol with subsequent ultrasonic treatment or proteolytic enzyme or sodium hypochlorite solution (50 mg/l to 60 mg/l) or 3 % hydrogen peroxide	Steam autoclave or ethylene oxide
Ceramic implant components	Proteolytic enzyme solution, with ultrasonic treatment or sodium hypochlorite solution (50 mg/l to 60 mg/l) or 3 % hydrogen peroxide	Buffered, alkaline 2 % solution of glutaraldehyde or ethylene oxide gas

[a] When tissues are to be preserved, methods such as glutaraldehyde fixation may be used.

[b] Percentages are volume fractions.

[c] For disinfecting, a soaking time of 2 h to 3 h is sufficient. However, a 24 h contact time may be used to provide an extra margin of safety.

[d] **WARNING — Peracetic acid is an explosive; it should be used with caution and stored in an explosion-proof refrigerator.**

[e] KOH (c = 4 mol/l) shall be used for final disposition of central nervous system explants.

3.8 Decontaminating the retrieved surgical implant

After cleaning, all surgical implants which are retrieved for analysis shall be decontaminated, unless they are to be packaged and sealed without being decontaminated.

Retrieved and cleaned surgical explants shall be decontaminated as follows.

The retrieved surgical implant shall be decontaminated as recommended by the manufacturer. If the manufacturer cannot be contacted or is unable to supply a means for decontaminating the surgical implant, the method chosen shall be that given in Table 1 or any other method which has been shown to be effective while preserving the integrity of the implant.

CAUTION — Unless approved by the manufacturer, do not apply the autoclave method for devices with batteries. Use alternative methods instead.