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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 12891-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

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 metallic surgical implants*

— *Part 3: Analysis of retrieved polymeric surgical implants*

— *Part 4: Analysis of retrieved ceramic surgical implants*

Future parts will deal with other relevant aspects of retrieval and analysis of surgical implants.

Annexes A, B, and C of this part of ISO 12891 are for information only.

Introduction

The investigation of retrieved surgical implants and adjacent tissues can be of diagnostic value in case of clinical complications, can deepen the knowledge about clinical implant performance and interactions between implants and the body, provide information on implant failure and safety, and thus furthers the progress of the development of biocompatible implant materials and implants with improved functional longevity.

This part of ISO 12891 offers guidelines for the handling and analysis of removed implants and tissues to prevent their damage, and to allow comparisons between investigation results from different sources. These guidelines may also serve for the documentation of clinical investigations. They may also be useful for retrieval and analysis studies in animals. Further parts of this International Standard describe methods of detailed analysis of implants.

Retrieval and analysis of surgical implants

Part 1:
Retrieval and handling

1 Scope

This International Standard, with its several parts, gives recommendations for the retrieval, handling and analysis of surgical implants, medical implants and associated specimens which are removed from patients routinely, during revision surgery, or post mortem. The aim is to provide guidance in preventing damage to the associated specimens which could obscure investigation results, and in gathering data at the proper time and circumstance to validate the study.

ISO 12891-1 is intended to be the overall guidance document for the retrieval and handling of surgical implants, ensuring their safe and proper retrieval, sterilization and handling.

In the associated parts of this International Standard, protocols for the collection of data and examinations are provided for specific types of material in relation to their typical applications. For particular investigation programmes, additional, more specific, protocols may be required. If special analytical techniques are employed, the appropriate handling procedures need to be specified.

This part of ISO 12891 should be applied in accordance with national regulations or legal requirements regarding the handling and analysis of retrieved implants and tissues.

2 Terms and definitions

For the purposes of this part of ISO 12891, the following terms and definitions apply.

2.1
absorbent material
material that is capable of absorbing liquids

NOTE The material may be either particulate or non-particulate.

2.2
adulteration
any unintentional addition to or modification of a specimen

2.3
biological product
any material of human or animal origin

2.4
clinical specimen
any human or animal material, including, but not limited to, excreta, secreta, blood and its components, body fluids, tissue and tissue fluids

2.5
contamination
adulteration of a specimen, including exposure to a potentially infectious agent

2.6
clinical waste
all waste, including infectious waste

2.7
coolant material
material that is included in the package to cool the contents

EXAMPLE Ice, dry ice and gel packs.

2.8
aetiologic agent
microbiological agent or its toxin that causes, or can cause, human disease

2.9
infectious waste
waste containing or suspected to contain human pathogenic microbiological agents

2.10
outer shipping container
outermost container in which the package is finally shipped

2.11
primary container
tube, envelope, or otherwise impermeable container which holds the material to be shipped

2.12
secondary container(s)
container(s) into which the primary container is placed

3 General information on procedures related to the retrieval of the implant

3.1 General

Implants and related tissue-adjacent specimens should be removed in a manner which causes minimal damage to both the implant and the tissues. It is particularly important that functional surfaces, such as bearing surfaces of joint protheses and fracture surfaces of broken implants, e.g. fractured heart-valve occluded surfaces, be protected.

3.2 Clinical history of the implant/patient

In any analysis of an explanted surgical implant, knowledge of the clinical history of the implant is advantageous. When possible, this should include information on the original diagnosis which resulted in the use of the surgical implant, information on the lifestyle activity level of the individual, including substance abuse, work habits and sports and recreational preferences, other available medical history and information on the individual's experience with the implant just prior to the implant removal. An example of the information to be obtained is shown in annex B.

3.3 Pre-explantation functional check

Whenever possible, a pre-explantation functional check of the implant is recommended to assist in understanding the post-explantation behavior. An objective measurement of functional level should be performed when possible.

3.4 Explantation record

Non-invasive examination of the implantation site with the implant *in situ*, e.g. X-ray and CAT scan, are recommended before removal.

, of the surgical site, and of the implant *in situ* are recommended.

moved implant components to each other and their placement in relation to the
al. If not self-explanatory, the proximal end of the implant should be marked.

Fragments, debris, breakable components which may be destroyed if dropped must be placed in appropriate containers for handling and transport.

3.5 Microbiological study of the surrounding tissue

Take swabs and/or tissue samples for microbiological investigation as early as possible after the implant has been exposed. Special culturing techniques may be required to reveal delicate or unexpected organisms. Sampling for immunological investigations requires expert advice and may call for special procedures. Where and how the specimens are taken should be recorded.

3.6 Tissue and fluid sampling for histological examination

Tissue samples should be taken from a location adjacent to the implant or at other relevant sites (e.g. lymph nodes or any tissue with abnormal appearance). In addition, consider the need to assess toxicity in remote tissues, e.g. liver, kidney, etc. These samples should include portions extending into the normal tissue. Media used to preserve tissues attached to an explanted implant shall not affect the associated implant.

Record the site of the tissue excision and indicate the tissue orientation relative to the implant. Where possible, mark the proximal end of the tissue. The original length of the tissue should be maintained (e.g. with plastic muscle biopsy clamps or by other means, avoiding metal which could corrode). The tissue samples should be transferred as early as possible to an appropriate fixative or other media and be treated in a routine manner as required for histological examination, unless otherwise requested for special investigations.

When it is not possible to preserve the tissues and not affect the associated implant, decide which portions of the explant shall be analysed and preserve the tissue accordingly.

Fluids obtained by aspiration should be appropriately preserved for examination unless otherwise requested for special investigation.

3.7 Identification of the explant

3.7.1 General

Three steps in the handling of retrieved surgical implants are critical to the prevention of changes in the implant that can have an adverse effect on its scientific value:

— collecting the implant;

— labelling the implant for future identification; and

— maintaining the proper record documentation.

3.7.2 Collecting the implant

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. For proper scientific examination, the implant must be preserved in a state as close as possible to that in which it existed at the time of removal from the patient. Therefore, it is important that care be given during the handling, examination and storage of these implants to ensure that they are not damaged or altered. Special care should be given to the protection of the implant surfaces from damage during handling, shipment, etc.

3.7.3 Labelling the implant for future identification

Label all recovered implants immediately and properly to ensure their precise identification at some later date. The orientation of all explant components relative to adjacent components should be marked. Mark each implant as

soon as it is removed from its original position. Either of two basic methods for labelling surgical implants is appropriate:

a) affixing a nonremovable label (labels that tear when someone tries to remove them); or

b) sealing them in a container that is subsequently labelled.

Labels used on retrieved implants should be of a nonremovable type that contain at least the retriever's initials, and the date and time of retrieval. In addition, the access number and any similar identifying information should be included on this label if at all possible.

If a label cannot be affixed directly to the implant or would compromise further investigation, the implant should be placed in an appropriate container that can be sealed and a label with the above-described information affixed to the container. It is important that the container be sealed in such a way that any subsequent opening of the container can be detected. For example, when using an envelope, the flap of the envelope should be taped so that the tape covers both the flap and the envelope itself, with the originator placing his name or initials across the tape. In this way opening the envelope tears the tape and disturbs the initials. When containers such as jars are used, the juncture of the lid and the jar should be taped and initialed so that opening the jar disturbs the tape and the initials.

3.7.4 Documentation

Forward documentation with the retrieved materials; this will assist in their identification and examination. Annex B provides a guideline for the collection of clinical data. The annex may be modified for special investigation programmes. Treat the filled-in form as a confidential document. The data are intended as information for the chief investigator.

Documentation shall begin when the implant is recovered and continue until examination and analysis is complete. Everyone who handles, examines or stores the implant shall be required to amend the documentation to ensure a complete history and understanding of the analytical findings.

The following procedure should be used for recording retrieval information:

a) In accordance with 4.2.2 of this part of ISO 12891, the surgical implant manufacturer should be contacted to obtain recommendations concerning proper methods for cleaning and disinfecting the implant. Record the name of the individual who provides such recommendations. Record the recommended cleaning and sterilizing method.

b) Record the name of the shipping service (i.e. postal service, courier, etc.), shipping number, date of shipment and time of release.

c) If the surgical implant is to be stored following examination, record the storage location.

d) The documentation shall reflect the names of all responsible individuals handling the implant during retrieval and preparation for shipping, and all activities performed in conjunction with this handling

4 Explant handling

4.1 Preservation methodology

Because preservation techniques may affect the material properties or function of the implant being retrieved, information on preservation techniques specific to the type of implant being recovered is contained in the relevant clauses of this part of ISO 12891.

As outlined below, the implant manufacturer's recommendations regarding the preservation of the implant shall be observed.

4.2 Cleaning and sterilization of surgical implants

4.2.1 General

Clean and sterilize all explanted surgical implants recovered for analysis before examination, unless otherwise specifically instructed. Where possible, handle explanted implants with forceps or other instruments. Clean medical implants in accordance with the procedures described below.

Implants destined to be cleaned and/or sterilized at a location outside of the biosafety cabinet (described below) should be placed into a sealable container for transport. Spray or surface-wipe the transport container with a 1:100 aqueous dilution of sodium hypochlorite before removal from the cabinet. Generic recommendations for these procedures are given below.

4.2.2 Selection of a cleaning/sterilization method

Contact the manufacturer of the explanted implant to select the proper method of cleaning and sterilization. Enter the choice of cleaning and sterilization method, as well as the name of the contact person from the manufacturer, into the disinfection/sterilization documentation.

In the event the manufacturer cannot be contacted, or is unable to supply a means for cleaning and sterilization of the implant, the choice of method shall proceed using either Table 2, or any other procedure which has been shown effective while preserving the integrity of the implant. Include the method used in the disinfection/sterilization documentation discussed in 3.7 of this part of ISO 12891.

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

4.2.3 Generic methods for surgical implant cleaning

To facilitate subsequent sterilization, surgical explants must first be thoroughly cleaned to remove all biological contaminants, unless they are important to the analysis. If a substantial amount of tissue adheres to the implant it should be treated as for tissue samples. Adherent tissues considered important to the analysis shall be treated as a tissue sample. Loosely adherent material of possible interest should be preserved prior to implant rinsing. Retrieved implants may be rinsed under running water but not scrubbed.

The implants may either be packed and sealed without disinfecting treatment or may be disinfected prior to packing. Either treatment should be mentioned on a label on the package. Because disinfection techniques may affect the properties of the implant material being retrieved, information on disinfection techniques which are specific to the materials of the implant being explanted is contained in the relevant clauses of this part of ISO 12891.

Any method of cleaning used must be entered onto the disinfection/sterilization document, discussed in 3.7. In addition, the biological debris removed from the surgical implants shall be sterilized by autoclaving, or disinfected via a chemical disinfectant, before disposal (see 6.5). When chemical cleaning agents and/or an ultrasonic bath are used, cleaning should be performed inside a Class II, Type B[1], biological safety cabinet, which should be exhausted to the outside. Small surgical implants can be cleaned in an ultrasonic bath. 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 histologic investigation is planned.

Table 1 — Generic recommendation for cleaning, disinfecting and sterilizing explanted surgical implants

Device/implant[a] disinfected	Cleaning method	Sterilizing or disinfecting[b] method
Dialyser	1:100 solution sodium hypochlorite or 3 % hydrogen peroxide	4 % formaldehyde solution in conjunction with 3 % hydrogen peroxide treatment
Haemodialysis membranes	4 % formaldehyde or 2 % glutaraldehyde	4 % formaldehyde or 2 % glutaraldehyde
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 valves: 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[c] with subsequent ultrasonic treatment *or 1:50 solution sodium hypochlorite*	Ethylene oxide gas or 70 % aqueous solutions of ethanol or isopropanol
Breast prostheses	*Intense water rinse,* proteolytic enzyme solution with subsequent ultrasonic treatment	2 % glutaraldehyde, 4 % formaldehyde or ethylene oxide gas
Hydrocephalus shunts	Proteolytic enzyme solution or 3 % stabilized hydrogen peroxide with subsequent ultrasonic treatment	Buffered, alkaline 2 % glutaraldehyde, ethylene oxide gas or 4 % formaldehyde[d]
Nasogastric tubes	3 % stabilized hydrogen peroxide with subsequent ultrasonic treatment *or 1:100 solution sodium hypochlorite*	Ethylene oxide gas
Endoscopes (fibre-optic)		Buffered, alkaline 2 % solution of glutaraldehyde or ethylene oxide gas
Tracheostomy tubes	3 % stabilized hydrogen peroxide with subsequent ultrasonic treatment *or 1:100 solution sodium hypochlorite*	Ethylene oxide gas
Vascular port and peritoneal access implants	*1:100 solution sodium hypochlorite*	Buffered, alkaline 2 % solution of glutaraldehyde or 70 % ethanol or isopropanol with 0,2 % glutaraldehyde
Urinary catheters (Foley) latex	70 % to 80 % aqueous ethanol or isopropanol with subsequent ultrasonic treatment *or 1:100 solution sodium hypochlorite*	Ethylene oxide gas
Silicone elastomers and polymers	70 % to 80 % aqueous ethanol or isopropanol with subsequent ultrasonic treatment	Ethylene oxide gas or buffered, alkaline 2 % solution of glutaraldehyde
Polymeric orthopaedic components (PMMA, PE-UHMW)	Proteolytic enzyme solution, with ultrasonic treatment, *or* 3 % stabilized hydrogen peroxide, *or 1:100 solution sodium hypochlorite*	Buffered, alkaline 2 % solution of glutaraldehyde or ethylene oxide gas
Metallic orthopaedic components	Intense water rinse, 70 % to 80 % aqueous ethanol or isopropanol with subsequent ultrasonic treatment *or proteolytic enzyme or 1:100 solution sodium hypochlorite*	Steam autoclave or ethylene oxide

Ceramic orthopaedic components	Proteolytic enzyme solution, with ultrasonic treatment or 3 % stabilized hydrogen peroxide *or 1:100 solution sodium hypochlorite*	Buffered, alkaline 2 % solution of glutaraldehyde or ethylene oxide gas
Intraocular lenses HEMA		Ethylene oxide gas
PMMA	Water *or with care proteolytic enzyme*	3 % solution of hydrogen peroxide

a) When tissues shall be preserved, methods such as glutaraldehyde fixation may be used.

b) For disinfecting, a soaking time of 2 h to 3 h is sufficient. However, a 24-h contact time can be used to provide an extra margin of safety.

c) **Warning: Peracetic acid is an explosive; it should be used with caution and stored in an explosion-proof refrigerator**.

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

Prepare all solutions used in the cleaning of surgical implants at the time of cleaning, and do not store them in the laboratory for future use. Proteolytic enzyme solutions and ultrasonic bath solutions may be decontaminated using a chemical disinfectant, and discarded in the sanitary sewer. Neutralize chemical cleaning agents before discarding in the sanitary sewer.

Medical implants which are too large for placement in an ultrasonic bath shall be sprayed or surface-wiped with an appropriate chemical cleaning agent. Clean in an isolated and well-ventilated area in the laboratory. Follow proper protective precautions, as described in clause 6. Disposable swabs, brushes and wipes may be used to remove visible debris from such implants, in conjunction with an appropriate chemical agent.

4.2.4 Generic procedures for surgical implant sterilization

Generic procedures which have been shown to be effective for sterilization of retrieved implantable surgical implants are given in annex A.

4.3 Packaging the explant for shipment

4.3.1 General

Package all explanted implants which are intended for shipment in a manner which minimizes the potential for breakage, surface damage and possible contamination of the environment or exposure of those handling such packages during transit.

Treat, handle and package all surgical implants, regardless of origin, in accordance with the general requirements set forth in clause 6 of this part of ISO 12891. Follow proper precautions at all times.

This clause shall apply to the packaging and shipping of explanted implants via the national postal service, and any private courier or overnight carrier.

The requirements of this clause are in addition to, and do not replace, any other packaging or other requirements for the transportation of biological materials prescribed by governmental bodies.

4.3.2 Shipping surgical implants and biological materials — Minimum packaging requirements

4.3.2.1 Contamination

No person shall knowingly ship or cause to be shipped, directly or indirectly, any surgical implant or biological material which is thought to be contaminated by an infectious biological material unless it is packaged, labelled and shipped in accordance with the requirements specified in this clause.

4.3.2.2 Packaging

Place medical implants in a durable, securely closed watertight primary container. Package the primary container in an outer shipping container using shock-resistant packing material to withstand shocks, pressure changes and ordinary handling. Use absorbent or leakproof material should there be potential for leakage from the primary