INTERNATIONAL STANDARD

**ISO 12891-1**

First edition
1998-11-15

# 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 12891-1:1998(E)

## Contents







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Printed in Switzerland

## 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.

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

Clearly record the orientation of all removed implant components to each other and their placement in relation to the body and associated excised material. 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<br>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 glutar-aldehyde 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

container. The net contents of any single package containing liquid shall not exceed 50 ml, which may be in one or more primary containers.

#### 4.3.2.3 Coolant material

Package coolant material in such a way that, if it is subject to melting or creation of condensation, the liquid produced does not escape from the outer shipping container. If ice or dry ice is used, place shock-absorbent material to immobilize the inner container as the ice or dry ice melts or sublimates. Packages containing dry ice shall be packed in containers that permit the venting of the carbon dioxide gas and shall be marked with the words "DRY ICE" as well as the net mass of the dry ice.

#### 4.3.2.4 Labelling

The inner and outer shipping containers shall bear a label with the name, address and telephone number of the sender. Each package containing an unsterilized surgical implant shall be so labelled on both the inner and outer containers. The outer shipping container shall contain a label, which instructs anyone handling the package to isolate the package upon discovery of damage or leakage and to notify the sender.

#### 4.3.2.5 Documents

Affix all packing slips, documents and correspondence to the outer mailing container so that the receiving facility will not be required to open the package in order to identify its contents or intended receiver.

### 4.4 Unpacking and preparation

**4.4.1** Unpacking and preparation for cleaning and sterilization shall proceed in accordance with the general practices outlined in this part of ISO 12891. First remove all paperwork and disinfection/sterilization documents (as described in 4.3.2.5) from the package, and place away from direct contact with the potentially contaminated surgical implant.

**4.4.2** If the package is small, it should be placed within the biological safety cabinet to be opened. The primary container should be removed from the secondary outer container, and examined for any visible signs of contamination or leakage. If the package is too large to fit into the cabinet, it should be placed on the floor immediately outside of the cabinet and opened. The contents should then be immediately placed within the cabinet for further processing.

**4.4.3** If the primary container is intact, the secondary outer container and packing material may be discarded as non-contaminated waste, and should be removed from the cabinet before opening the primary container. Primary containers which immediately surround the surgical implant shall be handled as infectious waste, in accordance with clause 6 of this part of ISO 12891.

## 5 Examination of surrounding tissues, fluids and interface

For specifics of analysis of explanted implants, see the other parts of ISO 12891.

## 6 Infection control

### 6.1 General

Protect employees who come into contact with explanted implants from exposure. All retrieved implants and associated tissues should be assumed to be nonsterile. Due to the risk of infection, corresponding precautions should be taken, such as handling with gloved hands. The risk of infection by bacterial, viral or other agents always exists when contamination with blood is present.

## 6.2 Work practices

Employees shall wash their hands as soon as possible after removal of gloves or other personal protective equipment, after hand contact with potentially infectious surgical implants. A commercially-available germicidal soap may be used, but this may become irritating to the skin after frequent application.

NOTE Many surgical colleges and institutions recommend that gloves be checked for punctures after removal.

If overtly contaminated, all personal protective equipment shall be removed and placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses is prohibited in work areas having a potential for occupational exposure to pathogens.

Food and drink shall not be stored in refrigerators, freezers or cabinets where implants are stored or in other areas of possible contamination.

Fluid-proof shoe covers shall be worn if there is a potential for shoes becoming contaminated and/or soaked with blood or other body fluids associated with explanted implants.

All procedures involving the handling of explanted implants shall be performed in such a manner as to minimize splashing, spraying and aerosolization of infectious materials.

## 6.3 Personal protective equipment

### 6.3.1 General

Use appropriate personal protective equipment when handling surgical implants. Equipment includes, but is not limited to, gloves; gowns; fluid-proof aprons; laboratory coats; head and foot coverings; face shields or masks; and eye protection.

Clean and/or sanitize regularly all reusable laboratory coats and protective equipment.

Repair or replace all protective equipment, as needed, to maintain its effectiveness.

### 6.3.2 Gloves

Wear gloves when there is potential for direct skin contact with a surgical implant. Replace disposable gloves, such as surgical or examination gloves, as soon as their ability to function as a barrier is compromised. Do not wash or disinfect them for re-use.

Utility (housekeeping, industrial, heavy vinyl) gloves may be disinfected for re-use if the integrity of the glove is not compromised, however, discard them if they are cracked, peeling, discolored, torn, punctured, or exhibit other signs of deterioration.

### 6.3.3 Masks, eye protection and face shields

Wear masks and eye protection or chin-length face shields whenever splashes, spray, spatter droplets, or aerosols of blood or other potentially infectious materials may be generated and there is a potential for eye, nose, or oral contamination.

### 6.3.4 Gowns, aprons and other protective body clothing

Wear appropriate protective clothing when handling explanted implants. The type and characteristics depend upon the task and degree of exposure anticipated. However, the clothing selected shall form an effective barrier.

Change this clothing whenever soiled, or on a regular basis, in accordance with the facility laundry services.

Wear fluid-resistant clothing if there is a potential for splashing or spraying of blood or other fluids associated with explanted implants. Waterproof clothing is not required.

Wear surgical caps or hoods if there is a potential for splashing or splattering of blood or other body fluids associated with explanted implants.

## 6.4 Maintenance of the worksite

### 6.4.1 Cleaning and disinfection of worksites

Maintain all worksites in a clean and sanitary condition.

Decontaminate all equipment and working surfaces associated with the handling of surgical implants with a 1:100 dilution of sodium hypochlorite ($500 \times 10^{-6}$ household bleach) after completion of procedures, when surfaces are overtly contaminated, and at the end of the workshift [2].

If there is any spill of blood or other body fluid associated with handling of the implant, or if an implant is dropped onto the floor, cover the spill site with absorbent towels. One of the disinfectants cited in Table 2 should then be poured onto the towels covering the contaminated area. Allow approximately 20 min for any aerosols to settle. Other towels soaked in disinfectant may then be used to wipe any contaminated areas. Appropriate personal protective equipment, such as gloves, lab coats and shoe covers, should be used when cleaning spills. Face shields of goggles may be used if there is a potential for aerosol generation during the cleanup (e.g. scraping).

### 6.4.2 Protective coverings

Protective coverings such as plastic wrap, aluminum foil, or imperviously backed absorbent paper may be used to cover equipment and environmental surfaces. Remove and replace these coverings at the end of the workshift or when they become overtly contaminated (see 6.5 for disposal procedures).

### 6.4.3 Equipment and tools

Equipment and tools which may become contaminated from the removal, handling or examination of surgical implants shall be routinely cleaned and decontaminated after use and prior to servicing. The cleaning of surgical implants is described in 4.2.

Small hand tools, such as forceps, haemostats, brushes, dust pans and shears shall be placed in a horizontal sterilization pan containing a disinfecting solution, or wrapped and placed into an autoclave for sterilization. Appropriate disinfecting solutions are listed in Table 1 and should be used in accordance with the manufacturer's instructions for preparation and contact time [3]. For most of the indicated disinfectants, a 2 h to 3 h contact time is sufficient. However, as a general rule, a 24-h contact time can be used to provide an extra margin of safety. Containers (e.g. pans) used for cold soaking shall be placed in a ventilated fumehood or a Class II, type B, (vented to the outside) biological safety cabinet.

**Table 2 — Disinfection solutions for contaminated equipment and tools**

| |
|---|
| 2 % aqueous glutaraldehyde |
| 4 % aqueous formaldehyde |
| 8 % formaldehyde + 70 % ethanol or isopropanol |
| 25 % hydrogen peroxide |
| 70 % to 80 % ethanol or isopropanol |
| 50 mg/l iodophor compound |
| 1 % sodium hypochlorite |

Prepare all disinfecting solutions immediately prior to use, and discard immediately after use. Solutions of ethanol, isopropanol, sodium hypochlorite, or hydrogen peroxide may be poured down the sanitary sewer. Solutions of glutaraldehyde, formaldehyde and iodophors should be properly neutralized before discarding. Iodophors may be neutralized with sodium thiosulfite, and aldehydes may be neutralized with ammonium carbonate. Take appropriate care to prevent fires when employing flammable disinfecting solutions.

Large equipment, which cannot be autoclaved or soaked in cold disinfectant, shall be sprayed or wiped down on all potentially exposed surfaces with one of the appropriate disinfectants listed above.

#### 6.4.4 Reusable receptacles

Bins, pails, cans and other receptacles intended for re-use which have a potential for becoming contaminated with blood or other potentially infectious materials shall be inspected, cleaned and disinfected on a regularly scheduled basis, and cleaned and disinfected immediately or as soon as possible upon visible contamination. Line such receptacles with appropriate, impenetrable removable plastic bags.

#### 6.4.5 Contaminated glassware

Do not pick up broken contaminated glassware directly with the hands. Clean up using mechanical means, such as a brush and dust pan, tongs, cotton swabs, towelling or forceps.

#### 6.4.6 Reusable items

Reusable items potentially contaminated with blood or other body fluids shall be decontaminated prior to washing and/or reprocessing.

#### 6.4.7 Contaminated materials

Place in durable, leakproof containers all materials to be decontaminated at a site away from the work area. Close the containers before removing from the work area.

### 6.5 Human waste disposal

**6.5.1** Place all human waste destined for disposal into closable, leakproof containers or bags that are constructed of autoclavable clear plastic, and label them "Infectious waste" or other official label. Seal bags loosely with autoclave-indicator tape to leave an opening for penetration of the steam.

If outside contamination of the container or bag is likely to occur, place a second "leakproof" container or bag over the first and close to prevent leakage during handling, storage and transport. Enclosure within a second container is recommended when an infectious agent is known or suspected. Reusable outside containers, such as trash cans, shall be routinely sprayed with a 1:100 dilution of sodium hypochlorite or an equivalent disinfecting agent after contents have been emptied for decontamination. Remove disposable outside containers (plastic bags) and decontaminate along with the waste material.

Disposal of all infectious waste shall be in accordance with applicable national and local regulations.

**6.5.2** Immediately after use, dispose of sharps in closable, puncture-resistant, disposable containers that are leakproof on the sides and bottom and are labelled with an appropriate warning.

These containers shall be easily accessible to personnel, located in the immediate area of use, replaced routinely and not allowed to overfill.

Autoclave or otherwise sterilize all infectious waste by a validated sterilization method. An acceptable method is described in clause A.2.

### 6.6 Special practices

**6.6.1** Keep work area doors closed when working with potentially contaminated surgical implants. Work areas shall be adequately ventilated with exhaust to the exterior. Attention is drawn to specific requirements of local and national authorities to protect health and safety.

**6.6.2** Limit access to the work area to authorized persons only. Only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all standard operating procedures shall be allowed to enter.

**6.6.3** Whenever there is a potential for producing contamination from surgical implants, post a warning sign incorporating the universal biohazard symbol on all access doors.

**6.6.4** All activities involving potentially infectious areosols, for example packaging, unpacking and examination of contaminated surgical implants, shall be conducted in biological safety cabinets or physical containment implants. Such work shall not be conducted on the open bench. Transfer medical implants to the containment areas in leakproof, sealed containers.

**6.6.5** All materials to be removed from a biological safety cabinet shall be surface-sprayed or wiped with a 1:100 dilution of sodium hypochlorite or suitable disinfecting agent before removal.

**6.6.6** Spills or accidents that result in overt exposures of personnel to potentially infectious materials shall be immediately reported to the work area supervisor.

**6.6.7** Biological safety cabinets shall be certified when installed, serviced, repaired or whenever they are moved, and at least annually.

**6.6.8** Autoclaves shall be certified at least annually. All certification records shall be maintained in the immediate work area.

# Annex A
(informative)

# Generic procedures for sterilization of retrieved implantable surgical implants

## A.1 Dry oven

The following procedures apply to those surgical implants for which the manufacturer recommends dry-oven sterilization. Medical implants for which the manufacturer recommends dry-oven sterilization are allowed to air-dry in a biological safety cabinet for at least 24 h before sterilization.

a) A dry-oven log sheet shall be maintained and shall contain space for indicating the following minimum information:

   — dry-oven identification number;

   — date of use;

   — item;

   — start time for sterilization;

   — end time for sterilization;

   — status of indicator(s);

   — operator.

   Completed log sheets shall be filed for future reference.

b) Preheat the oven to 65 °C [4], [5].

c) Check to see that the dry-oven log sheet (discussed above) is current. Indicate on the log sheet the operating temperature, date, time and description of item to be sterilized.

d) Place the implant and chemical indicator and spore strips in the centre of the preheated oven and close the oven door.

e) Allow the item to remain in the oven for 4 h or more.

f) Remove the item and indicator strips, and allow to cool in a dry location.

g) Indicate on the log sheet the time of item removal from the oven.

h) Process the indicator strips and log the results on the log sheet.

i) Record the date, method of sterilization and employee who conducted the sterilization on the disinfection/sterilization document (see 3.7.4).

## A.2 Autoclave

The following procedures apply to those surgical implants for which the manufacturer recommends autoclave sterilization and to all infectious waste.

By definition, autoclaving is performed at 121 °C at a gauge pressure of 1 atm (760 mmHg) for a minimum of 15 min. These are the minimal criteria to sterilize under optimal conditions (i.e. when the implant to be sterilized is free of debris and excessive bioburden). In order to ensure sterility, loads may be autoclaved for up to 1,5 h. The following steps shall be followed when autoclaving.

a) Check the chamber drain trap for debris. Remove any material found. Be certain that the chamber inlet and exhaust valves are closed.

b) Open the steam line to the jacket and allow the jacket to come up to pressure.

c) Place the implant to be sterilized into a sterilization bag and seal. Load the autoclave chamber with the implant or material to be autoclaved.

d) Place a commercially-available colorimetric indicator (to indicate sufficient temperature and humidity, via a color change) in the centre of the autoclave, near the implant or material. Place a commercially-available indicator spore strip, selected for its suitability for use with moist-heat processing, next to or into (if possible) the surgical implant, or inside the opening of a bag of infectious waste. Forceps are to be used for inserting strips into bags. Close the autoclave door.

e) Check to see that the autoclave log sheet (discussed below) is current.

f) Open the steam line to the chamber and make sure that the chamber exhaust is closed.

g) When the pressure gauge reads 760 mmHg and the temperature gauge reads [4] 121 °C, fill out the autoclave log (discussed below).

h) Autoclave materials for the specified amount of time. In general, autoclaving should proceed for longer than 15 min for surgical implants and 60 min for infectious waste. However, it should be noted that large loads placed in the autoclave (e.g. infectious waste) may require longer sterilization time, to allow for complete penetration of heat and steam to all implant surfaces and waste materials.

i) Check the chart to see that the proper temperature is maintained. This chart shall not exceed in length one complete revolution of the recorder.

j) Close the steam line to the chamber and slightly open the chamber vent valve.

k) When the pressure gauge reads zero, slowly open the door. Avoid any escaping steam.

l) The surgical implant or material can then be removed.

m) Check the colorimetric indicator. If it has changed to the proper colour, autoclaving was successful. Record the results and chart observations on the autoclave log. Check for dark coloration of the autoclave indicator tape.

n) Process the indicator spore strip.

o) After autoclaving, solid waste with a dark-coloured indicator tape may be placed in a standard waste receptacle for disposal. Remove or deface all biohazard labels before discarding sterile solid waste.

p) Record the date, method of sterilization and employee who conducted the sterilization on the disinfection/sterilization document (see 3.7.4).

q) Maintain an autoclave log sheet. File autoclave log sheets for future reference as they are completed. This log sheet format shall conform with the example shown in Table A.1.

**Table A.1 — Example of information required on autoclave data sheets**

| Date | Material | Time on | Pressure | Time off | Indicators | Chart | Operator |
|---|---|---|---|---|---|---|---|
| 10/3 | Bone plate | 12:00 | 15 psi | 12:35 | OK, OK | OK | SW |
| 11/12 | Infectious waste | 11:45 | 15 psi | 1:00 | OK, OK | OK | GM |

## A.3 Ethylene oxide gas

The following procedures apply to surgical implants for which the manufacturer recommends ethylene oxide (EO) gas sterilization:

a) The packaged surgical implant shall be personally handed to the individual designated as the ethylene oxide sterilizer operator. The name of the operator and the date of transfer of the package shall be indicated on the disinfection/sterilization document, discussed in 3.7.4 of this part of ISO 12891. EO sterilization shall be carried out using manufacturer's recommended procedures.

b) The following generic procedures shall be used for EO sterilization when a recommended procedure is not available from the implant manufacturer:

   1) An initial vacuum period, to prevent dilution of the EO, should be used for 5 min to 45 min, allowing for the vacuum pressure to reach a level of approximately 2,0 kPa.

   2) A dwell period, lasting approximately 60 min, should be allowed for introducing 40 % to 50 % humidity, at 54 °C.

   3) An EO gas charge period, lasting approximately 2 min, should follow, to allow the sterilant to be brought up to concentration within the chamber.

   4) While maintaining a controlled humidity level of 40 % to 50 %, the sterilization cycle should be allowed to continue for an appropriate exposure time. This time should be predetermined by the size of the sterilization load and exposure times dictated by the manufacturer of the surgical implant.

   5) A terminal vacuum stage, in which the EO gas is evacuated and replaced with filtered, fresh air, should then be provided before opening the sterilization chamber.

c) Place the sterilized surgical implant in a well-ventilated storage room, fume hood or Class II biological safety cabinet, at the sterilization facility, and allowed to degas for a prescribed period in accordance with the degassing requirements for the implant or material.

d) Indicate the length of time of sterilization and degassing on the disinfection/sterilization document.

e) Upon completion of EO sterilization and degassing, place the implant in a sealed container and transport back to the analytical laboratory. Indicate the date, time and name of the employee involved in this transportation on the disinfection/sterilization document.

An EO monitoring programme is required for all facility personnel involved in this type of sterilization.

## A.4 Formaldehyde gas

For those surgical implants for which the manufacturer recommends formaldehyde gas sterilization, the following procedures apply:

a) The packaged surgical implant shall be personally handed to the individual designated as the formaldehyde gas sterilizer operator. Indicate the name of the operator and the date of transfer of the package on the disinfection/sterilization document discussed in 3.7.4 of this part of ISO 12891. Carry out sterilization using the manufacturer's recommended procedures. Medical implants destined to be sterilized by formaldehyde gas shall be packaged in accordance with 4.3.2.2 of this part of ISO 12891 if transported to another facility.

b) Use the following generic procedures for formaldehyde sterilization when a recommended procedure is not available from the implant manufacturer.

1) Place implants destined to be sterilized using formaldehyde gas in Class II biological safety cabinets, vented to the outside, which have been prepared for gas sterilization.

2) Then seal all openings to the cabinet. A commercially available electric frying pan equipped with a thermostatic temperature controller should be placed within the cabinet and set to just above 150 °C. Attach an extension cord to the frying pan, to be plugged in when decontamination begins.

3) Powdered or flaked paraformaldehyde should be used as the source of formaldehyde gas. Each 2 700 $cm^3$ volume of space in the cabinet requires 0,3 g of paraformaldehyde. Place the required amount of paraformaldehyde on the surface of the frying pan, and seal the cabinet opening and around the electric cord.

4) If the cabinet is designed to discharge air directly into the room, attach a flexible hose to the cabinet exhaust port and extend to a room exhaust. Caution: If the building exhaust air is partially recirculated, the hose from the cabinet must be extend to the outside through an open window or door. Exercise caution to make certain that the exhaust air will not expose anyone to formaldehyde.

5) The frying pan containing flaked paraformaldehyde should be turned on. After evaporation is completed, the cabinet containing the surgical implant should be allowed to stand for a minimum of 2 h. Whenever possible, the sterilant exposure should be continued for 8 h, or overnight.

6) After allowing sufficient contact time with the sterilant, the cabinet should be ventilated, with the surgical implant inside, for several hours to remove all traces of formaldehyde.

7) Considerable caution should be exercised in handling, storing and using formaldehyde, as repeated exposure is known to produce a hypersensitive condition in some individuals. Whenever exposure to formaldehyde is possible, self-contained breathing apparatus, or air supplied masks should be immediately available to all workers. The pungent and irritating odour of formaldehyde can be detected by most individuals at a concentration of $1 \times 10^{-6}$. This serves as an excellent warning mechanism to avoid excessive exposure.

c) Indicate the length of time of sterilization in the documentation.

d) Upon completion of formaldehyde gas sterilization, place the implant in a sealed container and transport back to the laboratory. Indicate the date, time, and name of the employee involved in this transportation on the disinfection/sterilization document.

e) Large implants may be sterilized with formaldehyde gas before shipping to the analysis laboratory. This field sterilization shall be conducted by an individual experienced in equipment sterilization. For such implants which have been sterilized via formaldehyde gas at the field location, no sterilization is required at the analytical laboratory.

An exposure monitoring programme is required for all facility personnel involved in this type of sterilization.

## A.5 Verification of sterilization method

### A.5.1 General

The most reliable means for determining whether a sterilizing cycle has been successful is by placing indicators throughout the load, or next to a surgical implant, before it is subjected to the sterilizing process.

Verify the effectiveness of sterilization methods used for potentially contaminated surgical implants, and enter the results of the verification test onto the appropriate log and disinfection/sterilization document for future reference. Various indicators which shall be used for sterility verification are discussed below.

### A.5.2 Biological indicators which employ the use of spores

The proper organisms to use for challenging the various sterilization processes include:

Autoclave: *Bacillus stearothermophilus*

Dry oven: *Bacillus subtilis* var. niger

Ethylene oxide: *Bacillus subtilis* var. *niger*

Formaldehyde gas: *Bacillus subtilis* var. *niger* and/or *B. stearothermophilus*.

When using commercially available paper strips inoculated with bacterial spores to determine the efficacy of sterilization processes, care should be taken to use biological indicators which meet published guidelines for the sterilant and temperature ranges being tested, and have not exceeded the expiration date assigned by the manufacturer.

It is also necessary to ensure proper placement of each strip in the portion of the load most inaccessible to the steam, dry heat or EO. When sterilizing infectious waste loads, select one or more of the largest and most dense bags and insert the envelopes containing the inoculated strips in the centre of each bag. Add the remainder of the waste load in a like manner without indicators, and operate the sterilizer according to standard procedure.

Upon completion of a sterilizing cycle, remove all indicators using sterile forceps, and immediately place in a sterile Petri dish for transfer to a biological safety cabinet for processing.

Aseptically open the envelope or glassine cover to reveal the inoculated paper strip. This can be accomplished by using sterile forceps and/or scissors.

Carefully transfer the spore strip, using sterile forceps, to a tube of sterile culture media or broth which has been prepared in accordance with the spore strip manufacturer's recommendations. In addition, remove and transfer the control strip to a separate tube of sterile culture media.

Following the manufacturer's recommendations, spore strips should be incubated for the specified period of time, at the specified temperature.

The tubes should be observed for 7 d for the presence of turbidity or other indicators, as recommended by the manufacturer.

One or more positive controls should be included in each test. This requires the transfer of an unexposed spore strip to a tube of sterile culture media, followed by incubation at the same temperature as the test strips. Microbiological growth indicates that the medium possesses suitable growth-promoting properties, and the spore strips contained viable spores prior to the sterilizing process.

A microbiological media control, co nsisting of one or two tubes of sterile culture media from the same manufacturer's lot as used with the processing steps above, should also be included in each test. The absence of growth following incubation would show that the media was sterile prior to the sterility test procedure.

All tests for sterility should be conducted in a biological safety cabinet.

### A.5.3 Colorimetric indicators

Commercially prepared colorimetric indicator strips shall be used when surgical implants are to be sterilized, via an autoclave. One strip shall be placed along side each surgical implant, or suspended from the top of the autoclave, to be located in the centre of the chamber. The results of these strips shall be interpreted in accordance with the manufactuer's instructions.

### A.5.4 Test packs as an indicator

If feasible, a test pack which simulates the surgical implant to be sterilized may be used to hold the commercially-available colorimetric and spore strips. The purpose of the test pack is to allow insertion of the indicator without contacting contaminated surfaces. The test pack should be constructed with the identical material and configuration of the implant, and should be an identical implant if possible. The indicator strips should be placed in a location within the test pack which appears most inaccessible to the sterilant [5].