INTERNATIONAL STANDARD

ISO 12891-1

Second edition
2011-05-01

Implants for surgery — Retrieval and analysis of surgical implants —

Part 1: Retrieval and handling

Implants chirurgicaux — Retrait et analyse des implants chirurgicaux —

Partie 1: Retrait et manipulation

Reference number
ISO 12891-1:2011(E)

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Published in Switzerland

Contents

Page

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 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 12891-1:1998), which has been technically revised.

ISO 12891 consists of the following parts, under the general title *Implants for surgery — 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*

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;

— 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 to ISO 12891-4 specify methods for the detailed analysis of specific types of surgical implants, in which protocols are provided for the collection of data and examinations for metallic, polymeric and ceramic 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 the implants, the 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;

— 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, the surgical implant manufacturer, the investigator, and the 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. In particular, it focuses on the practical requirements. 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.

Implants for surgery — 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 Absorbent material can be either 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:

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

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

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

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

— the 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;

— the date of retrieval;

— the 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) the 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) the 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) an 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) the container number or identifier, if there is more than one container;

f) the 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 may 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 via 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[bc]
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
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.

Implants destined to be decontaminated at a location outside the biosafety cabinet (described above) shall be placed into a sealable container for transport. The transport container shall be sprayed or surface wiped with a sodium hypochlorite solution (50 mg/l to 60 mg/l) or 3 % hydrogen peroxide before removal from the cabinet.

Generic procedures which have been shown to be effective for the decontamination of retrieved surgical implants are given in Annex B.

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

NOTE 2 Inappropriate decontamination techniques can adversely affect the material properties or function of the retrieved surgical implant.

3.9 Packaging the retrieved surgical implant, tissues and fluids for shipment

All retrieved surgical implants which are intended for shipment shall be packed in a manner which minimizes the potential for breakage, surface damage, contamination of the environment or exposure of those handling such packages during transit.

Retrieved surgical implants and, if applicable, associated tissue samples and fluids shall be packed using three layers of packaging, namely:

a) a primary container;

b) a secondary container;

c) an outer shipping container.

Each retrieved surgical implant, tissue sample or fluid shall be packed separately in its own primary container, which shall be durable, watertight and securely closed. Each primary container(s) shall be placed in a secondary container which shall be durable and securely closed. If there is a potential for leakage from the primary container, the secondary container shall be watertight and may contain absorbent material. The secondary container(s) shall be placed in an outer shipping container using shock-resistant packing material to withstand shocks, pressure changes and ordinary handling. The outer shipping container shall make use of absorbent or leakproof material, if there is a potential for leakage from the secondary container. The net contents of any single package containing liquid shall comply with local or national transportation shipping regulations.

All retrieved surgical implants should be handled and packaged in accordance with the infection control requirements specified in Clause 5.

The requirements in this clause apply, if the retrieved materials are to be cleaned, decontaminated, analysed or processed in an off-site location, e.g. when they are to be returned to the implant manufacturer for these purposes.

The requirements in this clause apply to the packaging and shipment of retrieved surgical implants and associated tissue samples and fluids via national postal services or private couriers.

The requirements in this clause apply also to the shipment of retrieved surgical implants or tissue samples or fluids which are thought to be contaminated by an infectious biological agent.

The requirements in 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.

NOTE 1 References given in the bibliography provide further information.

NOTE 2 Some multi-component surgical implants can be packed in the same container, e.g. implantable pulse generators and their leads.

NOTE 3 Some surgical implants can be packed moist or wet using an appropriate fluid, e.g. when returning certain active surgical implants to the implant manufacturer.

3.10 Use of coolant materials

If the contents of the primary container need to be cooled, then coolant materials shall be used. Coolant materials include ice, dry ice and gel packs.

Coolant materials shall be packed in such a way that, if they are 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, shock-absorbing material shall be included to immobilize the primary 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. Usually the package shall be marked with the words “DRY ICE” and/or the international symbol for dry ice, UN 1845[1)], shall be used.

3.11 Labelling of the packing materials

The primary, secondary and outer shipping containers shall each bear a label which gives the following information:

— the name, address and the telephone number of the sender;

— the biological risks symbol (see ISO 15223-1:—, symbol 5.4.1);

— the word “Decontaminated”, if the surgical implant has been decontaminated.

If the package contains an undecontaminated surgical implant, the outer shipping container shall include a label, which states that upon discovery of damage or leakage the package should be isolated and the sender notified.

3.12 Documentation to be supplied with retrieved surgical implants

The documentation to be supplied with retrieved surgical implants and associated tissue samples and fluids is:

— the clinical history as specified in 3.1 or Annex A, if available;

— the results of the pre-explantation checks and examinations as specified in 3.2, if available;

— the position, orientation or state of the retrieved components and the location and type of any damage caused during explantation as specified in 3.3, if applicable;

1) Symbol developed by the United Nations Committee of Experts on the Transport of Dangerous Goods.

— the details of the tissue and/or fluid samples taken for microbiological and/or histological examination as specified in 3.4, if applicable;

— the photographic record of the explantation as specified in 3.5, if available;

— the label information for future identification as specified in 3.6;

— the details of the cleaning of the retrieved surgical implant as specified in 3.7, if applicable;

— the details of the decontamination of the retrieved surgical implant as specified in 3.8, if applicable;

— the name and contact details of the retriever.

The above documents and any other correspondence shall be placed inside the outer shipping container so that the receiving facility is not required to open the secondary container to retrieve any documents or correspondence. All packing slips and address label(s) shall be affixed to the outer shipping container so that the receiving facility is not required to open the outer shipping container in order to identify its contents or the intended receiver.

3.13 Unpacking following shipment

Unpacking shall proceed in accordance with the general practices outlined in Clause 5.

If the outer shipping container is small, it should be placed within a biological safety cabinet to be opened. If the outer shipping container is too large to fit into the cabinet, it should be placed on the floor immediately outside the cabinet and opened. If the secondary container is intact, it should then be immediately placed within the cabinet for further processing.

First, all paperwork and decontamination documentation and correspondence as specified in 3.12 shall be removed from the outer shipping container and placed away from direct contact with the potentially contaminated surgical implant.

Next, the secondary container shall be opened and the primary container removed. The primary container should be examined for any visible signs of contamination or leakage.

If the primary container is intact, the secondary container, the outer shipping container and any 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 5.

3.14 Cleaning and decontamination following shipment

If required, cleaning and decontamination may be performed after shipment, in which case the processes specified in 3.7 and 3.8 shall be followed, as applicable.

3.15 Documentation to be maintained during examination, analysis and storage

As explained in 3.12, the documentation shall begin when the surgical implant is retrieved. In addition, it shall continue until examination and analysis are complete. Everyone who handles, examines or stores the implant shall be required to add to the documentation to ensure a complete history and understanding of the analytical findings.

The following information shall be added to the retrieval documentation:

a) the name of the shipping service (postal service, courier, etc.), shipping number, date of shipment and time of release;

b) the state of the surgical implant following unpacking;

c) the details of any post-shipment cleaning or decontamination;

d) the location and details of storage, if the surgical implant is to be stored before or after examination;

e) the name and contact details of the individual(s) responsible for the handling, analysis and storage of the surgical implant.

4 Analysis of retrieved surrounding tissues and fluids

An example of the analyses to be performed on retrieved tissues and fluids is given in Annex C.

NOTE The analysis of retrieved surgical implants and associated interfaces is specified in ISO 12891-2 to ISO 12891-4.

5 Infection control

5.1 General

Protect employees who come into contact with explanted implants from exposure. All retrieved implants and associated tissues should be assumed to be potentially infectious. 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 or other potentially infectious material is present.

5.2 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 can become irritating to the skin after frequent application.

Many surgical colleges and institutions recommend that gloves should 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 are 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.

5.3 Personal protective equipment

5.3.1 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.

5.3.2 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, discoloured, torn or punctured, or exhibit other signs of deterioration.

5.3.3 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 can be generated and there is a potential for eye, nose, or oral contamination.

5.3.4 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 standardized laboratory operating procedures and site-specific safety practices.

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.

5.4 Maintenance of the worksite

5.4.1 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 5 mg/l to 6 mg/l sodium hypochlorite after completion of procedures, or with any other method which has been shown to be effective, when surfaces are overtly contaminated, and at the end of the workshift (see Reference [3]).

If there is any spill of blood or other body fluid associated with handling of the implant, or if an implant is dropped on to the floor, cover the spill site with absorbent towels. One of the disinfectants cited in Table 2 should then be poured on to 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, e.g. gloves, lab coats and shoe covers, should be used when cleaning spills. Face shields or goggles may be used if there is a potential for aerosol generation during the cleanup (e.g. scraping).

5.4.2 Protective coverings

Protective coverings such as plastics wrap, aluminium 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 5.5 for disposal procedures).

5.4.3 Equipment and tools

Equipment and tools which can become contaminated during 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 specified in 3.7.

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 2 and should be used in accordance with the manufacturer's instructions for preparation and contact time (see Reference [4]). 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 may 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, see Reference [2]), biological safety cabinet.

Table 2 — Disinfection solutions for contaminated equipment and tools[a]

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 % solution hypochlorite

[a] Percentages are volume fractions.

Prepare all disinfecting solutions immediately prior to use, and discard immediately after use. Solutions of ethanol, isopropanol, sodium hypochlorite or hydrogen peroxide should be disposed of by specialist chemical collection or may be poured down the sanitary sewer where this is allowed. 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 in Table 2.

5.4.4 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 plastics bags.

5.4.5 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.

5.4.6 Reusable items

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

5.4.7 Contaminated materials

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

5.5 Human waste disposal

5.5.1 Place all human waste destined for disposal into closable, leakproof containers or bags that are constructed of autoclavable clear plastics material, 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 sodium hypochlorite solution (500 mg/l to 600 mg/l) or an equivalent disinfecting agent after contents have been emptied for decontamination. Remove disposable outside containers (plastics bags) and decontaminate along with the waste material.

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

If human waste is to be incinerated, it should be placed in a leakproof, burnable container, labelled “HAZARDOUS BIOLOGICAL WASTE”.

5.5.2 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 B.2.

5.6 Special practices

5.6.1 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.

5.6.2 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.

5.6.3 Whenever there is a potential for producing contamination from surgical implants, post a warning sign incorporating the universal biohazard biological risk symbol on all access doors (see ISO 15223-1:— symbol 5.4.1).

5.6.4 All activities involving potentially infectious areosols, e.g. 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 surgical implants to the containment areas in leakproof, sealed containers.

5.6.5 All materials to be removed from a biological safety cabinet shall be surface-sprayed or wiped with a sodium hypochlorite solution (500 mg/l to 600 mg/l) or suitable disinfecting agent before removal.

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

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

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

Annex A
(informative)

Suggested minimum information to be obtained for retrieved surgical implants

The suggested minimum information should be modified according to national regulations.

Clinical information (confidential)

Record number _____ Record date _____

Hospital (Name, address) _____

Surgeon (Name, address) _____

Patient (Name and/or identification number) _____

Female [ ] Male [ ]

Age at retrieval or date of birth _____

Occupation _____

Weight _____ Height _____

History of substance abuse (smoking, etc.) _____

Reason for investigation

Routine series [ ] Documentation [ ]

Complaint [ ] Liability claims [ ]

Research [ ] Clinical investigation [ ]

Other _____

Implant information

Implant type _____ Number of components _____

Catalogue number _____ Serial number _____

Manufacturer _____

Size _____ Material _____

Diagnosis at insertion (or reason for insertion) _____

Additional diagnoses and complications _____

Anatomical site of implantation _____

Antibiotics and drugs used

_____

Pre-op. [ ] peri-op. [ ] post-op. [ ] prophylactic [ ]

Duration

_____

Post-operative treatment

_____

Duration of use _____

Complications between insertion and removal

Infection [ ] yes

Reason for removal

Routine [ ] Pain [ ] Failure [ ]

Infection [ ] Allergy [ ] Other reasons:

Implant diagnosis (per triage)

Observations prior to removal (functional) _____

Observations at removal (indicate yes, no, not applicable, doubt, etc.)

Normal tissue _____

Bursal fluid _____

Scar tissue _____

Loose implant _____

Granulation tissue _____

Bone reaction _____

Discoloration, implant debris _____

Infection _____

Other _____

Additional material provided for analysis

Radiographs	no [ ]	yes [ ]	how many
Other imaging files	no [ ]	yes [ ]	how many
Tissue	no [ ]	yes [ ]	type origin
Bacteriol. specimen	no [ ]	yes [ ]	type origin
Immunol. specimen	no [ ]	yes [ ]	type origin
Fluid	no [ ]	yes [ ]	type origin
Photographs	no [ ]	yes [ ]	type origin
Pathology reports	no [ ]	yes [ ]	type origin
Surgical reports	no [ ]	yes [ ]	type origin
Additional documentation	no [ ]	yes [ ]	type origin

Annex B
(informative)

Generic procedures for the decontamination of surgical implants

B.1 Dry oven

The following procedures apply to those surgical implants for which the manufacturer recommends dry-oven sterilization. Surgical 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:

   1) dry-oven identification number;

   2) date of use;

   3) item;

   4) start time for sterilization;

   5) end time for sterilization;

   6) status of indicator(s);

   7) operator.

   Completed log sheets shall be filed for future reference.

b) Preheat the oven to 65 °C (see References [5][6]).

c) Check to see that the dry-oven log sheet [see a)] 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 in the disinfection, sterilization and retrieval documentation (see 3.12).

B.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 or 101,3 kPa) 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 colour 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 [see q)] 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 1 atm (760 mmHg or 101,3 kPa) and the temperature gauge reads 121 °C (see Reference [5]), fill out the autoclave log [see q)].

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) can 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 in the disinfection, sterilization and retrieval documentation (see 3.12).

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 B.1.

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

Date	Material	Time on	Pressure	Time off	Indicators	Chart	Operator
XX-10-03	Bone plate	12:00	100 kPa	12:35	OK, OK	OK	SW
XX-11-12	Infectious waste	11:45	100 kPa	13:00	OK, OK	OK	GM

B.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 is to 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 in the disinfection, sterilization and retrieval documentation (see 3.12 or 3.15). The EO sterilization shall be carried out using the 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 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 (see Reference [2]), 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 in the disinfection, sterilization and retrieval documentation (see 3.12 or 3.15).

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 and retrieval documentation.

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

B.4 Formaldehyde gas

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

a) The packaged surgical implant is to 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 in the disinfection, sterilization and retrieval documentation (see 3.12 or 3.15). Carry out sterilization using the manufacturer's recommended procedures. Package surgical implants destined to be sterilized by formaldehyde gas in accordance with 3.9, 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 (see Reference [2]), 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 shall extend to the outside through an open window or door. Exercise caution to make certain that the exhaust air does 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 supply masks, should be immediately available to all workers. The pungent and irritating odour of formaldehyde can be detected by most individuals at a volume fraction of 1×10^{-6}. This serves as an excellent warning mechanism to avoid excessive exposure.

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

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.

B.5 Verification of sterilization method

B.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 on to the appropriate log and disinfection, sterilization and retrieval documentation for future reference. Various indicators which shall be used for sterility verification are described in B.5.2 to B.5.4.

B.5.2 Biological indicators which employ the use of spores

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

— Autoclave: *Geobacillus stearothermophilus*

— Dry oven: *Bacillus atrophaeus*

— Ethylene oxide: *Bacillus atrophaeus*

— Formaldehyde gas: *Bacillus atrophaeus* and/or *Geobacillus stearothermophilus*.

When using commercially available paper strips or other appropriate vehicles 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 densest 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, consisting 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.

B.5.3 Colorimetric indicators

Use commercially prepared colorimetric indicator strips when surgical implants are to be sterilized, via an autoclave. One strip shall be placed alongside each surgical implant, or suspended from the top of the autoclave, to be located in the centre of the chamber. Interpret the results of these strips in accordance with the manufacturer's instructions.

B.5.4 Test packs as an indicator

If feasible, a test pack which simulates the surgical implant to be sterilized can 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 from the identical material and with the 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 (see Reference [6]).

Annex C
(informative)

Analyses to be performed on retrieved tissue samples and fluids

Non-invasive analysis

Macroscopic examination

- General appearance
- Discoloration

Histological examination

- Implant-tissue interface reactions
- Evidence of tissue alteration, e.g. infection, inflammation, calcification

Special analyses

Microbiological and immunological evaluation

- Results of bacteriological tests:
  - Sterile yes [ ] no [ ]
  - Type of microorganisms

Functional testing (performance characteristics)

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ICS 11.040.40

Price based on 23 pages