INTERNATIONAL STANDARD

ISO 12891-1

Second edition
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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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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