
**Retrieval and analysis of surgical
implants —**

**Part 2:
Analysis of retrieved surgical implants**

Retrait et analyse des implants chirurgicaux —

Partie 2: Analyse des implants chirurgicaux métalliques retirés

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This third edition cancels and replaces the second edition (ISO 12891-2:2014), of which it constitutes a minor revision. The changes compared to the previous edition are as follows:

- normative references have been updated; [ISO 12891-2:2020](https://standards.iteh.ai/catalog/standards/iso/572399fa-cafc-4c0f-b273-98d3cdb7e6a8/iso-12891-2-2020)
- editorial improvements have been made to the language of this document.

A list of all parts in the ISO 12891 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The investigation of retrieved implantable medical devices and adjacent tissues can be of diagnostic value in the event of clinical complications, can deepen our knowledge of clinical implant performance and safety, and can improve our understanding of the interactions between implants and the body, thus, furthering the development of implants with improved biocompatibility and functional longevity.

This document specifies methods for the retrieval, handling, and analysis of surgical implants and associated specimens which are retrieved from patients during revision surgery or post-mortem. The aim is to provide guidance in preventing damage to the specimens which could obscure the investigation results, and in gathering data at the proper time and under the proper circumstances. ISO 12891-1 deals with retrieval and handling. This document concerns the analysis of implants of specific materials and includes protocols for reporting the data collected. For particular investigation programmes, additional, more specific protocols can be required. If special analytical techniques are employed, it is important to specify the procedures used.

This document specifies methods for the analysis of retrieved surgical implants to ensure they are not damaged, to indicate typical investigation techniques, and to allow comparisons between investigation results from different sources. These methods can be useful for retrieval and analysis studies in animals.

This document provides for a thorough examination of all aspects of an explanted prosthesis. In many cases only a subset of these examinations will be appropriate to the investigation of a specific explanted device.

ISO 12891-1 specifies methods for retrieval and handling and applies to this document. Annexes A and C of ISO 12891-1 include examples of protocols for reporting data concerning the retrieval process. These protocols are not repeated in this document. They can be reduced or expanded depending on the retrieved surgical implant, the presence of any attached or accompanying biological material, and the purpose of the retrieval and analysis.

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Retrieval and analysis of surgical implants —

Part 2: Analysis of retrieved surgical implants

1 Scope

This document specifies methods for the analysis of retrieved surgical implants.

This document describes the analysis of retrieved metallic, polymeric and ceramic implants. The analysis is divided into three stages which are increasingly destructive.

This document can also be applied to other materials, e.g. animal tissue implants.

NOTE National regulations or legal requirements regarding the handling and analysis of retrieved implants and tissues and associated biological material can also apply to specific topics covered in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12891-1:2015, *Retrieval and analysis of surgical implants — Part 1: Retrieval and handling*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

surgical implant implant

medical device intended to be inserted into the body by surgical techniques

Note 1 to entry: The medical device is hereafter referred to as an “implant”.

Note 2 to entry: The implant can be a component of a modular or multicomponent implant.

4 Procedures for retrieval, handling and packaging

Procedures for retrieval, handling, packaging, and protection of the personnel involved shall be in accordance with ISO 12891-1:2015.

As a precautionary measure, retrieved implants shall be decontaminated by an appropriate means that does not adversely affect the implant or the planned investigation. Appropriate methods are given in ISO 12891-1:2015, 3.8.

Any difficulty in the implant retrieval procedure leading to unavoidable implant damage during it shall be reported together with a description of the produced damage.

Cleaning solutions (see ISO 12891-1:2015, Table 1) can interact with the material, e.g. corrosion or dissolution and should be chosen to minimize this risk.

Photographic records of the surgical field should be made before the implant retrieval, if appropriate.

5 Analysis of the implant interfaces

5.1 Implant/tissue interface

A significant part of the information associated with a retrieved surgical implant is often at the implant/tissue interface. Attention shall be given to the interface and to the peri-implant tissue and its contents. Where required, analyses of the chemistry and nature of the by-products of degradation of the implant and a study of the cellular response to the implant shall be considered.

In cases where implant surfaces are designed to promote tissue ingrowth or ongrowth, a study of the implant tissue interface can be of particular interest, and the findings shall be recorded. If residues are adherent to the surface of the implant, this shall be recorded.

Since the appearance of the tissue can vary significantly with the distance from the implant surface, it is important that the tissue is analysed in its context with the implant. Where possible, tissue, fluid, and particulate samples should be collected for further analysis (see ISO 12891-1:2015, 3.4).

5.2 Implant/implant interfaces

Where implants articulate on or are in contact with other implant components, the condition of the contacting surface areas of the implant can be of particular interest. Their study shall be considered in the context of the opposing surfaces.

In addition to studying the condition of contacting surfaces, the surrounding area shall also be studied to determine whether wear debris is present.

6 Analysis of the implant

6.1 General

This clause describes the different degrees of characterization to be considered when a retrieved implant is under investigation.

The analyses of the retrieved implant are divided into three stages, with the degree of characterization and destruction increasing from stage I to stage III. The implant characterizations can include macroscopic and microscopic examinations, chemical analyses, and the determination of physical and mechanical properties.

Because of the complexity of the materials that can be used for implants, and because of the large number of potential analyses and tests suggested in this document, the stage and type of analysis to be performed shall be chosen as a function of the type of implant and the purpose of the investigation.

The examinations selected to be performed shall depend upon the reason for removal and examination of the implant, and possible restrictions in destructive testing. Perform a minimum number of investigations for routine removals where the implant is not suspected to have malfunctioned, more examinations for implants suspected of having a functional impairment, and extensive investigations for implants retrieved because of a suspected malfunction.

Each component of an implant shall be analysed separately, if possible and necessary.

NOTE 1 [Annex A](#) lists the most important characteristics to be assessed at each investigational stage.

NOTE 2 Applicable international standards and national standards for the evaluation of implant properties are given in [Annex B](#) and in the Bibliography.

6.2 Forms for recording the results of the analyses

Standard forms for metallic (see [A.2](#)), polymeric (see [A.3](#)), and ceramic (see [A.4](#)) implants, indicating the information to be recorded at each stage of the investigation are given as a framework. Further information regarding the use of the forms is given in [A.1](#).

For other materials, e.g. animal tissue implants, a form based on [A.2](#) to [A.4](#) can be used for the preparation of a relevant list.

NOTE A standard form for the recording of clinical and implant-related information is given in ISO 12891-1:2015, Annex A.

6.3 Stage I investigation (macroscopic examination — non-destructive)

6.3.1 General

The primary aim of this stage of the investigation is to describe the product (e.g. type, manufacturer), to collect the pertinent visual information and to establish the failure assessment plan.

For the assessment of the Stage I investigation, use [A.2](#), [A.3](#), or [A.4](#), sections 1 and 2.

6.3.2 Identification/photography

Markings found on the implant or its components such as the manufacturer's name or trademark, the batch code (lot number) or serial number, dimensions, shall be recorded. Photographic records shall be made of relevant findings, where useful.

6.3.3 Visual examination

The implant surface shall be observed to ascertain the mode of failure, destruction, or surface alteration, if any such appears.

In no event shall any surface of a failed implant be destructively evaluated at this stage.

6.3.4 Low-power optical examination

An overall examination shall be performed under a low-power optical stereomicroscope.

6.3.5 Further evaluation

If at the conclusion of stage I further investigation is required to clarify any observations made, or to evaluate other characteristics or the failure mode of the implant, it shall be carried out subsequently in stage II.

6.4 Stage II investigation (microscopic examination — mostly non-destructive)

6.4.1 General

Stage II investigation shall be carried out after stage I investigation, if deemed necessary, to further investigate or identify the characteristics and/or failure mode of the implant.

The primary aim of this stage of the investigation is to assess the mode of failure and/or the deterioration of the implant in the most non-destructive manner possible. For the assessment of the Stage II investigation, use [A.2](#), [A.3](#), or [A.4](#), sections 3 to 5.

6.4.2 Microscopic examination

Optical or scanning electron microscopy examination techniques suitable for the material under investigation shall be used.

Normal incidence of transmission optical microscopy or polarizing, interference, phase-contrast or other optical microscopy techniques can be used, when applicable to the implant.

When scanning electron microscopy is used, special preparation techniques can be required to obtain the necessary conditions for imaging and analyses.

X-ray methods or micro-CT systems can be used, when applicable. Describe any artefact reduction algorithm or other image processing, if applicable.

6.4.3 Fractographic examination

If the implant is fractured, analysis of the fracture surface by suitable techniques can help to ascertain the mode of fracture or to detect defects in the material. It might be necessary to excise a portion of the implant to conduct the examination. Destructive evaluation of the fracture surface shall be avoided. If the implant has suffered mechanical failure, it is important to remember that it can become legal evidence and so the necessary precautions need to be taken. If the fracture surface has been altered before, during or after retrieval then the existence of this damage should be recorded.

When conducting the fracture analysis, the investigator should take into account the possibility of damage of the fracture surfaces due to relative movement between the implant fractured parts before retrieval as well the loss of fractured parts during retrieval.

6.4.4 Surface topography

Where worn and unworn areas of the surfaces of retrieved implants are of interest, surface topography tests can be carried out in addition to the morphological assessment.

6.5 Stage III investigation (material investigation — mostly destructive)

6.5.1 General

If further investigation is necessary to assess the properties of the implant, the tests listed under Stage III in [Annex A](#) shall be carried out as deemed necessary to further characterize the implant and its history. For the assessment of the Stage III investigation, use [A.2](#) or [A.4](#), sections 6 to 9 or [A.3](#), sections 6 to 10.

NOTE Applicable international standards and national standards for the evaluation of implant properties are given in [Annex B](#) and in the Bibliography.

6.5.2 Material composition

6.5.2.1 General

Determine the physical and chemical composition and identity of the material and report the technique employed with the results. The type of material can be characterized by means of material standards listed in [Annex B](#).

It can be sufficient in the study of a given retrieved implant to verify that the type of material corresponds to the information provided by the manufacturer. If more details are required or the

nature of the material is unknown, appropriate techniques shall be used to determine the required physical and chemical properties.

The location of the area or portion of the implant that has been analysed shall be identified in relation to the full implant and reported with the result. The method of analysis shall be clearly identified.

6.5.2.2 Metals

Where necessary, analysis of the composition shall be carried out by appropriate methods (e.g. electron diffraction X-ray analysis, X-ray fluorescence analysis, atomic absorption spectroscopy, or recognized chemical analysis techniques).

6.5.2.3 Polymers

Differential thermal analysis, gel permeation chromatography, or other applicable molecular weight methods, infrared analysis as well as other spectrographic techniques can be useful to further characterize the implant material.

If applicable, the thermal properties of polymers, e.g. transition temperature, heat of fusion, and heat of crystallization, shall be determined in accordance with applicable test methods. The fractions extractable from the polymer shall be determined in accordance with suitable test methods.

Depending on the polymer, certain structural characteristics can be determined by optical or electron microscopy. For the determination of inclusions and particulate constituents, similar methods should be used.

Considering that bulk properties can differ considerably from surface properties (e.g. texture, strengths) due to processing characteristics (e.g. flow in moulds, differences in solidification rate), representative data shall be sampled from different portions of the implant, if possible.

6.5.2.4 Ceramics

Recognized analytical methods shall be used to determine the chemical composition of the ceramic implant. The method of analysis shall be specified, such as X-ray fluorescence analysis and EDX analysis, and highly quantitative and specific techniques such as atomic absorption spectroscopy and spectrophotometric analysis.

Where of interest, the degree of crystallinity and the atomic structure can be determined by X-ray diffraction techniques.

6.5.3 Microstructure

Standard preparation and evaluation techniques suitable for the material under investigation shall be used.

The grain size, in accordance with the applicable material standard and method, shall be determined.

The inclusion content, in accordance with the applicable material standard, shall be determined, if appropriate.

The process condition of the material (e.g. annealed, recrystallized, work-strengthened, hot-forged, cold-forged, moulded, extruded), and other relevant features shall be indicated, where possible.

Evidence of corrosion or cracking shall be noted and recorded.

To check for voids and defects, scanning electron micro-analysis can be employed.

If a porous material is under investigation, the porosity shall be characterized.