INTERNATIONAL STANDARD

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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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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*.

This second edition cancels and replaces the first editions (ISO 12891-2:2000, ISO 12891-3:2000, ISO 12891-4:2000), which have been merged and technically revised.

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 surgical implants*

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 part of ISO 12891 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 part of ISO 12891 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, the procedures used should be specified.

This part of ISO 12891 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 may be useful for retrieval and analysis studies in animals.

This part of ISO 12891 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 part of ISO 12891. 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 part of ISO 12891. They may 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.

Retrieval and analysis of surgical implants —

Part 2:
Analysis of retrieved surgical implants

1 Scope

This part of ISO 12891 specifies methods for the analysis of retrieved surgical implants.

This part of ISO 12891 describes the analysis of retrieved metallic, polymeric and ceramic implants. The analysis is divided into three stages which are increasingly destructive.

This part of ISO 12891 can also be applied to other materials, e.g. animal tissue implants.

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12891-1:2011, *Implants for surgery — 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.

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.

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 3.8 of ISO 12891-1:2011.

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 12891-1:2011, 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 byproducts 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, 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 part of ISO 12891, 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 12891-1:2011, 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 (type, manufacturer, etc.), to collect the pertinent visual information and to establish the failure assessment plan.

For the assessment of the Stage I investigation, use sections 1 and 2 in A.2, A.3, or A.4.

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, etc., 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 sections 3 to 5 in A.2, A.3, or A.4.

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 sections 6 to 9 in A.2 or A.4 or sections 6 to 10 in A.3.

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 (texture, strengths, etc.) due to processing characteristics (flow in moulds, differences in solidification rate, etc.), 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 (annealed, recrystallized, work-strengthened, hot-forged, cold-forged, moulded, extruded, etc.), 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.

6.5.4 Mechanical properties

IMPORTANT — Except for hardness measurements, which can be carried out on the implant surface, the mechanical tests are destructive. The performance of such tests can be restricted or inhibited by the size and/or shape of the implant or by legal conditions.

The types of measurement to be carried out at this stage of characterization depend upon the implant and its application. Some materials (e.g. shape memory alloys, degradable metals, certain polycarbonate urethanes, or polydimethasiloxanes) have unique mechanical considerations that shall also be addressed.

Where applicable, the density and hardness shall be determined in accordance with suitable material standards.

Where required and possible, the mechanical properties (tensile, flexural, compressive, etc.), shall be determined in accordance with applicable material specifications and test methods. Other tests can also be performed as appropriate to the test specimen.

Where dimensions allow, test specimen shall be fabricated from the implant. Deviation from the test specimen dimensions specified in standard methods may be made necessary by the shape and size of the implant under investigation. This shall be taken into account when evaluating the test results.

In performing hardness tests, results can vary depending on the method, the area, the direction of the measurements (surface, centre, longitudinal, transverse, etc.), deformation, etc. This shall be taken into account when evaluating the test results.

Shape memory materials can have a different set of properties to report (e.g. plateau stresses, austenite finish strain, elastic modulus, etc) that are not covered in Annex A.

6.6 Surface-treated or coated implants

In cases where implants have surface treatments or coatings, the following shall be considered.

a) The implant shall be examined for structural integrity. In particular, note the occurrence of any surface regions which have become altered, such as by delamination, coating loss, or other changes.

b) The location of any fragments or debris shall be recorded and any relationship to tissues shall be examined, when accessible.

   In the case of metallic implants for joint replacement, particles released from a surface coating might cause secondary damage to functional parts of the implant. These occurrences shall be recorded.

c) Where appropriate, specific tests to evaluate the surface treatment, coating or substrate properties (e.g. chemical, microstructural, and mechanical characteristics) shall be carried out.

d) Where appropriate and accessible, the tissue associated with the implant and any fragments or debris shall be analysed.

NOTE Debris can consist of substances of synthetic or biological origin.

6.7 Biodegradable implants

If the implant was intentionally manufactured from biodegradable materials, test procedures specified in this part of ISO 12891 can still be used. However, the interpretation of the results shall allow for the time-dependent physical and chemical changes to be expected with such materials.

a) The implant shall be examined for structural integrity. In particular, note the occurrence of any surface regions which have become altered, such as by delamination or other changes.

b) The location of any fragments or debris shall be recorded and any relationship to tissues shall be examined, when accessible.

