INTERNATIONAL STANDARD

ISO 12891-3

First edition
2000-02-15

Retrieval and analysis of surgical implants —

Part 3: Analysis of retrieved polymeric surgical implants

Retrait et analyse des implants chirurgicaux —
Partie 3: Analyse des implants chirurgicaux en polymères retirés

Reference number
ISO 12891-3:2000(E)

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Printed 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 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 12891 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 12891-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

ISO 12891 consists of the following parts, under the general title *Retrieval and analysis of surgical implants*:

— *Part 1: Retrieval and handling*

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

— *Part 3: Analysis of retrieved polymeric surgical implants*

— *Part 4: Analysis of retrieved ceramic surgical implants*

Future parts will deal with other relevant aspects of surgical implant retrieval and analysis.

Annexes A and B of this part of ISO 12891 are for information only.

Introduction

The investigation of retrieved implantable surgical implants and adjacent tissues can be of diagnostic value in case of clinical complications, can deepen the knowledge about clinical implant performance and interactions between implants and the body, provide information on implant performance and safety, and thus further the progress of the development of biocompatible implant materials and devices with improved functional longevity.

This International Standard, with its several parts, gives guidance on the retrieval, handling, and analysis of surgical implants and associated biological specimens which are removed from patients routinely, during revision surgery, post mortem or for other reasons. The aim is to provide guidance in limiting iatrogenic damage to associated biological material which could obscure the investigation results, and in gathering data at the proper time and circumstance to validate the study. In associated portions of the various parts of ISO 12891 protocols for the collection of data and examinations are provided relating specific types of material in relation to their typical applications. For particular investigation programs, additional, more specific protocols may be required. If special analytical techniques are employed, the appropriate procedures should be specified.

This part of ISO 12891 offers guidelines for the analysis of retrieved polymeric surgical implants to limit damage to them, to indicate typical investigation techniques, and to allow comparisons between investigation results from different sources. These guidelines may also serve for the documentation of clinical investigations. They may be useful as well for retrieval and analysis studies in animals. Further parts of this International Standard describe the detailed procedures for the retrieval and handling, and analysis methods applicable to surgical implants manufactured from other than polymeric materials.

ISO 12891-1 gives general guidelines on retrieval and handling, and applies to this and the other parts of ISO 12891 which are related to the analysis of different categories of material. In the informative annexes B and C of ISO 12891-1, examples are included for the collection of clinical and retrieval data. These data sets are not repeated in the other parts of ISO 12891; they may be reduced or expanded depending on the retrieved surgical implant, possibly attached or accompanying biological material, and the purpose of the retrieval and analysis.

Retrieval and analysis of surgical implants —

Part 3:
Analysis of retrieved polymeric surgical implants

1 Scope

This part of ISO 12891 provides guidance on the analyses of retrieved polymeric surgical implants. Three stages of investigations are described that are increasingly destructive. Guidance is given on the choice of stage and type of investigation corresponding to the type of implant and purpose of the investigation.

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

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 12891. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 12891 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 12891-1:1998, *Retrieval and analysis of surgical implants — Part 1: Retrieval and handling.*

ASTM D-883, *Standard Terminology Relating to Plastics.*

3 Term and definition

For the purposes of this part of ISO 12891, the following term and definition applies.

3.1
polymeric surgical implant
medical device consisting of polymeric material intended to be inserted into the body by surgical techniques

NOTE 1 The device is hereafter addressed as "implant".

NOTE 2 The polymeric implant may be a component of a modular or multicomponent implant.

4 Procedures for retrieval, handling and packaging

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

NOTE As a precautionary measure, removed implants should be sterilized by an appropriate means that does not adversely affect the implant or the planned investigation. Corresponding descriptions are found in ISO 12891-1:1998, annex A.

5 Analysis of the implant interfaces

5.1 Implant/tissue interface

A significant portion of the information associated with a retrieved implant device is often at the device/tissue interface. Attention should be given to a study of particles in the peri-implant tissue. Where possible, a chemical analysis of the byproducts of degradation of the implant and a study of the cellular response to the implant shall be considered.

Since the appearance of the tissue may vary rapidly with its distance from the implant surface, it is important that the tissue is analysed in its context with the implant (see also relevant subclauses of ISO 12891-1:1998, such as 4.5).

5.2 Implant/implant interfaces

Due to the properties of polymers, implants made of polymers can be comparatively soft. Therefore, in cases of concern, interfaces between polymeric components and other components and their surroundings should be checked for wear debris.

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 through stage III. The implant characterizations may include macroscopic and microscopic examinations, chemical composition, as well as physical and mechanical properties.

Because of the complexity of analyses of the variety of polymeric materials that may be used for implants, and because of the large number of potential analyses and tests suggested in this standard, the investigation is divided into different stages. The investigations selected to be performed should depend upon the reason for removal of the implant and possible restrictions in destructive testing. Perform a minimum number of investigations for routine removals where the implant is not suspect; more examinations for devices suspected of impaired function, and extensive investigations for implants removed because of their performance, behavior or malfunction.

Perform a separate analysis for each component of a device, if possible and necessary. Consider other relevant parts of this International Standard if materials other than polymers are involved.

6.2 Standard forms

A standard form indicating the information to be recorded in each stage of investigation is given in annex A. This form in annex A is a framework. Portions of this form that do not apply in an implant analysis can be omitted. On the other hand, the form may be expanded and modified.

A standard form for the recording of a minimum of clinical information and of additional clinical material is provided in annex B of ISO 12891-1:1998.

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

6.3.1 Identification/Photography

Markings found on the implant such as logos, article numbers, lot numbers, dimensions etc., shall be recorded (see annex A). Where useful, photographic documentation of relevant findings should be kept.

6.3.2 Visual examination

Observe the implant surface by suitable techniques to ascertain any mode of failure, surface alteration or destruction, if such appears.

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

6.3.3 Low-power optical examination

Perform an overall examination under a low-power optical stereomicroscope. Record an estimate as to the degree of findings as suggested in annex A.

6.3.4 Further evaluation

If at the conclusion of stage I further investigation is required to clarify 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 evaluation should be carried out after stage I investigation, if deemed necessary, to further evaluate or identify the characteristics and/or failure mode of the implant. This level of investigation primarily relates to an assessment of the modes of failure and deterioration of an implant in the most non-destructive manner possible (see annex A).

6.4.2 Microscopic examination

Use standard light optical or scanning electron microscopic examination techniques suitable for the material under investigation.

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

When scanning electron microscopy is applied, special preparation techniques may be required to provide conductivity.

6.4.3 Fractographic examination

If the implant shows a fracture or crack, analysis of the fracture surface by suitable techniques may help to ascertain the mode of fracture. In general, destructive evaluation should be avoided. If the device has mechanically failed, it is important to be aware that it may be classified as legal evidence.

6.5 Stage III investigation — Material investigation (mostly destructive)

6.5.1 General

If further testing 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 information, recognized test methods are listed in annex B.

6.5.2 Material characterization

6.5.2.1 It may suffice for a given explant study to verify by simple means the type of polymer indicated by the manufacturer. If more details are required or the nature of the polymeric material is unknown, appropriate techniques shall be used to determine the required physical and chemical properties. Such methods as differential

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

6.5.2.2 Depending on the polymer, certain structural characteristics can be determined by light optical or electron optical microscopy on appropriately thin sections of the material.

For the determination of inclusions, electron optical microanalysis may be employed (e.g. electron diffraction X-ray analysis in the scanning electron microscope).

6.5.2.3 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.

Considering that bulk properties may differ considerably from surface properties (texture, strengths, etc.) due to processing characteristics (flow in molds, differences in solidification rate, etc.), representative samples should be provided from different portions of the implant.

6.5.3 Mechanical properties

6.5.3.1 The types of measurement to be carried out at this stage of characterization will depend upon the implant and its application. Suggested tests are shown in annex A under Mechanical Properties (see annex B for recognized methods).

6.5.3.2 Determine the density and hardness according to the applicable material standard. See annex B for recognized methods.

6.5.3.3 Where required, determine the tensile, flexural, compressive, etc., properties in accordance with applicable material specification if possible, and such other tests as are appropriate to the test specimen which may be fabricated from the implant where dimensions allow. Deviation from the test specimen dimensions as described by standard methods may be necessary to accommodate the shape and size of the implant under investigation. This shall be considered in the evaluation of the test results.

6.5.4 Thermal behaviour properties

Determine the thermal properties of polymers, e.g. transition temperature, heat of fusion and heat of crystallization, in accordance with applicable test methods. Recognized methods are listed in annex B.

6.5.5 Extraction of polymers

Determine the fractions extractable from the polymer in accordance with applicable test methods. Recognized methods are listed in annex B.

6.6 Provisions relating to surface-treated coated implants

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

a) Examine the implant for structural integrity. In particular note the occurrence of altered surface regions of the implant, such as delamination, loss or other changes in the coating.

b) Record the location of any fragments or debris and examine any relationship to tissues, when accessible.

c) Where indicated, carry out specific tests to evaluate surface treatment, the coating or substrate (e.g. chemical, microstructural and mechanical characteristics).

d) Where indicated, analyse the tissue associated with the implant or any fragments or debris.

NOTE Debris may consist of substances of synthetic or biological origin related to the implant or implant function.

6.7 Provisions relating to biodegradable implants

In the case of implants manufactured from polymers intended as biodegradable, test procedures described in this part of ISO 12891 may be used; however, results should be interpreted with regard to time-dependent physical and chemical changes which are expected with biodegradable polymers.

a) Examine the implant for structural integrity. In particular note the occurrence of altered regions at the surface of the implant delaminations, losses or cracks or other changes. Describe the findings in detail.

b) Record the location of any fragments or debris and examine any relationship to tissues when accessible.

c) Where indicated, analyse the tissues associated with the implant or any fragments or debris.

NOTE Debris may consist of substances of synthetic or biologic origin related to the implant or implant function.

7 Implant performance

For the evaluation of the clinical performance of the implant under investigation, in particular in case of failure or deterioration, the implant application, physiological conditions, clinical history and implant loading shall be considered.