INTERNATIONAL STANDARD

ISO 12891-2

First edition
2000-02-15

Retrieval and analysis of surgical implants —

Part 2: Analysis of retrieved metallic surgical implants

Retrait et analyse des implants chirurgicaux —

Partie 2: Analyse des implants chirurgicaux métalliques retirés

Reference number
ISO 12891-2:2000(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 734 10 79
E-mail copyright@iso.ch
Web www.iso.ch

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 12891-2 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 medical device retrieval and analysis.

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

Introduction

The investigation of retrieved implantable medical devices 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 either 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 this International Standard, protocols for the collection of data and examinations are provided relating to specific types of material and their typical applications. For particular investigation programmes, 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 metallic 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 specific procedures for the retrieval and handling, and analysis methods applicable to surgical implants manufactured of other than metallic 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 2:
Analysis of retrieved metallic surgical implants

1 Scope

This part of ISO 12891 provides guidance on the analyses of retrieved metallic 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 associated biological material.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 12891. For dated references, subsequent amendments to, or revisions of, this publication 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 edition of the normative document 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.*

3 Term and definition

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

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

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

NOTE 2 The implant may consist of different components and may be covered or coated with metallic or non-metallic material.

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 tissue/implant interface

A significant portion of the information associated with a retrieved implant device is often found at the device/tissue interface. Attention should be given to a study of particles and degradation products in the peri-implant tissue. 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).

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 lll. 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 metallic materials that may be used for implants, and because of the large number of potential analyses and tests suggested in this International 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 testing for implants suspected of impaired function, and extensive investigations for implants removed because of their performance, behaviour or malfunction.

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

6.2 Standard forms

A standard form, indicating the information to be recorded at each stage of investigation, is given in annex A as 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 extended 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 destruction or failure, 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 testing 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 electron optical microscopic examination techniques suitable for the material under investigation.

6.4.3 Fractographic examination

If the implant is fractured, analyze the fracture surface by suitable techniques 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 investigation is necessary to assess the properties of the implant, tests listed under stage lll in annex A shall be carried out as deemed necessary to further characterize the implant and its history.

6.5.2 Material composition

Determine the physical and chemical composition and identity of the metallic material. The type of material may be characterized by means of material standards listed under annex B, clause B.1. Where necessary, analysis of the composition may be carried out by appropriate methods (e.g. electron diffraction X-ray analysis in the scanning electron microscope, X-ray fluorescence analysis, atomic absorption spectroscopy, and recognized chemical analysis techniques). If analysis of the chemical composition is carried out, the technique employed shall be reported with the results.

6.5.3 Microstructure

6.5.3.1 Use standard metallographic preparation and evaluation techniques suitable for the material under investigation (see annex B, clause B.2).

6.5.3.2 Determine the inclusion content, in accordance with the applicable material standard, if appropriate.

6.5.3.3 Determine the grain size, in accordance with the applicable material standard and method.

6.5.3.4 Indicate the condition of the material if possible (soft or recrystallized, work-strengthened, hot-forged, cold-forged, etc.), and other relevant features.

6.5.3.5 Evidence of corrosion or cracking should be noted and recorded (compare annex A).

6.5.4 Mechanical properties

6.5.4.1 The type of testing to be carried out at this stage of characterization will depend upon the implant and its application. Suggested tests are listed in annex A under Mechanical Properties (see annex B, clause B.3 for recognized methods).

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 shape of the implant or by legal conditions.

In performing hardness tests, one should be aware that the results can vary depending on the method, the area, and the direction of the measurements (surface, centre, longitudinal, transverse, etc.).

6.5.4.2 Determine the hardness according to the type of material and by consulting related material standards (see annex B).

6.5.4.3 Where required, determine the tensile properties, bending properties, or other mechanical properties in accordance with applicable material specifications if possible, and such other tests as are appropriate to the test specimen which may be fabricated from the implant. Deviation from the specimen dimensions as described in standard test 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 (see annex B, clause B.3).

6.6 Provisions for coated implants

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

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

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

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

6.6.4 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.

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.

Annex A
(informative)

Standard form for guiding the analysis of retrieved metallic surgical implants

NOTE This form is a guideline for the organization of the implant analyses and presentation of results of the examination. Sections which are not applicable may be deleted or marked as such. Individual forms based on this example may be created. Where required, additional observations and findings should be written out.

Examination of Retrieved Implant

Record No. .....
Record date .....

This report applies to component No. _____ of _____ total components.

Condition: intact □; broken □; cracked □; corroded □; damaged □

Stage I Investigation

1. Implant type (manufacturer and model if available)

Identification marks _____ dimensions _____

2. Type of material (be as specific as possible in this characterization: refer to ISO 5832, all parts, and other material standards if applicable; see annex B.1)

3. Macroscopic examination (characterize with YES, NO, DOUBT, or NOT APPLICABLE [N/A]; specify further if required)

	Location	Estimated degree
a) wear or burnishing	_____	_____
b) galling	_____	_____
c) corrosion	_____	_____
d) scratching	_____	_____
e) cracking	_____	_____
f) change of shape	_____	_____
g) mechanical damage	_____	_____
h) macroporosity	_____	_____
i) other	_____	_____

Stage II Investigation

4. Corrosion (if YES, identify and describe location and method of examination)

a) general corrosion_____

b) pitting corrosion_____

c) crevice corrosion_____

d) galvanic corrosion_____

e) fretting corrosion_____

f) stress corrosion_____

g) unable to identify_____

h) other_____

5. Wear (If YES, identify and describe location and method of examination)

a) adhesive wear_____

b) abrasive wear_____

c) wear and corrosion_____

d) wear and degradation_____

e) wear and fatigue_____

f) multicomponent wear_____

6. Mechanical failure (if YES, identify mode, indicate location of failure and method of identification)

a) static overload with plastic deformation _____

b) shear_____

c) bending_____

d) torsion_____

e) impact_____

f) fatigue_____

g) corrosion-fatigue_____

h) stress-corrosion_____

i) combination of above (identify)_____

j) other (specify)_____

k) unable to identify_____

Stage III Investigation

7. Type of material (indicate analysis method, see annex B 1)

a) chemical composition_____

8. Microstructure (microscopic examination, indicate sample location and orientation)

a) grain size _____
b) inclusion content _____
c) grain boundary constituents_____
d) homogeneity_____
e) condition (recrystallized, cold-worked, forged, etc.) _____
f) microporosity _____
g) other features_____

9. Mechanical properties (N/A = not applicable)

a) hardness (indicate method and location)_____
b) tensile test (sample size, orientation, gauge length) _____
c) ultimate tensile strength_____
d) yield stress, 0,2 % offset_____
e) elongation (%)_____
f) reduction of area (%)_____
g) bending test_____
h) other types of test_____

10. Metallic coating (N/A = not applicable)

a) coating material_____
b) coating condition_____
c) estimated fraction of coating missing_____
d) shear strength determined_____
e) tensile strength determined_____

Annex B
(informative)

Referee methods for the evaluation of metallic materials

B.1 Characteristics of chemical analysis

NOTE In these standards, indications for mechanical properties and their testing are also found.

B.1.1 International Standards

— ISO 5832-1, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel*

— ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

— ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

— ISO 5832-4, *Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy*

— ISO 5832-5, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy*

— ISO 5832-6, *Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*

— ISO 5832-7, *Implants for surgery — Metallic materials — Part 7: Forgeable and cold formed cobalt-chromium-nickel-molybdenum alloy*

— ISO 5832-8, *Implants for surgery — Metallic materials — Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy*

— ISO 5832-9, *Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel*

— ISO 5832-11, *Implants for surgery — Metallic materials — Part 11: Wrought titanium 6-aluminium 7-niobium alloy*

— ISO 5832-12, *Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy*

— ISO 13782, *Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications*

B.1.2 Other standards

— ASTM E 353, *Standard Test Methods for Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel-Iron Alloys*

— ASTM E 354, *Standard Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys*

B.2 Characteristics of microstructure

B.2.1 International Standards

— ISO 643, *Steel — Micrographic determination of the ferritic or austenitic grain size*

— ISO 4967, *Steel — Determination of the contents of nonmetallic inclusions-micrographic-methods using standard diagrams*

B.2.2 Other standards

— ASTM E45, *Standard Test Methods for Determining the Inclusion Content of Steel*

— ASTM E112, *Standard Test Methods for Determining the Average Grain Size*

B.3 Mechanical characteristics

B.3.1 International Standards

— ISO 4545, *Metallic materials — Hardness test — Knoop test* (for particular conditions)

— ISO 6507, *Metallic materials — Hardness test — Vickers test*

— ISO 6508, *Metallic materials — Hardness test — Rockwell test (scales A-B-C-D-E-F-G-H-K)*

— ISO 6892, *Metallic materials — Tensile testing at ambient temperature*

— ISO 7438, *Metallic materials — Bend test*

B.3.2 Other standards

— ASTM F 1044, *Standard Test Method for Shear Testing of Porous Metal Coatings*

— ASTM F 1147, *Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings*

B.4 Additional information

— ASTM E 860, *Standard Practice for Examining and Testing Items That Are or May Become Involved in Products Liability Litigation.*

ICS 11.040.40

Price based on 9 pages