

BS ISO 12891-2:2014



BSI Standards Publication

Retrieval and analysis of surgical implants

Part 2: Analysis of retrieved surgical
implants

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National foreword

This British Standard is the UK implementation of ISO 12891-2:2014.

The UK participation in its preparation was entrusted to Technical Committee CH/150, Implants for surgery.

A list of organizations represented on this committee can be obtained on request to its secretary.

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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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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 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 polydimethylsiloxanes) 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.

- c) 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.

7 Implant performance

To evaluate the clinical performance of the implant under investigation, in particular, the implant failure or deterioration, the implant application, the physiological conditions, the clinical history, and the implant loading have to be considered.

Annex A (normative)

Standard forms for the analysis of retrieved surgical implants

A.1 General

[A.2](#), [A.3](#), and [A.4](#) list the steps to be followed in a typical series of analyses for metallic (see [A.2](#)), polymeric (see [A.3](#)), and ceramic (see [A.4](#)) implants and show how the test results can be presented.

Sections which are not applicable shall be marked as such. Additional observations, findings, and conclusions can be included at the end of the form or in the individual sections, as appropriate.

A.2 Form for examination of retrieved metallic surgical implant

Record no.: _____

Record date: _____

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

Condition of implant: intact ; broken ; cracked ; corroded ; damaged

Stage I investigation (macroscopic examination — non-destructive)

1. Implant information

Implant type _____ Number of components _____

Catalogue number _____ Serial, batch or lot number(s) _____

Manufacturer _____

Dimensions _____ Material _____

2. Macroscopic examination both visually and with low-power microscope

(state YES, NO, DOUBTFUL or N/A in the assessment column)

	Location	Assessment
a) wear (describe appearance)	_____	_____
b) galling	_____	_____
c) corrosion	_____	_____
d) scratching	_____	_____
e) cracking	_____	_____
f) change of shape	_____	_____
g) burnishing	_____	_____
h) mechanical damage	_____	_____
i) macroporosity	_____	_____
j) other	_____	_____

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

Microscopic examination of surface and of defects at higher magnifications (optical and electron microscopy).

3. Wear (if YES, describe location and state method of examination)

- a) adhesive wear -----
- b) abrasive wear -----
- c) wear and corrosion -----
- d) wear and degradation -----
- e) wear and fatigue -----
- f) multicomponent wear -----

4. Corrosion (if YES, describe location and state 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. Mechanical failure (if YES, state mode, location 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 (material investigation — mostly destructive)

6. Type of material (be as specific as possible and state applicable International Standards, see [B.1](#))

- a) chemical composition _____

7. Microstructure and defects (microscopic examination, indicate sample location, orientation and preparation technique)

- a) grain size _____
- b) inclusions _____
- c) grain boundary constituents _____
- d) homogeneity _____
- e) condition (recrystallized, cold-worked, forged, etc.) _____
- f) micro-porosity (%) _____
- g) other features _____

8. Mechanical properties (state N/A if not applicable, method used and sample location and orientation)

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

9. Coatings (state N/A if not applicable)

- a) coating material _____
- b) coating condition _____
- c) estimated fraction of coating missing _____
- d) shear strength determined _____
- e) tensile strength determined _____

A.3 Form for examination of retrieved polymeric surgical implant

Record no.: _____

Record date: _____

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

Condition of implant: intact ; broken ; cracked ; corroded ; damaged

Stage I investigation (macroscopic examination — non-destructive)

1. Implant information

Implant type _____ Number of components _____

Catalogue number _____ Serial, batch or lot number(s) _____

Manufacturer _____

Dimensions _____ Material _____

2. Macroscopic examination both visually and with low-power microscope

(state YES, NO, DOUBTFUL or N/A in the assessment column)

	Location	Assessment
a) wear (describe appearance)	_____	_____
b) discoloration	_____	_____
c) material transfer	_____	_____
d) scratching or pitting	_____	_____
e) embedded particles	_____	_____
f) cracking	_____	_____
g) warping	_____	_____
h) change of shape	_____	_____
i) burnishing	_____	_____
j) mechanical damage	_____	_____
k) tissue attachment	_____	_____
l) macroporosity	_____	_____
m) dimensions	_____	_____
n) others	_____	_____

Stage II Investigation (microscopic examination — mostly non-destructive)

Microscopic examination of surface and of defects at higher magnifications (optical and electron microscopy).

3. Wear (if YES, describe location and state method of examination)

- a) adhesive wear _____
- b) abrasive wear _____
- c) wear and delamination _____
- d) wear and degradation _____
- e) wear and fatigue _____
- f) multicomponent wear _____
- g) other degradation features _____

4. Deterioration (if YES, describe location and state method of examination)

- a) discoloration, staining _____
- b) material transfer _____
- c) cracking _____
- d) pitting _____
- e) scratching _____
- f) tissue adhesion _____
- g) delamination _____
- h) other features _____

5. Mechanical damage or failure (if YES, state mode, location and method of identification)

- a) overload _____
- b) shear _____
- c) bending _____
- d) torsion _____
- e) impact _____
- f) fatigue _____
- g) creep _____
- h) stress-cracking _____
- i) combination of above
(identify) _____
- j) other (specify) _____
- k) unable to identify _____

Stage III Investigation (material investigation — mostly destructive)

6. Type of material (be as specific as possible and state applicable International Standards, see [B.1](#))

- a) characteristics of composition _____

7. Microstructure and defects (microscopic examination, indicate sample location, orientation and preparation technique)

- a) inclusions _____
- b) inhomogeneity, no , yes ,
describe _____
- c) micro-porosity (%) _____
- d) other defects _____
- e) other features _____

8. Mechanical properties (state N/A if not applicable, method used and sample location and orientation)

- a) hardness _____
- b) density _____
- c) ultimate tensile strength _____
- d) elongation (%) _____
- e) tear strength _____
- f) flexural strength (or modulus) _____
- g) shear strength _____
- h) compressive strength _____
- i) other types of test _____

9. Physicochemical properties (most applicable technique)

- a) molecular weight (distribution) _____
 - 1) solution viscometry _____
 - 2) gel permeation chromatography _____
 - 3) osmometry _____
 - 4) light scattering _____
 - 5) viscometry _____
 - 6) melt index _____
- b) thermal characterization _____
 - 1) differential thermal analysis _____
 - 2) differential scanning calorimetry _____
 - 3) thermometric analysis _____
 - 4) thermo gravimetric analysis _____
- c) dynamic mechanical measurements _____
- d) infrared spectroscopy _____
- e) nuclear magnetic resonance _____
- f) lipid content of implant _____
- g) density _____
- h) other analyses (describe) _____

10. Coatings (state N/A if not applicable)

- a) coating material _____
- b) coating condition _____
- c) estimated fraction of coating missing _____
- d) shear strength determined _____
- e) tensile strength determined _____

A.4 Form for examination of retrieved ceramic surgical implant

Record no.: _____

Record date: _____

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

Condition of implant: intact ; broken ; cracked ; corroded ; damaged

Stage I investigation (macroscopic examination — non-destructive)

1. Implant information

Implant type _____ Number of components _____

Catalogue number _____ Serial, batch or lot number(s) _____

Manufacturer _____

Dimensions _____ Material _____

2. Macroscopic examination both visually and with low-power microscope

(state YES, NO, DOUBTFUL or N/A in the assessment column)

	Location	Assessment
a) wear (describe appearance)	_____	_____
b) discoloration	_____	_____
c) material transfer	_____	_____
d) scratching or pitting	_____	_____
e) fragmentation	_____	_____
f) major cracks	_____	_____
g) surface cracks/crazing	_____	_____
h) chipping	_____	_____
i) surface erosion	_____	_____
j) mechanical damage	_____	_____
k) macro-porosity	_____	_____
l) tissue attachment	_____	_____
m) other signs of degradation	_____	_____

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

Microscopic examination of surface and of defects at higher magnifications (optical and electron microscopy).

3. Wear (if YES, describe location and state method of examination)

- a) adhesive wear _____
- b) abrasive wear _____
- c) material transfer _____
- d) wear and degradation _____
- e) wear and fatigue _____
- f) multi-component wear _____

4. Deterioration (if YES, describe location and state method of examination)

- a) cracking/crazing _____
- b) deterioration, dissolution
(describe in detail) _____

5. Mechanical damage or failure (if YES, state mode, location and method of identification)

- a) static overload _____
- b) shear _____
- c) bending _____
- d) torsion _____
- e) impact _____
- f) fatigue _____
- g) fatigue combined with _____
- h) stress-cracking _____
- i) deterioration and cracking _____
- j) combination of above (iden-
tify) _____
- k) other (specify) _____
- l) unable to identify _____

Stage III Investigation (material investigation — mostly destructive)

6. Type of material (be as specific as possible and state applicable International Standards, see [B.1](#))

a) chemical composition _____

7. Microstructure and defects (microscopic examination, indicate sample location, orientation and preparation technique)

a) grain size _____

b) inclusions _____

c) grain boundary constituents _____

d) homogeneity _____

e) different phases _____

f) micro-porosity (%) _____

g) other flaws _____

h) internal cracking _____

 1) single crack _____

 2) multiple cracks _____

 3) crack origin _____

 4) grain boundary cracks _____

i) other features _____

8. Mechanical properties (state N/A if not applicable, method used and sample location and orientation)

a) hardness _____

b) density _____

c) open porosity _____

d) closed porosity _____

e) tensile test (indicate specimen size and orientation, gauge length) _____

f) flexural strength _____

g) compressive strength _____

h) bending test _____

i) other types of test _____

9. Coatings (state N/A if not applicable)

- a) coating material _____
- b) coating condition _____
- c) estimated fraction of coating missing _____
- d) shear strength _____
- e) tensile strength _____

Annex B (informative)

ISO Standards applicable for the evaluation of materials

NOTE International Standards for the evaluation of materials are listed in this Annex. Other standards for evaluating materials, which can also be applicable, are listed in the Bibliography.

B.1 Metallic materials

B.1.1 Chemical, microstructural and mechanical properties

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-iron 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 5832-14, *Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy*

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

ISO 15374, *Implants for surgery — Requirements for production of forgings*

B.1.2 Microstructural and surface testing

ISO 643, *Steel — Micrographic determination of the apparent grain size*

ISO 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 4288, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture*

ISO 4967, *Steel — Determination of content of nonmetallic inclusions — Micrographic method using standard diagrams*

ISO 20160, *Implants for surgery — Metallic materials — Classification of microstructures for alpha+beta titanium alloy bars*

B.1.3 Mechanical testing

ISO 4545-1, *Metallic materials — Knoop hardness test — Part 1: Test method*

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 6508-1, *Metallic materials — Rockwell hardness test — Part 1: Test method (scales A, B, C, D, E, F, G, H, K, N, T)*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 6892-2, *Metallic materials — Tensile testing — Part 2: Method of test at elevated temperature*

ISO 7438, *Metallic materials — Bend test*

B.2 Polymeric materials

B.2.1 Chemical, physicochemical, thermal and mechanical properties

ISO 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 4288, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture*

ISO 5833, *Implants for surgery — Acrylic resin cements*

ISO 5834 (all parts), *Implants for surgery — Ultra-high-molecular-weight polyethylene*

ISO 14949, *Implants for surgery — Two-part addition-cure silicone elastomers*

ISO 15309, *Implants for surgery — Differential scanning calorimetry of poly ether ether ketone (PEEK) polymers and compounds for use in implantable medical devices*

B.2.2 Physicochemical testing

ISO 60, *Plastics — Determination of apparent density of material that can be poured from a specified funnel*

ISO 61, *Plastics — Determination of apparent density of moulding material that cannot be poured from a specified funnel*

ISO 62, *Plastics — Determination of water absorption*

ISO 1183-1, *Plastics — Methods for determining the density of non-cellular plastics — Part 1: Immersion method, liquid pycnometer method and titration method*

ISO 1183-2, *Plastics — Methods for determining the density of non-cellular plastics — Part 2: Density gradient column method*

ISO 1183-3, *Plastics — Methods for determining the density of non-cellular plastics — Part 3: Gas pycnometer method*

ISO 3451-1, *Plastics — Determination of ash — Part 1: General methods*

ISO 5833, *Implants for surgery — Acrylic resin cements*

ISO 5834-2, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms*

ISO 13781, *Poly(L-lactide) resins and fabricated forms for surgical implants — in vitro degradation testing*

ISO 15814, *Implants for surgery — Copolymers and blends based on polylactide — in vitro degradation testing*

B.2.3 Mechanical testing

ISO 178, *Plastics — Determination of flexural properties*

ISO 179-1, *Plastics — Determination of Charpy impact properties — Part 1: Non-instrumented impact test*

ISO 179-2, *Plastics — Determination of Charpy impact properties — Part 2: Instrumented impact test*

ISO 458-1, *Plastics — Determination of stiffness in torsion of flexible materials — Part 1: General method*

ISO 527-1, *Plastics — Determination of tensile properties — Part 1: General principles*

ISO 604, *Plastics — Determination of compressive properties*

ISO 899-1, *Plastics — Determination of creep behaviour — Part 1: Tensile creep*

ISO 899-2, *Plastics — Determination of creep behaviour — Part 2: Flexural creep by three-point loading*

ISO 5833, *Implants for surgery — Acrylic resin cements*

ISO 6721-1, *Plastics — Determination of dynamic mechanical properties — Part 1: General principles*

ISO 16402, *Implants for surgery — Acrylic resin cement — Flexural fatigue testing of acrylic resin cements used in orthopaedics*

ISO 22088-1, *Plastics — Determination of resistance to environmental stress cracking (ESC) — Part 1: General guidance*

ISO 22088-2, *Plastics — Determination of resistance to environmental stress cracking (ESC) — Part 2: Constant tensile load method*

ISO 22088-3, *Plastics — Determination of resistance to environmental stress cracking (ESC) — Part 3: Bent strip method*

ISO 22088-4, *Plastics — Determination of resistance to environmental stress cracking (ESC) — Part 4: Ball or pin impression method*

ISO 22088-5, *Plastics — Determination of resistance to environmental stress cracking (ESC) — Part 5: Constant tensile deformation method*

ISO 22088-6, *Plastics — Determination of resistance to environmental stress cracking (ESC) — Part 6: Slow strain rate method*

B.3 Ceramic materials

B.3.1 Chemical, microstructural and mechanical properties

ISO 6474-1, *Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina*

ISO 6474-2, *Implants for surgery — Ceramic materials — Part 2: Composite materials based on a high purity alumina matrix with zirconia reinforcement*

ISO 13356, *Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*

ISO 13779-1, *Implants for surgery — Hydroxyapatite — Part 1: Ceramic hydroxyapatite*

ISO 13779-2, *Implants for surgery — Hydroxyapatite — Part 2: Coatings of hydroxyapatite*

ISO 13779-3, *Implants for surgery — Hydroxyapatite — Part 3: Chemical analysis and characterization of crystallinity and phase purity*

NOTE Various International Standards are available for the chemical analysis of alumina.

B.3.2 Physical testing

ISO 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 4288, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture*

ISO 5017, *Dense shaped refractory products — Determination of bulk density, apparent porosity and true porosity*

B.3.3 Mechanical testing

ISO 4545, *Metallic materials — Hardness test — Knoop test*

ISO 6474-1 *Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina*

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 6508-1, *Metallic materials — Rockwell hardness test — Part 1: Test method (scales A, B, C, D, E, F, G, H, K, N, T)*

ISO 9385, *Glass and glass-ceramics — Knoop hardness test*

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1.2 Microstructural testing

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- [4] ASTM E112, *Standard Test Methods for Determining Average Grain Size*

1.3 Mechanical testing

- [5] ASTM F1044, *Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings*
- [6] ASTM F1147, *Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings*

1.4 Additional information

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2 Polymeric materials

2.1 Chemical, physicochemical, thermal and mechanical properties

- [8] ASTM F 1925, *Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants*
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2.2 Physicochemical testing

- [10] ASTM D570, *Standard Test Method for Water Absorption of Plastics*
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- [33] ASTM D1601, *Standard Test Method for Dilute Solution Viscosity of Ethylene Polymers*
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3 Ceramic materials

3.1 Chemical testing

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3.2 Physical testing

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