INTERNATIONAL STANDARD

ISO 12891-2

Second edition
2014-09-15

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

Reference number
ISO 12891-2:2014(E)

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

Published in Switzerland

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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.