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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
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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.

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.