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Non-active surgical implants — Implants for osteosynthesis — Particular requirements

Implants chirurgicaux non actifs — Implants pour ostéosynthèse — Exigences particulières

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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14602 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

This second edition cancels and replaces the first edition (ISO 14602:1998), which has been technically revised.

Introduction

In general, non-active surgical implants for osteosynthesis are used in trauma treatment or corrective surgery. They maintain the reduction of fractured bones and stabilize bony (or adjacent) structures to allow bone healing or fusion and/or to provide support or correction. When they have achieved their objective, the implants are either retrieved or left *in situ*.

This International Standard, in addition to the requirements in ISO 14630, provides a method for addressing the fundamental principles in ISO/TR 14283 as they apply to non-active surgical implants for osteosynthesis. Annex A shows the correspondence between the clauses of this International Standard and those of ISO/TR 14283:2004.

This International Standard also provides a method of demonstrating compliance with the relevant essential requirements (ERs) as outlined in general terms in Annex 1 of European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, amended by Directive 2007/47/EC of 5 September 2007, as they apply to non-active surgical implants for osteosynthesis. It might also assist manufacturers to comply with the requirements of other regulatory bodies.

Alternative methods of demonstrating compliance might be acceptable, in particular with respect to implants which have demonstrated satisfactory long-term clinical performance.

There are three levels of standard concerned with non-active surgical implants and related instrumentation. For the implants themselves, there are the following levels, with level 1 being the highest:

— level 1: general requirements for non-active surgical implants;

— level 2: particular requirements for families of non-active surgical implants;

— level 3: specific requirements for types of non-active surgical implants.

Level 1 standards contain requirements that apply to all non-active surgical implants. They also indicate that additional requirements are given in the level 2 and level 3 standards.

Level 2 standards, such as this International Standard, contain requirements that apply to a more restricted set or family of non-active surgical implants. This International Standard is a Level 2 standard that lays down particular requirements for non-active surgical implants for osteosynthesis that are in addition to those general requirements stated in ISO 14630 for non-active surgical implants. It is to be applied in conjunction with ISO 14630.

Level 3 standards, such as those listed in the annexes, apply to specific types of implant within a family of non-active surgical implants, in this case particular types of non-active surgical implant for osteosynthesis.

To address all requirements for a specific implant, it is advisable that the standard of the lowest available level be consulted first.

NOTE The requirements in this International Standard correspond to international consensus. Individual or national standards or regulatory bodies can prescribe other requirements.