
**Instruments for use in association
with non-active surgical implants —
General requirements**

*Instruments à utiliser en association avec les implants chirurgicaux
non actifs — Exigences générales*

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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).

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 16061:2015), which has been technically revised. The main changes compared to the previous edition are as follows:

- A requirement to include intended purpose has been added in the list of items to be included when establishing the intended performance of the instrument.
- The list of design attributes in [Clause 5](#) has been reorganized and several new attributes have added to the list.
- The selection of materials to be used in the instrument has been based on a risk analysis and the clause now includes a list of the minimum factors to be considered in the risk analysis.
- The requirement for pre-clinical evaluation has been expanded and includes the requirement for testing and biological evaluation of the final instrument.
- A clinical evaluation of the instrument has been added as a requirement in all cases. However, if the pre-clinical evaluation demonstrates the safety and intended performance of the instrument in the conditions of intended use, the results of the pre-clinical evaluation will satisfy the requirement for the clinical evaluation.
- A new requirement for post-market surveillance has been added to [Clause 7](#).
- The requirements in [Clause 11](#) have been reorganized and clarified to reflect current practice and to reference ISO 17664:2017, Clause 6 for instructions for applicable processing step (i.e. cleaning, disinfection, drying, packaging, and sterilization) that need to be carried out by someone other than the manufacturer.