

# DRAFT INTERNATIONAL STANDARD

## ISO/DIS 16061

ISO/TC 150

Secretariat: DIN

Voting begins on:  
2020-01-16

Voting terminates on:  
2020-04-09

---

---

## 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*

ICS: 11.040.40; 11.040.99

**iTeh STANDARD PREVIEW**  
(standards.iteh.ai)  
Full standard:  
<https://standards.iteh.ai/catalog/standards/sist/25e31dc5-a185-428a-8127-b036ff3e9300/iso-dis-16061>

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

This document is circulated as received from the committee secretariat.

**ISO/CEN PARALLEL PROCESSING**



Reference number  
ISO/DIS 16061:2020(E)

© ISO 2020

**iTeh STANDARD PREVIEW**  
(standards.iteh.ai)  
Full standard:  
<https://standards.iteh.ai/catalog/standards/sist/25e31dc5-a85-428a-8127-b036ff3e9300/iso-dis-16061>



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Fax: +41 22 749 09 47  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

	Page
Foreword.....	iv
Introduction.....	v
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 Intended performance</b> .....	<b>2</b>
<b>5 Design attributes</b> .....	<b>3</b>
<b>6 Selection of materials</b> .....	<b>4</b>
<b>7 Design evaluation</b> .....	<b>4</b>
7.1 General.....	4
7.2 Pre-clinical evaluation.....	4
7.3 Clinical evaluation.....	5
7.4 Post-market surveillance.....	5
<b>8 Manufacture</b> .....	<b>5</b>
<b>9 Sterilization</b> .....	<b>6</b>
9.1 Instruments supplied sterile.....	6
9.2 Instruments supplied non-sterile.....	6
9.3 Instruments that are resterilizable.....	6
<b>10 Packaging</b> .....	<b>6</b>
10.1 Protection from damage in storage and transport.....	6
10.2 Maintenance of sterility in transit.....	6
<b>11 Information supplied by the manufacturer</b> .....	<b>7</b>
11.1 General.....	7
11.2 Marking on instruments.....	7
11.3 Label.....	8
11.4 Instructions for use.....	9
11.5 Additional information for instruments with a measuring function.....	10
<b>Annex A (informative) Examples of typical applications of instruments to be used in association with non-active surgical implants and materials found acceptable for instrument manufacture</b> .....	<b>11</b>
<b>Bibliography</b> .....	<b>13</b>

## 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](http://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](http://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 fourth edition cancels and replaces the third edition (ISO 16061:2015), which has been technically revised.

## Introduction

This document provides a method of addressing the fundamental principles outlined in ISO/TR 14283 [16] 1) as they apply to instruments to be used in association with non-active surgical implants. It also provides a method that can be used to demonstrate compliance with applicable regulatory requirements relevant to the general safety and performance of medical devices as they apply to instruments to be used in association with non-active surgical implants.

There are three levels of standards dealing with instruments to be used in association with non-active surgical implants. They are as follows, with level 1 being the highest.

- Level 1: General requirements for instruments to be used in association with non-active surgical implants.
- Level 2: Particular requirements for families of instruments to be used in association with non-active surgical implants.
- Level 3: Specific requirements for types of instruments to be used in association with non-active surgical implants.

Level 1 standards include this document which contains requirements that apply to all instruments to be used in association with non-active surgical implants, ISO 14630 [17] which contains requirement for non-active surgical implants and ISO 14708-1 [18] which contains requirements for active implants. They also anticipate that there are additional requirements in the level 2 and level 3 standards.

Level 2 standards apply to a more restricted set or family of instruments, such as those designed for use with non-active surgical implants used in neurosurgery, cardiovascular surgery, or joint replacement.

Level 3 standards apply to specific types of instruments within a family of instruments used in association with non-active surgical implants such as hip joints or arterial stents.

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

Compliance with a level 3 standard is intended to imply compliance with the applicable level 2 standards, if available, and with the applicable level 1 standard.

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

---

1) Numbers in square brackets refer to the Bibliography.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

Full standard:  
<https://standards.iteh.ai/catalog/standards/sist/25e31dc5-a185-428a-8127-b036ff3e9300/iso-dis-16061>

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

## 1 Scope

This document specifies general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are supplied after refurbishment.

NOTE In this document, unless otherwise specified, the term “instrument” refers to an instrument for use in association with non-active surgical implants.

This document also applies to instruments which can be connected to power-driven systems, but does not apply to the power-driven systems themselves.

With regard to safety, this document gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, and information supplied by the instrument manufacturer, hereafter referred to as the manufacturer.

This document is not applicable to instruments associated with dental implants, transendodontic and transradicular implants and ophthalmic implants.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO/TS 13004, *Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD*

## ISO/DIS 16061:2020(E)

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 80000-1, *Quantities and units — Part 1: General*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971:2019 and the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

#### 3.1 associated implant

specific non-active surgical implant in association with which a specific instrument is intended to be used during a surgical procedure

#### 3.2 instrument

non-active medical device intended for use during surgical procedures related to specific non-active surgical implants

Note 1 to entry: Examples of typical applications of instruments to be used in association with non-active surgical implants are presented in the [A.1](#).

#### 3.3 non-active surgical implant

surgical implant, the operation of which does not depend on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

[SOURCE: ISO 14630:2013, 3.6]

### 4 Intended performance

The intended performance of an instrument shall be described and documented by addressing the following, with particular regard to safety:

- a) intended purpose;
- b) functional characteristics; and
- c) intended conditions of use.

Instruments shall be evaluated to demonstrate that the intended performance is achieved (see [Clause 7](#)).

NOTE Information to support the description of the intended performance can be found in sources such as:



- published standards;
- published clinical and scientific literature;
- validated test results.

## 5 Design attributes

The development of the design attributes of an instrument to meet the performance intended by the manufacturer shall take into account at least the following:

- a) role of the instrument in conjunction with the associated the non-active surgical implant (e.g. implantation, positioning, alignment, removal, etc.);
  - b) biocompatibility of materials for their intended use, including the influence of material by-products from manufacturing and chemical residuals;
  - c) physical, mechanical, biological and chemical properties of the instrument materials;
  - d) potential deterioration of the material characteristics;
  - e) usability;
  - f) for instruments requiring user processing (e.g. sterilization) or intended to be reused, compatibility with intended processing agent (e.g. cleaning agent, disinfectant, and sterilizing agent) and intended processing conditions (e.g. temperature, pressure, vacuum, humidity, time, etc.);
  - g) stability of instrument materials under intended manufacturing conditions (e.g. chemicals, temperature, pressure, vacuum, humidity, time, etc.);
  - h) ease of cleaning, disinfection (if intended by the manufacturer) and sterilization both by the manufacturer and the user;
  - i) ease of maintenance;
  - j) effects of contact between the instrument and the body;
  - k) effects of contact between the instrument and the non-active surgical implant, and other instruments;
  - l) shape and dimensions of the instrument, including their possible effects on the body;
  - m) wear characteristics of materials and the effect of wear and wear products on the instrument and the body;
  - n) insertion, removal, and interconnection of parts;
  - o) extent of fluid leakage and/or diffusion of substances into or out of instruments;
  - p) accuracy and stability of instruments with a measuring function;
  - q) reciprocal interference with other devices in the specified use environment;
- EXAMPLE Compatibility with diagnostic imaging systems such magnetic resonance imaging (MRI) equipment. See the Bibliography for standards related to the hazards associated with the MR environment.
- r) ability of the instrument or fragment of instrument to be located by means of an external imaging device (see [11.4 o](#)); and
  - s) compatibility with medicinal substances incorporated into or intended to be used with the instrument.

## 6 Selection of materials

The selection of materials to be used for the manufacture of instruments shall be based on a risk analysis, which shall take into account at least the following:

- a) the properties required for the intended purpose considering factors such as mechanical/functional requirements, anatomical location, size, geometry, and conditions for use; and, duration and frequency of use over the lifetime of the instrument;
- b) any intended treatment to the material or to the surface of the instrument (e.g. chemical, electro-chemical, thermal, mechanical, coating, etc.);
- c) the effects of instrument manufacturing, handling, cleaning, packaging, sterilization, storage, and processing (if applicable); and

NOTE For information on processing of health care products, see ISO 17664.

- d) possible adverse reactions by the human body and body fluids to the instrument materials.

EXAMPLE Adverse reaction to leachable chemicals, degradation products, additives (e.g., plasticisers and fillers) and impurities.

NOTE [Annex A](#) lists some of the materials that have been found acceptable in certain applications. Reference to [Annex A](#) does not eliminate the need to conduct a risk analysis taking into account the factors outlined above.

A biological evaluation of the final, finished instrument shall be performed and shall form part of the pre-clinical evaluation (see [7.2](#)).

## 7 Design evaluation

### 7.1 General

Instruments shall be evaluated in association with the non-active surgical implant they are designed for, in order to demonstrate that the safety and the intended performance is achieved (see [Clause 4](#)). Safety and intended performance shall be demonstrated by pre-clinical evaluation, clinical evaluation and, if available, post-market surveillance, including appropriate risk management at all stages of the life cycle of the instrument.

NOTE Further information on risk management can be found in ISO 14971.

### 7.2 Pre-clinical evaluation

Instruments shall undergo pre-clinical evaluation based on a critical review of:

- a) data obtained from testing of the instrument or demonstrably similar instruments and, when available, data from validated techniques for evaluating instrument safety and intended performance; and
- b) all available field data, safety reports, relevant complaint information, and adverse event data for the instrument or demonstrably similar instruments.

The pre-clinical evaluation can be supported by a critical review of:

- c) applicable standards; and
- d) the relevant scientific literature relating to the safety, performance, design characteristics, and intended use of the instrument or of demonstrably similar instruments.

Testing of the instrument is required unless the critical review above is sufficient to demonstrate the safety and intended performance of the instrument. If testing of the instrument is required, the testing shall simulate conditions of intended use and, if applicable, re-use.