

This is a preview of "ISO 16061:2015". [Click here to purchase the full version from the ANSI store.](#)

Third edition  
2015-05-15

---

---

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

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



Reference number  
ISO 16061:2015(E)

© ISO 2015

This is a preview of "ISO 16061:2015". [Click here to purchase the full version from the ANSI store.](#)



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, 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  
Ch. de Blandonnet 8 • CP 401  
CH-1214 Vernier, Geneva, Switzerland  
Tel. +41 22 749 01 11  
Fax +41 22 749 09 47  
[copyright@iso.org](mailto:copyright@iso.org)  
[www.iso.org](http://www.iso.org)

This is a preview of "ISO 16061:2015". [Click here to purchase the full version from the ANSI store.](#)

## Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<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>2</b>
<b>6 Selection of materials</b> .....	<b>3</b>
<b>7 Design evaluation</b> .....	<b>3</b>
7.1 General .....	3
7.2 Pre-clinical evaluation .....	3
7.3 Clinical evaluation .....	3
<b>8 Manufacture</b> .....	<b>3</b>
<b>9 Sterilization</b> .....	<b>4</b>
9.1 Products supplied sterile .....	4
9.2 Products provided non-sterile .....	4
<b>10 Packaging</b> .....	<b>4</b>
10.1 Protection from damage in storage and transport .....	4
10.2 Maintenance of sterility in transit .....	4
<b>11 Information supplied by the manufacturer</b> .....	<b>4</b>
11.1 General .....	4
11.2 Labelling .....	5
11.3 Instructions for use .....	6
11.4 Instruments with measuring function .....	7
11.5 Restrictions in combinations .....	7
11.6 Marking on instruments .....	7
11.7 Instruments intended for single use .....	7
<b>Annex A (informative) Examples of typical instrument applications, together with materials found acceptable for instrument manufacture</b> .....	<b>8</b>
<b>Bibliography</b> .....	<b>17</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 third edition cancels and replaces the second edition (ISO 16061:2008), which has been technically revised.