

This is a preview of "ISO 8828:2014". [Click here to purchase the full version from the ANSI store.](#)

Second edition  
2014-11-15

---

---

## **Implants for surgery — Guidance on care and handling of orthopaedic implants**

*Implants chirurgicaux — Principes directeurs pour l'entretien et la  
manipulation des implants orthopédiques*



Reference number  
ISO 8828:2014(E)

© ISO 2014

This is a preview of "ISO 8828:2014". [Click here to purchase the full version from the ANSI store.](#)



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2014

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  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

This is a preview of "ISO 8828:2014". Click here to purchase the full version from the ANSI store.

## Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Terms and definitions</b> .....	<b>1</b>
<b>3 General guidance</b> .....	<b>1</b>
3.1 Manufacturer's instructions.....	1
3.2 On receipt.....	1
3.3 Transport.....	2
3.4 Stock records.....	2
3.5 Storage.....	3
3.6 Stock rotation.....	3
3.7 Cleaning and sterilization of non-sterile implants.....	3
3.8 Appearance.....	4
3.9 Contouring and modifying implants.....	4
3.10 Re-use.....	4
<b>4 Additional guidance on polymeric implants and materials</b> .....	<b>4</b>
4.1 Sterilization.....	4
4.2 Acrylic bone cement.....	4
4.3 Silicone implants.....	4
4.4 Biodegradable implants.....	4
<b>5 Additional guidance on ceramic components</b> .....	<b>5</b>
5.1 Sterilization and handling.....	5
5.2 Dropping of ceramic components.....	5
5.3 Manufacturer's instructions.....	5
<b>6 Additional guidance on implants or components of implants with rough surfaces or surfaces with intrinsic porosity</b> .....	<b>5</b>
6.1 Sterile implants.....	5
6.2 Subsequent cleaning of implants.....	5
6.3 Non-sterile implants.....	5
<b>Bibliography</b> .....	<b>6</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 second edition cancels and replaces the first edition (ISO 8828:1988), which has been technically revised.

This is a preview of "ISO 8828:2014". [Click here to purchase the full version from the ANSI store.](#)

## Introduction

The guidance given in this International Standard on the care and handling of orthopaedic implants after delivery to the purchaser is intended to help ensure that implants remain free from contamination or damage prior to insertion into the patient. Guidance is given on the procedures for receiving, storing, transporting, handling, cleaning, and sterilizing implants. Guidance on procedures for preparing the implants for use, as well as handling during the surgery, are also outlined. This guidance is aimed at all personnel involved in receiving and handling implants, including surgeons. It is important that all personnel be familiar with recommended procedures in order to minimize the risk and occurrence of damage to implants.