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

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

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Foreword

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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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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.

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.

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

1 Scope

This International Standard specifies the recommended procedures for handling orthopaedic implants, hereafter referred to as implants, from receipt at the hospital until they are implanted or discarded.

This guidance applies to implants (such as currently used metal, ceramic, or polymeric implants) and also to acrylic resin and other bone cements.

This guidance does not apply to the implant manufacturer. However, it contains references to the stocking of implants that can be useful for manufacturers and especially for third-party suppliers.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
orthopaedic implant
implant
device implanted surgically, wholly or partially, in the body, either temporarily or permanently, and used either as an aid in the repair of bone or related tissues, or as a temporary or permanent replacement for these tissues

Note 1 to entry: Acrylic resin cement, used for fixing certain devices, is deemed to be an "implant".

3 General guidance

3.1 Manufacturer's instructions

All of the manufacturer's instructions should be followed and take precedence over the guidance provided in this International Standard.

3.2 On receipt

3.2.1 General

Packaged implants can arrive either

a) pre-sterilized (see 3.2.2), or

b) non-sterilized (see 3.2.3).

3.2.2 Products supplied sterile

The packaging of products supplied sterile shall be left intact until the time of use. The packaging shall be inspected for damage. If damage is found, the implant shall be considered non-sterile. The implant shall then either

a) be returned to the manufacturer for reprocessing, or,

b) if appropriate and not prohibited by the device manufacturer, be taken out of the damaged packaging and re-sterilized in the user facility following the directions for an applicable method of sterilization provided in the instructions for use.

NOTE Guidance about information to be provided by the manufacturer for the processing of re-sterilizable medical devices is given in ISO 17664.

3.2.3 Non-sterile implants

Some non-sterile implants can be received in special packaging that is suitable for sterilization using the method(s) specified by the manufacturer in the instructions for use. The implant shall not be removed from this packaging prior to sterilization. Non-sterile implants not packaged in this way should only be unwrapped immediately prior to sterilization so as to preserve the surface finish and configuration intact, and they should be handled as infrequently as possible. The implant shall be sterilized following the directions for an applicable method of sterilization provided in the instructions for use.

3.2.4 Usability of implants

Any implant that has been dropped or mishandled and which is suspected of having suffered damage shall not be used. The implant should be disposed of or returned to the manufacturer as directed in the instructions for use. However, the final judgement as to the suitability of the implant shall always lie with the surgeon who uses the implant provided there are no restrictions in the instructions for use. If such an implant is used, the patient record shall include a description of the mishandling and any methods used to mitigate the possible effects of the mishandling on the safety and efficacy of the device.

3.3 Transport

Care shall be exercised during transport and handling of the implants so as to preclude any damage or alteration to the condition of the implant and its packaging as received. Attention shall be paid to the handling conditions specified by the manufacturer on the label of the outermost layer of packaging.

3.4 Stock records

3.4.1 General

Stock records are required to facilitate inventories, stock rotation, traceability to the manufacturer, and, in some instances, for transfer to patient's records.

3.4.2 Lot or batch code or serial number

The label of the implant package should bear the model designation of the device and in most cases a lot or batch code or serial number of the implant. Also, some implants are marked on their surface with the lot or batch code or serial number. The lot, batch code, or serial number of the implant shall be transferred to the patient's record.

3.4.3 Records to be compiled

The following information shall be recorded:

a) the name of the manufacturer;

b) a description of the implant including, if applicable,

- the model designation,
- the implant material(s), and
- the characteristic dimensions;

c) the lot or batch code or serial number of the implant;

d) the number of implants in a package unit;

e) the "use by" date or date of manufacture as appropriate;

f) the date of receipt by the hospital.

3.5 Storage

3.5.1 General

In all storage areas, implants shall be stored prior to use so as to maintain the configuration and surface finish of the implant and to avoid damage to its packaging, particularly to the sterile packaging. Implants should be stored separately from instruments. Non-sterile implants shall be stored separately from those that have been sterilized.

3.5.2 Storage conditions

The implant shall be stored in a suitable area following the conditions specified by the manufacturer on the label of the outermost layer of packaging or in the instructions for use (e.g. temperature, humidity, and ambient pressure). If there are no such instructions, implants shall be stored in dry conditions and shall not be exposed to direct sunlight, ionizing radiation, extremes of temperature, or particulate contamination.

3.6 Stock rotation

The principle of "first in, first out" is recommended. The practice of stock rotation should be adopted for all implants, sterile and non-sterile, in all storage areas.

3.7 Cleaning and sterilization of non-sterile implants

3.7.1 Non-sterile implants can be sterilized without prior cleaning if the manufacturer's packaging has been removed immediately prior to sterilization.

3.7.2 After each surgical procedure, all implants that can be subjected to a resterilization procedure shall be thoroughly and carefully cleaned according to the manufacturer's instructions for use. Ultrasonic cleaning, mechanized washing, or scrubbing by hand are suitable methods provided that they are carried out carefully. The method used shall prevent impact, scratching, bending, or surface contact with any materials that might affect the implant surface or configuration.

3.7.3 The manufacturer's recommendations on cleaning shall be closely complied with. If scrubbing by hand is used, soft brushes shall be used and harsh chemicals or harsh cleaning solutions shall be avoided.

3.7.4 After cleaning, the implants shall be rinsed completely free of all residues, soap, detergent, or cleaning solutions. After rinsing, the implants shall be thoroughly dried. Special attention shall be paid to recesses since both chemicals and rinse water can be entrapped in them. If a cloth is used for the final implant cleaning or drying, this cloth shall be made of antistatic material so that dirt and dust from the environment are not attracted by the implant surface because of an electrostatic charge.

3.7.5 All implants shall be sterilized in accordance with the method(s) specified by the manufacturer in the instructions for use.

3.7.6 Implants shall not be sterilized in contact with instruments or with implants of other materials as metallic oxide and other contaminants could transfer to the implant, thus causing an unacceptable condition when implanted.

3.8 Appearance

Implants that show signs of surface or configuration damage shall be disposed of or returned to the manufacturer if directed in the instructions for use.

3.9 Contouring and modifying implants

3.9.1 Performance characteristics of the implant can be altered by contouring or modifying the implant. Contouring or modifying the implant should be avoided, but if strictly necessary, the manufacturer's given instructions for use shall be followed.

3.9.2 Contouring or clamping of implants, a procedure which is frequently necessary, shall be carried out by the surgeon in a manner that will least alter the performance of the implant. However, it is recommended that metallic implants should not be bent sharply, re-bent, angulated at a screw hole, notched, or scratched.

3.9.3 Implants shall not be contoured or modified by the use of instruments that have been damaged or the effectiveness of which has been impaired.

3.10 Re-use

Implants previously implanted shall not be re-used.

4 Additional guidance on polymeric implants and materials

4.1 Sterilization

Special attention shall be given when using the manufacturer's recommended methods to sterilize most polymeric implants and materials; otherwise the process can cause degradation or other adverse effects. In those instances where resterilization is possible, the manufacturer's recommended methods shall be complied with. Polymers that require special attention are ultra-high molecular weight polyethylene, acrylic bone cements, and degradable materials. Silicone elastomers, however, can be resterilized by steam autoclaving.

4.2 Acrylic bone cement

Acrylic bone cement (where the liquid and solid components are packed in bottles, bags, or other immediate containers) shall be discarded at the end of the surgical procedure if the outer of the two enveloping wrappings has been opened, unless maintaining of open components is permitted in the manufacturer's instructions for use.

4.3 Silicone implants

The contamination of silicone implants by dust, lint, talc, skin oils, and other surface contaminants can cause subsequent fluid and fibrous tissue build-up in the tissues after implantation. Silicone implants shall always be handled using strict aseptic technique and preferably handled only with blunt metal instruments.

4.4 Biodegradable implants

Biodegradable polymer implants typically degrade during resterilization and cannot be resterilized by any method. To ensure the intended product performance, it is essential to follow the manufacturer's given instructions for use.

5 Additional guidance on ceramic components

5.1 Sterilization and handling

Ceramic components, such as the femoral heads and acetabular cups of hip joint prostheses, can be supplied in either a sterile or non-sterile condition. It is important that when sterilization is carried out, the components are separated and not assembled, especially ceramic-to-metal assemblies. Unless explicitly stated in the manufacturer's instructions for use, ceramic components shall not be quenched in water after steam sterilization, but shall be allowed to cool slowly to ambient temperature. Only instruments having protective plastics coating shall be used to handle the ceramic components and the surfaces of the spigot of femoral stems.

5.2 Dropping of ceramic components

If a ceramic component is dropped, it shall be disposed of or returned to the manufacturer if directed in the instructions for use even if there are no signs of damage.

5.3 Manufacturer's instructions

The manufacturer's instructions shall be closely complied with when ceramic components are being assembled and when ceramic femoral heads are being placed on and taken off from femoral stems.

6 Additional guidance on implants or components of implants with rough surfaces or surfaces with intrinsic porosity

6.1 Sterile implants

Implants supplied sterile by the manufacturer shall be maintained in the sterile packaging. If this packaging is damaged and no longer intact, the implant shall be

a) disposed of or returned to the manufacturers as directed in the instructions for use, or

b) cleaned and resterilized according to the manufacturer's instructions for use. If there is evidence that there has been no particulate contamination, the cleaning step can be omitted. The patient's record shall include an indication that the implant was cleaned and resterilized as appropriate.

6.2 Subsequent cleaning of implants

For implants which have been removed from the package and inserted into the surgical site, but which have not been implanted or contaminated by other sources, subsequent cleaning might be impossible. In this case, the implant shall be discarded unless instructions for cleaning of components are provided in the manufacturer's instructions for use. The patient's record shall include an indication that the implant was cleaned and resterilized.

6.3 Non-sterile implants

For implants supplied non-sterile, special precautions shall be followed to prevent contamination and to clean and sterilize the implant prior to surgery.