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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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Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

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Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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

0 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, cleansing and sterilizing implants; guidance on cautions necessary for preparing implants for use are also outlined. The guidance is aimed at all personnel involved in receiving and handling implants. It is important that all personnel should be familiar with recommended procedures in order to minimize the risk and occurrence of damage to implants.

1 Scope and field of application

This International Standard gives guidance on the recommended procedures for handling orthopaedic implants (such as currently used metal, ceramic or polymeric implants, and also including acrylic resin and other bone cements) from receipt at the hospital until they are implanted or discarded.

NOTE — The guidance does not apply to the implant manufacturer.

2 Definition

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

NOTES

1 Throughout this International Standard, the term "implant" has been used to mean "orthopaedic implant".

2 Acrylic resin cement, used for fixing certain devices, is deemed to be an "implant".

3 General guidance

3.1 On receipt

3.1.1 General

Packaged implants may arrive either

a) pre-sterilized (see 3.1.2), or

b) non-sterilized (see 3.1.3).

3.1.2 Sterile implants

The packaging of pre-sterilized implants shall be left intact until the time of use. The packaging shall be inspected for damage. If damage is found, the implant should be considered unsterile. The implant should then either be returned to the supplier for reprocessing or, if appropriate, be repackaged and resterilized in the operating area.

3.1.3 Non-sterile implants

Some non-sterile implants may be received in special sterilizable packaging and this should not be removed. 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.

3.1.4 Usability of implants

Any implant that has been dropped or mishandled and which is suspected of having suffered damage shall not be used and shall be returned to the supplier. However, the final judgement as to the suitability of the implant shall always lie with the surgeon who uses the implant.

3.2 Transport

The implants shall be transported so as to preclude any damage or alteration to the condition of the implant and its packaging as received.

3.3 Stock records

3.3.1 General

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

3.3.2 Unique numbers

Some implants are marked on their surface with a unique number, lot or batch number, or serial number which also appears on the package. This number will usually be transferred to the patient's records.

3.3.3 Records to be compiled

The following information shall be recorded :

a) type of implant(s);

b) size of implant(s);

c) unique number of implant or batch or lot;

d) material of implant;

e) the number of implants in a package unit;

f) date of manufacture or receipt.

3.4 Storage

3.4.1 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 not damage its packaging. Implants should be stored separately from instruments.

3.4.2 Storage conditions

Where provided, the manufacturer's instructions for storage should be followed. If there are no such instructions, implants shall be stored in dry conditions and should not be exposed to direct sunlight, ionizing radiation, extremes of temperature or particulate contamination.

3.5 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.

3.6 Cleaning and sterilization of non-sterile implants

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

3.6.2 After each surgical procedure, all implants that may be subjected to a resterilization procedure shall be thoroughly and carefully cleaned. Ultrasonic cleaning, mechanized washing or scrubbing by hand are suitable methods provided that they are carried out carefully. The method used should be that which prevents impact, scratching, bending or surface contact with any materials that might affect the implant surface or configuration.

3.6.3 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.

3.6.4 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 may be entrapped in them.

3.6.5 Sterilization shall be carried out by steam autoclaving or other methods which will ensure that the integrity of the implant is protected.

3.6.6 All implants shall be sterilized in accordance with the manufacturer's recommended methods.

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

3.7 Appearance

Implants that show signs of surface or configuration damage shall be discarded.

3.8 Contouring and modifying implants

3.8.1 Performance characteristics of the implant may be altered by contouring or modifying the implant.

3.8.2 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.

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

3.9 Re-use

Implants previously implanted shall not re-used.

4 Additional guidance on polymeric implants and materials

4.1 Sterilization

Special attention should be given when using the manufacturer's recommended methods to sterilize most polymeric implants and materials; otherwise the process may 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, may 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)

should be discarded at the end of the theatre session if the outer of the two enveloping wrappings has been opened.

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 should always be handled using strict aseptic technique and preferably handled only with blunt metal instruments.

5 Additional guidance on ceramic components

5.1 Sterilization and handling

Ceramic components, such as the heads and acetabular cups of hip joint prostheses, may 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. Ceramic components should not be quenched in water after steam sterilization, but should be allowed to cool slowly to ambient temperature. Only instruments having a protective plastics coating should 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 should be discarded 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 heads are being placed on and taken off 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 should be maintained in the sterile packaging. If this packaging is damaged and no longer intact, the implant shall be returned to the manufacturer for disposal.

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 may be impossible and the implant should be discarded.

6.3 Non-sterile implants

For implants supplied non-sterile, special precautions should be followed to prevent contamination and to clean and sterilize the implant prior to surgery. If the implant has been inserted into the surgical site, but has not been implanted or contaminated by other sources, subsequent cleaning may be impossible and the implant should be discarded.

7 Bibliography

The following documents will be of use in the application of this International Standard :

ISO 6018, *Implants for surgery — General requirements for marking, packaging and labelling.*

ASTM F 565-78, *Standard practice for care and handling of orthopedic implants and instruments.*

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