AS ISO 8828:2015
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Australian STANDARD

Implants for surgery—Care and handling of orthopaedic implants

STANDARDS Australia

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- Australian Dental Association
- Australian Society for Biomaterials
- Medical Technology Association of Australia
- Neurosurgical Society of Australasia
- Royal Australasian College of Surgeons
- Royal Perth Hospital
- Therapeutic Goods Administration
- University of Sydney

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Australian Standard®

Implants for surgery—Care and handling of orthopaedic implants

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PREFACE

This Standard was prepared by the Standards Australia Committee HE-012, Surgical Implants, to supersede AS/NZS 2817:1997, *Implants for surgery—Care and handling of orthopaedic implants*.

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

The objective of the revision is to adopt the current edition of ISO 8828.

This Standard is identical with, and has been reproduced from ISO 8828:2014, *Implants for surgery—Guidance on care and handling of orthopaedic implants*.

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text 'this International Standard' should read 'this Australian Standard'.

(b) A full point substitutes for a comma when referring to a decimal marker.

(c) In the Scope, the word 'guidance' should read 'Standard'. In Clause 3.1 and the titles of Clauses 4, 5 and 6, 'guidance' should read 'provisions'.

CONTENTS

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.

AUSTRALIAN STANDARD

Implants for surgery—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,