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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 24629-2009

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

外科植入物 矫形外科植入物维护和操作指南

(English Translation)

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Table of Contents

- Foreword
- Introduction
- 1 Scope
- 2 Terms and definitions
- 3 General guidelines
- 3.2 Transport
- 3.3 Inventory records

Foreword

This standard is equivalent to using ISO 8828. 1988 "Surgical implants orthopedic implants maintenance and operation." this standard of "discomfort implant manufacturers used" refers to post-implant product is delivered to the purchaser, for the maintenance and operation of the implant means South does not apply to manufacturers. Manufacturers should be the standard requirements, labels, brochures and other maintenance Ogata face implant product after delivery and Operation provides sufficient information.

This standard was proposed by the State Food and Drug Administration.

This standard by the national surgical implants and orthopedic instruments Standardization Technical Committee (SAC/TC110) centralized.

This standard was drafted. Tianjin, the State Food and Drug Administration Medical Device Quality Supervision and Inspection Center, China Association for Medical Devices Industry Society Professional Committee of surgical implants, China Pharmaceutical and Biological Products Inspection Center for Medical Devices.

Introduction

This standard gives orthopedic implants delivered to the purchaser after the maintenance and operating instructions are designed to help ensure that the implant implanted in a patient Before the body from contamination or damage. This standard gives the reception, storage, transport, handling, cleaning and sterilization procedures implants; as well as an overview of the issues prior to use of the implant must be taken to prepare for work. The standard for all personnel involved in the operation and receiving the implant.

Such persons should be familiar with the recommended procedures to reduce the risk of damage to the implant and damage occurring.

GB/T 24629-2009/ISO 8828. 1988 Surgical implants orthopedic implants and maintenance Operations Guide

1 Scope

This standard gives for orthopedic implants (such as a metal currently used ceramic or polymer implant, further comprising an acrylic resin and other bone cement) received from the hospital to be implanted or abandoned during the guidance of the program handling.

NOTE: This standard does not apply to the implant manufacturer.

2 Terms and definitions

The following terms and definitions apply to this standard.

Surgical instruments rely wholly or partially implantable device for temporarily or permanently repair of bone and/or related organizations, or temporary or Permanently replace these organizations.

Note 1: This standard, the term "implant" refers to "orthopedic implants."

Note 2: The acrylic resin for fixing some equipment is considered an "implant."

3 General guidelines

Received 3.1

3.1.1 Overview

The implant delivery status when packaged may be.

- a) pre-sterilized (see 3.1.2), or
- b) non-sterile (see 3.1.3).

3.1.2 Sterilized implants

Pre-sterilized implant packaging before use should be kept intact. Should check whether the packaging is damaged, if found to be damaged, the implant it shall be considered as non-sterile. In this case, the implant should be returned to the supplier reprocessing, or when conditions permit, in the operating area and repackaging Sterilization.

3.1.3 Non-sterile implants

Some non-sterile implants may, upon receiving the package can be sterilized in a special package, the package should not be removed. Without this package the non-sterile implants, only to open the package before sterilization process, in order to maintain the

shape and surface accuracy is not affected, and should add as little as possible Moving.

3.1.4 Implant availability

Any fall to the ground or through improper handling of the implant, if the suspect has been compromised, you must not use, should be returned to the supplier. However, should the total Surgeons use implants made implant is available in the final decision.

3.2 Transport

Transport the implant should be avoided in the state of the implant and its packaging when received any damage or change.

3.3.1 Overview

Inventory records should be easy to inventory, turnover, manufacturers retroactive, in some cases there should be transferred to the patient's medical record.

GB/T 24629-2009/ISO 8828. 1988