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Implants for surgery — Metallic materials

Part 1:
Wrought stainless steel

Implants chirurgicaux — Matériaux métalliques —

Partie 1: Acier inoxydable corroyé

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: + 41 22 749 01 11
~~Email~~E-mail: copyright@iso.org
Website: www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC ~~206, *[name of committee],*~~285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This sixth edition cancels and replaces the fifth edition (ISO 5832-1:2016), which has been technically revised.

The main changes are as follows:

— ~~—~~the introduction has been updated;

— ~~—~~normative references have been updated;

— ~~—~~the requirement for silicon in Table 1~~Table 1~~ has been changed to 0,75 max;

— ~~—~~the requirement for cobalt in Table 1~~Table 1~~ has been added;

— ~~—~~requirements for mechanical properties in Table 4~~Table 4~~ have been updated;

— ~~—~~this document has been ~~harmonised~~harmonized with the ISO 5832 series.

A list of all parts in the ISO 5832 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

While no known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body, long-term clinical experience with the material referred to in this document has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications. However, this document covers the raw material and ~~not finished~~unfinished medical devices~~,~~ where the design and fabrication of the device can impact the biological response.