Fourth edition
2022-03

Implants for surgery — Metallic materials —

Part 5: Wrought cobalt-chromium-tungsten-nickel

Implants chirurgicaux — Produits à base de métaux —

Partie 5: Alliage corroyé à base de cobalt, de chrome, de tungstène et de nickel

Reference number
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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This fourth edition cancels and replaces the third edition (ISO 5832-5:2005) which has been technically revised. The main changes are as follows:

— the introduction has been updated;

— limits for carbon, silicon, and manganese in Table 1 have been updated;

— requirements of inclusion content in Table 2 have been updated;

— tensile properties Clause 6 and Table 3 have been updated and harmonized to the ISO 5832 series;

— material conditions for grain size measurement in 5.1 have been updated.

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 the finished medical devices, where the design and fabrication of the device can impact biological response.