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Implants for surgery — Metallic materials —

Part 1: Wrought stainless steel

Implants chirurgicaux — Matériaux métalliques —

Partie 1: Acier inoxydable corroyé

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Contents

Page

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 document 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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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 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 has been changed to 0,75 max;

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

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

— this document has been 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 medical devices, where the design and fabrication of the device can impact biological response.

Implants for surgery — Metallic materials —

Part 1: Wrought stainless steel

1 Scope

This document specifies the characteristics of, and corresponding test methods for, wrought stainless steel for use in the manufacture of surgical implants.

NOTE 1 The mechanical properties of a sample obtained from a finished product made of this alloy can differ from those specified in this document.

NOTE 2 The alloy described in this document corresponds to UNS S31673 in ASTM F138 and ASTM F139.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 377, *Steel and steel products — Location and preparation of samples and test pieces for mechanical testing*

ISO 404, *Steel and steel products — General technical delivery requirements*

ISO 439, *Steel and cast iron — Determination of silicon content — Gravimetric method*

ISO 629, *Steel and cast iron — Determination of manganese content — Spectrophotometric method*

ISO 643, *Steels — Micrographic determination of the apparent grain size*

ISO 671, *Steel and cast iron — Determination of sulphur content — Combustion titrimetric method*

ISO 4967:2013, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams*

ISO 6892-1:2019, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 10714, *Steel and iron — Determination of phosphorus content — Phosphovanadomolybdate spectrophotometric method*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 6892-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/