



SLOVENSKI STANDARD
oSIST prEN ISO 5832-1:2023
01-maj-2023

Vsadki (implantati) za kirurgijo - Kovinski materiali - 1. del: Nerjavno jeklo (ISO/DIS 5832-1:2023)

Implants for surgery - Metallic materials - Part 1: Wrought stainless steel (ISO/DIS 5832-1:2023)

Chirurgische Implantate - Metallische Werkstoffe - Teil 1: Nichtrostender Stahl (ISO/DIS 5832-1:2023)

Implants chirurgicaux - Matériaux métalliques - Partie 1: Acier inoxydable corroyé (ISO/DIS 5832-1:2023)

Ta slovenski standard je istoveten z: prEN ISO 5832-1

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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DRAFT INTERNATIONAL STANDARD

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Implants for surgery — Metallic materials —

Part 1: Wrought stainless steel

*Implants chirurgicaux — Produits à base de métaux —**Partie 1: Acier inoxydable corroyé*

ICS: 11.040.40

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 *Implants for surgery*, Subcommittee SC 1, *Materials*.

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

The main changes are as follows:

- introduction has been updated;
- normative references has been updated;
- requirement for silicon in [Table 1](#) has been changed to 0,75 max;
- requirement for cobalt in [Table 1](#) has been added;
- requirements for mechanical properties in [Table 4](#) have been updated;
- document has been harmonised to 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 part of ISO 5832 has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications. However, this standard covers the raw material and not finished medical devices, where the design and fabrication of the device can impact biological response.

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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 part of ISO 5832 corresponds to UNS S31673 referred to in ASTM F138/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 terminological 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/>

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3.1 original gauge length

L_0
length between gauge length marks on the test piece measured at room temperature before the test

[SOURCE: ISO 6892-1:2019, 3.1.1]

4 Chemical composition

4.1 Test samples

The selection of samples for analysis shall be carried out in accordance with ISO 377.

4.2 Cast analysis

The cast analysis of the steel when determined in accordance with [Clause 6](#) shall comply with the chemical composition specified in [Table 1](#). The molybdenum and chromium contents shall be such that the C value obtained from [Formula \(1\)](#) is not less than 26.

$$C = 3,3w_{Mo} + w_{Cr} \quad (1)$$

where

w_{Mo} is the molybdenum content, expressed as a percentage by mass;

w_{Cr} is the chromium content, expressed as a percentage by mass.

Table 1 — Chemical composition

Element	Mass fraction %
Carbon	0,030 max.
Silicon	0,75 max. ^a
Manganese	2,0 max.
Phosphorus	0,025 max.
Sulfur	0,010 max.
Nitrogen	0,10 max.
Chromium	17,0 to 19,0 max.
Molybdenum	2,25 to 3,00
Nickel	13,0 to 15,0
Copper	0,50 max.
Cobalt	< 0,10 ^a
Iron	Balance

^a Values adjusted to ASTM F 138 and F 139. Reprinted with permission from ASTM F 138, copyright ASTM International. A copy of the complete standard may be obtained from www.astm.org

5 Microstructure in the fully annealed condition

5.1 Grain size

The austenitic grain size, determined in accordance with [Clause 7](#), shall not be coarser than grain size No. 5.