INTERNATIONAL STANDARD

**ISO 5832-9**

Third edition
2019-02

# Implants for surgery — Metallic materials —

## Part 9: Wrought high nitrogen stainless steel

*Implants chirurgicaux — Matériaux métalliques —*

*Partie 9: Acier inoxydable corroyé à haute teneur en azote*

Reference number
ISO 5832-9:2019(E)



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Published in Switzerland

 

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 ISO/TC 150, *Implants for surgery,* Subcommittee SC 1, *Materials.*

This third edition cancels and replaces the second edition (ISO 5832-9:2007), which has been technically revised.

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

No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience of the use of 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.

# Implants for surgery — Metallic materials —

# Part 9: Wrought high nitrogen stainless steel

## 1 Scope

This document specifies the characteristics of, and corresponding test methods for, wrought stainless steel containing a mass fraction of 0,25 % to 0,50 % nitrogen for use in the manufacture of surgical implants for which high levels of strength and corrosion resistance are required.

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 Requirements for other stainless steels for implants for surgery can be found in ISO 5832-1.

## 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 404:2013, *Steel and steel products — General technical delivery requirements*

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

ISO 3651-2, *Determination of resistance to intergranular corrosion of stainless steels — Part 2: Ferritic,austenitic and ferritic-austenitic (duplex) stainless steels — Corrosion test in media containing sulfuric acid*

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

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

## 3 Terms and definitions

No terms and definitions are listed in this document.

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 http://www.electropedia.org/

## 4 Chemical composition

### 4.1 Test samples

The selection of samples for analysis shall be in accordance with the provisions of ISO 377.