INTERNATIONAL STANDARD

ISO 13782

Second edition
2019-04

Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications

Implants chirurgicaux — Produits à base de métaux — Tantale non allié utilisé dans les implants chirurgicaux

Reference number
ISO 13782:2019(E)

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Published in Switzerland

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

This second edition cancels and replaces the first edition (ISO 13782:1996), which has been technically revised.

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.

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Introduction

No known surgical implant material has ever been shown to cause absolutely no adverse reaction 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.

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Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications

1 Scope

This document specifies the characteristics of, and corresponding test methods for, unalloyed tantalum sheet, rod and wire used in the manufacture of surgical implants.

NOTE 1 Provision is made for two grades of tantalum.

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

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

The heat analysis of a representative sample of the materials when determined in accordance with Clause 7 shall be in conformity with the chemical composition specified in Table 1. Ingot analysis shall be used for reporting all chemical requirements.

The analysis of hydrogen shall be carried out after the final heat treatment and the final surface treatment.

Requirements for the major and minor elemental constituents for unalloyed tantalum are listed in Table 1.

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