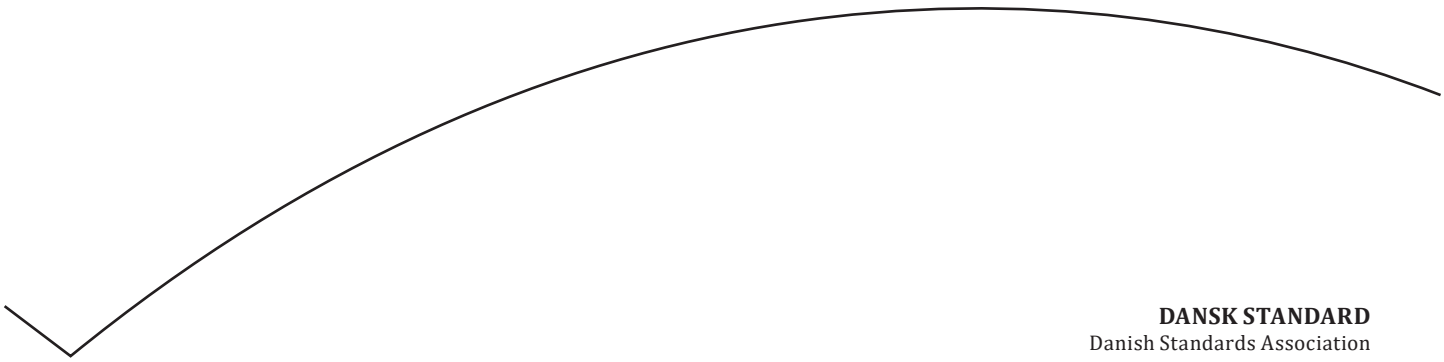
Kirurgiske implantater – Metalliske materialer – Del 2: Ulegeret titan

Implants for surgery – Metallic materials – Part 2: Unalloyed titanium (ISO 5832-2:2025)



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English Version

Implants for surgery - Metallic materials - Part 2: Unalloyed titanium (ISO 5832-2:2025)

Implants chirurgicaux - Matériaux métalliques - Partie 2: Titane non allié (ISO 5832-2:2025)

Chirurgische Implantate - Metallische Werkstoffe - Teil 2: Unlegiertes Titan (ISO 5832-2:2025)

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European foreword

This document (EN ISO 5832-2:2025) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery " in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2026, and conflicting national standards shall be withdrawn at the latest by March 2026.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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International

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Implants for surgery — Metallic materials —

Part 2: Unalloyed titanium

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Partie 2: Titane non allié

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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*, SC 1, *Materials* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fifth edition cancels and replaces the fourth edition (ISO 5832-2:2018), which has been technically revised.

The main changes are as follows:

— the introduction has been updated;

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

— the wording for mechanical properties in Table 2 has been updated;

— this document has been harmonized with the other parts of the ISO 5832 series.

A list of all parts in the ISO 5832 series can be found on the ISO website.

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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 2: Unalloyed titanium

1 Scope

This document specifies the characteristics of, and corresponding test methods for, unalloyed titanium for use in the manufacture of surgical implants.

Six grades of titanium based on tensile strength are listed in Table 2.

NOTE The mechanical properties of a sample obtained from a finished product made of this metal do not necessarily conform with those specified in this document.

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*

ISO 7438, *Metallic materials — Bend test*

ASTM E112, *Standard test methods for determining average grain size*