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Second edition
2021-09

Implants for surgery — Coatings on metallic surgical implants —

Part 1: Plasma-sprayed coatings derived from titanium or titanium-6 aluminum-4 vanadium alloy powders

Implants chirurgicaux — Revêtements des implants chirurgicaux métalliques —

Partie 1: Revêtements obtenus par projection plasma de poudres de titane non-allié ou d'alliage titane-6 aluminium-4 vanadium

Reference number
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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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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This second edition cancels and replaces the first edition (ISO 13179-1:2014), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the title and scope of the document were changed to include coatings derived from titanium-6 aluminum-4 vanadium alloy powder;

— two new terms 3.2 and 3.3 were introduced to add a distinction between vacuum plasma spraying and atmospheric plasma spraying;

— in 4.2.1, three separate tables were introduced to distinguish the chemical composition limits of different coating addressed by this document;

— in 4.4.3, the term shear fatigue maximum strain was corrected to shear fatigue maximum stress.

A list of all parts in the ISO 13179-1 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.

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Introduction

While no known surgical implant material has ever been shown to be completely free of 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, if the material is used in appropriate applications. However, this document covers the raw material, coating structures and properties and not finished medical devices, where the design and fabrication of the device can also impact biological response.

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