
Implants for surgery — Plasma-sprayed unalloyed titanium coatings on metallic surgical implants —

**Part 1:
General requirements**

Implants chirurgicaux — Revêtements en titane non-allié des implants chirurgicaux métalliques, obtenus par projection plasma —

Partie 1: Exigences générales



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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. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

ISO 13179 consists of the following parts, under the general title *Implants for surgery — Plasma-sprayed unalloyed titanium coatings on surgical implants*:

— *Part 1: General requirements*

Introduction

No known surgical implant material has ever been found 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 Standard has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

Implants for surgery — Plasma-sprayed unalloyed titanium coatings on metallic surgical implants —

Part 1: General requirements

1 Scope

This part of ISO 13179 specifies general requirements for plasma-sprayed unalloyed titanium coatings on metallic surgical implants.

This part of ISO 13179 applies to plasma spraying in air and in vacuum.

This part of ISO 13179 does not apply to coatings made of other materials than unalloyed titanium or coatings realized by another technology than plasma spraying.

NOTE 1 A quality management system can be useful, e.g. as described in ISO 13485. Requirements for the competence of testing laboratories can be found in ISO/IEC 17025.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ASTM F1044, *Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings*

ASTM F1147, *Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings*

ASTM F1160, *Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings*

ASTM F1580, *Standard specification for Titanium and Titanium-6 Aluminium-4 alloy powders for coatings of surgical implants*

ASTM F1854, *Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants*

ASTM F1978, *Standard Test Method for measuring abrasion resistance of metallic thermal spray coatings by using the Taber Abraser*

ASTM E2371, *Test Method for analysis of Titanium and Titanium Alloy by Atomic Emission Plasma Spectrometry*