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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

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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

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

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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*

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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.

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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.

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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.

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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*

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3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
plasma spraying
method of thermal spraying that produces coatings using a plasma jet

3.2
plasma-sprayed unalloyed titanium coatings
titanium which has been deposited onto the surface of a substrate, by means of a plasma spraying process

4 Requirements

4.1 Powder for plasma spraying

The powder used for plasma spraying shall comply with ASTM F1580.

4.2 Chemical analysis

4.2.1 Chemical composition

NOTE Although this standard applies to both atmospheric and vacuum plasma spraying coatings the vacuum plasma sprayed coating chemical composition values are likely to be lower than for atmospheric plasma sprayed coatings.

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The chemical composition of the unalloyed titanium plasma sprayed coatings shall be in accordance with Table 1.

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Table 1 — Chemical composition

Element	Composition limits (mass fraction)
Carbon (C)	≤ 0,10 %
Hydrogen (H)	≤ 0,20 %
Iron (Fe)	≤ 0,60 %
Nitrogen (N)	≤ 5,00 %
Oxygen (O)	≤ 10,00 %
Titanium (Ti)	Balance
The sum of the nitrogen, oxygen, hydrogen, carbon and iron, contents shall not be greater than 10 % mass fraction. NOTE If the mechanical properties specified in 4.4 are met and if there are no detrimental effects on the biocompatibility it can be acceptable to have higher limits for Hydrogen and Nitrogen content than those specified above.	

A risk analysis of the plasma spraying process shall be conducted to determine the elements not listed in Table 1 and likely to have a mass fraction greater than 0,5 %. The exact mass fraction shall be determined and the limit shall be specified by the manufacturer of the coating. The influence of these impurities on biocompatibility shall be assessed in accordance with ISO 10993-1.

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4.2.2 Sampling

In order to perform the chemical analysis of the coating, a minimum of 5 g of coating, which has been deposited onto a titanium substrate coupon produced in accordance with ISO 5832-2, shall be removed. If the removal of 5 g of coating is not possible or not sensible, the sample weight may be decreased provided that the chemical analysis is not affected. The technique used to remove the coating shall not generate contamination of the coating. If a cleaning step is performed on the implants after coating, the same cleaning step shall be applied on the sample before analysis.

4.2.3 Chemical analysis procedure

Iron content shall be determined by Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) in accordance with ASTM E2371.

Nitrogen, oxygen, carbon and hydrogen content, shall be determined by combustion using a recognized validated method.

The analysis accuracy with a level of confidence of 95 % shall be taken into account when claiming the conformity of the chemical analysis to the limits specified in Table 1.

EXAMPLE If the uncertainty for measuring the oxygen content is 1 % with a level of confidence of 95 %, the conformity shall be stated as ≤ 9 % for the measured values.

4.3 Morphology

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For validation purposes the morphology tests shall be performed on the final device, if possible. If the morphology tests are not performed on the final device because the requirements of the applied standard cannot be met due to geometry of the device, coupons may be used and their representativeness to the final device shall be justified.

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The average thickness and the tolerances, in µm, shall be determined in accordance with ASTM F1854.

Roughness (*Ra* or *Rt*), in µm, shall be determined in accordance with ISO 4287. The evaluation length shall be at least 8 mm.

For coatings having an average thickness ≥ 300 µm, the average volume % void content and mean void intercept length, and/or average void content and intercept length at distinct levels through the coating thickness ("tissue interface gradient method") shall be tested in accordance with ASTM F1854.

4.4 Coating mechanical properties

4.4.1 General

At least 5 test samples, manufactured from the same substrate as the final implant, shall be used for the tests specified in 4.4.2 to 4.4.4. The same pre-treatments (e.g. cleaning, sand-blasting) and post-treatments (e.g. cleaning, sterilization) shall be applied to the test samples and the final implant.

4.4.2 Static shear strength

When tested in accordance with ASTM F1044, the mean static shear strength of the coating shall be greater than 20 MPa.

4.4.3 Shear fatigue strength

When tested in accordance with ASTM F1160 with a shear fatigue maximum strain of at least 10 MPa, the coating shall withstand at least 10^7 cycles without any failure.

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