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Implants for surgery — Plasma sprayed coatings of unalloyed titanium —

Part 1: General requirements

Implants chirurgicaux — Revêtements en titane obtenus par projection plasma —

Partie 1: Exigences générales

ICS 11.040.40

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Foreword

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ISO 13179-1 was prepared by Technical Committee 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 coatings of unalloyed titanium*:

— *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 coatings of unalloyed titanium —

Part 1:
General requirements

1 Scope

This part of ISO 13179 specifies general requirements for unalloyed titanium coatings on surgical implants realised by plasma spraying.

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

2 Normative references

The following referenced documents are indispensable for the application 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 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 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes*

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

ASTM F 1044, *Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings*

ASTM F 1147, *Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings*

ASTM F 1160, *Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate / Metallic Coatings*

ASTM F 1580, *Standard specification for Titanium and Titanium-6 Aluminium-4 alloy powders for coatings of surgical implants*

ASTM F 1854, *Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants*

ASTM F 1978, *Standard Test Method for measuring abrasion resistance of metallic thermal spray coatings by using the Taber® Abraser*

ASTM E 2371, *Test Method for analysis of Titanium and Titanium Alloy by Atomic Emission Plasma Spectrometry*

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
titanium plasma sprayed coating
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 F 1580.

4.2 Chemical analysis

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

Table 1 — Chemical composition

Element	Composition limits % mass fraction
Nitrogen (N)	≤ 5,00
Oxygen (O)	≤ 10,00
Hydrogen (H)	≤ 0,20
Carbon (C)	≤ 0,10
Iron (Fe)	≤ 0,60
Silicon (Si)	≤ 0,06
Chlorine (Cl)	≤ 0,20
Sodium (Na)	≤ 0,50
Magnesium (Mg)	≤ 0,50
Titanium (Ti)	Balance

If appropriate, the chemical composition shall be determined by Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) in accordance with ASTM E 2371.

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

Chlorine shall be determined by ionic chromatography using a validated method. The method used shall be specified. The use of other analysis methods shall be justified.

In order to perform the chemical analysis, a minimum of 5 g of coating shall be removed from a titanium substrate coupon in accordance with ISO 5832-2. The technique used to remove the coating shall not generate pollution 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.

The sum of the nitrogen, oxygen, hydrogen, carbon, iron, silicon, chlorine, sodium and magnesium contents shall be not more than 10 % mass fraction:

The analysis accuracy with a level of confidence of 95 % shall be taken into account when declaring the conformity of the chemical analysis to the limits of 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 less than or equal to 9 % for the measured values.

4.3 Morphology

The average thickness and the tolerances in µm shall be specified and tested in accordance with ASTM F1854.

Roughness (R_t) in µm shall be specified and tested in accordance with ISO 4287. The evaluation length shall be at least 8 mm.

4.4 Coating mechanical properties

4.4.1 Static shear strength

The static shear strength of the coating shall be specified and tested in accordance with ASTM F1044.

The static shear strength shall not be less than 20 MPa.

4.4.2 Shear fatigue strength

The shear fatigue strength of the coating shall be specified and tested out to at least 10^7 cycles in accordance with ASTM F1160.

The shear fatigue strength shall not be less than 10 MPa.

4.4.3 Static tensile strength

The static tensile strength of the surface coating shall be specified and tested in accordance with ASTM F1147.

The static tensile strength shall not be less than 22 MPa.

4.4.4 Abrasion resistance

The abrasion resistance of the surface coating shall be specified and tested in accordance with ASTM F1978.

After 100 cycles the abrasion loss shall not be more than 65 mg.

4.5 Audit control

The tensile strength, composition and morphology of the coating shall be controlled periodically with a periodicity determined during the risk analysis in accordance with ISO 14971.

Routine control procedures of the coating shall specify the type and time interval of each control test.

4.6 Quality Management System (QMS)

The plasma coating producer shall maintain a quality management system in accordance with ISO13485.