

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
सर्जरी के लिए प्रत्यारोपण - धातु सर्जिकल प्रत्यारोपण पर
कोटिंग्स

भाग 1: टाइटेनियम या टाइटेनियम -6 एल्यूमीनियम -4 वैनेडियम मिश्र धातु
पाउडर से प्राप्त प्लाज्मा-स्प्रे कोटिंग

(IS/ISO 13179-1 : 2014 का पहला पुनरीक्षण)

Draft Indian Standard
Implants for surgery — Coatings on metallic surgical
implants

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

(First Revision of IS/ISO 13179-1 : 2014)

ICS 11.040.10

Orthopaedic Instruments, Implants And
Accessories Sectional Committee, MHD 02

Last date for comments: **12 July 2024**

NATIONAL FOREWORD

(Adoption clause will be added later)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those

used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’.
- b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 4288, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture	IS 18432 (Part 3) : 2023, Geometrical product specifications GPS Surface texture: Profile: Part 3 Specification operators	Modified

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

<i>International Standard/ Other Publication</i>	<i>Title</i>
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 Vanadium 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

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*Second Revision*)’.

Note: The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 13791-1:2021 or kindly contact:

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SCOPE

This document specifies general requirements for plasma-sprayed titanium coatings on metallic surgical implants.

This document applies to atmospheric plasma spraying and vacuum plasma spraying.

This document does not apply to coatings made of other materials than titanium or titanium-6 aluminum-4 vanadium alloy or to coatings realized by another technology than plasma spraying.

NOTE 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.