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PEOPLE'S REPUBLIC OF CHINA**

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**Implants for surgery - Hydroxyapatite - Part 2: Thermally
sprayed coatings of hydroxyapatite
(English Translation)**

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1 Scope

This document specifies the requirements for single-layer thermally sprayed coatings of hydroxyapatite used for metallic surgical implants.

These tests are intended to describe the characteristics of the material.

NOTE 1: for thin coatings with a thickness less than 50 μm , some of the test methods in this document may be difficult to implement without modification.

NOTE 2: the requirements for the hydroxyapatite coating of a duplex coating (composed of a lower metallic coating and an upper hydroxyapatite coating) may comply with this document, but the test methods described in this document are not applicable to duplex coating. If the hydroxyapatite layer in the duplex coating takes the requirements of this document as a reference, then, consideration needs to be given to the rationality of the single-layer test sample representing the duplex-coated implant.

This document does not apply to coatings made from glass, glass-ceramics, alpha- and beta-tricalcium phosphate, biphasic calcium phosphate, or other forms of calcium phosphate.

NOTE 3: although the requirements in this document are intended as a specification for thermally sprayed coatings of hydroxyapatite, a routine control procedure may be necessary, specifying control tests and their time intervals, to ensure that the coating properties remain within the specified limits.

NOTE 4: this document focuses on plasma thermally sprayed coatings of hydroxyapatite; however, it is also applicable to the characterization of other thermally sprayed coatings of hydroxyapatite. However, thermally sprayed coatings without a history record of clinical use may present different

risks and may require additional characterization items beyond that specified in this document.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 10610 Geometrical Product Specifications (GPS) - Surface Texture. Profile Method - Rules and Procedures for the Assessment of Surface Texture (GB/T 10610-2009, ISO 4288.1996, IDT)

GB/T 16886.1 Biological Evaluation of Medical Devices - Part 1.Evaluation and Testing within a Risk Management Process (GB/T 16886.1-2022, ISO 10993-1.2018, IDT)

GB/T 23101.3 Implants for Surgery - Hydroxyapatite - Part 3.Chemical Analysis and Characterization of Crystallinity Ratio and Phase Purity (GB/T 23101.3-2023, ISO 13779-3.2018, MOD)

GB/T 23101.4 Implants for Surgery - Hydroxyapatite - Part 4.Determination of Coating Adhesion Strength (GB/T 23101.4-2023, ISO 13779-4.2018, MOD)

GB/T 23101.6 Implants for Surgery - Hydroxyapatite - Part 6.Powders (GB/T 23101.6-2022, ISO 13779-6.2015, MOD)

YY/T 0988.12 Coatings of Surgical Implants - Part 12.Shear Testing Method of Calcium Phosphate Coating and Metallic Coatings

YY/T 0988.14 Coatings of Surgical Implants - Part 14.Stereological Evaluation Method of Porous Coatings

3 Terms and Definitions

The terms and definitions defined in GB/T 23101.3 and the following are applicable to this document.

3.1

thermally sprayed coating of hydroxyapatite

A coating formed by thermally spraying hydroxyapatite powder.

NOTE: in this document, the terms "coating" and "hydroxyapatite coating" refer to "thermally

sprayed coating of hydroxyapatite".

4 Coating Preparation

The powders used for thermally sprayed coatings of hydroxyapatite shall comply with the provisions of GB/T 23101.6.

Unless otherwise supported by the manufacturer, all test samples shall be prepared using the same production methods as conventional implants, including the initial hydroxyapatite powders, substrate material, production units, substrate surface preparation process, coating process parameters, cleaning and sterilization.

5.1 Overview

5.2 ~ 5.8 specify the minimum requirements for hydroxyapatite coatings.

Additional characterization tests described in A.2 ~ A.4 of Appendix A may also be required.

NOTE: in addition to the tests described in 5.2 ~ 5.8, regulatory authorities may require the tests in Appendix A to characterize hydroxyapatite coatings.

5.2 Calcium-to-phosphorus Atomic Ratio (Ca. P)

Before testing, the coating shall be stripped from the substrate.

The Ca. P ratio in hydroxyapatite ceramic coatings shall be determined in accordance with the provisions of GB/T 23101.3.

The Ca. P ratio shall be within the range of 1.61 ~ 1.76.

NOTE: the Ca. P ratio is generally unaffected by coating thickness.

5.3 Trace Elements

Before testing, the coating shall be stripped from the substrate. The sample volume required for chemical analysis depends on the chemical analysis technique used. The sample volume used shall be sufficient to achieve the appropriate limit of quantification. The coating stripping technique shall minimize the possibility of coating contamination. Care shall be taken to use appropriate tools and avoid contamination caused by substrate particles.

Trace element and heavy metal content shall be determined in accordance with the provisions of GB/T 23101.3.

The maximum permissible limits for specific trace elements and heavy metals in hydroxyapatite coatings are shown in Table 1.

All potential trace elements whose concentrations may exceed the manufacturer's specified limit of 1,000 mg/kg shall be identified. Quantitative test of these trace elements shall be performed. If there are trace elements with concentrations exceeding 1,000 mg/kg, their impact on biocompatibility and bone healing shall be evaluated in accordance with GB/T 16886.1.

5.6 Morphology

The morphology (thickness, roughness and micromorphology) of the hydroxyapatite coating on the final device shall be evaluated. If morphological examination of the final device is not possible because the geometric structure of the device does not satisfy the requirements of this document, specimens may be used and shall be proven to be representative of the final device.

The average thickness and tolerance [in micrometers (μm)] shall be determined in accordance with the provisions of YY/T 0988.14. This document does not specify the acceptance criteria for average thickness. The acceptance criteria for the average thickness and tolerance of the hydroxyapatite coating for different regions of the implant shall be specified and documented for each implant.

Roughness (R_a or R_t) shall be determined [in micrometers (μm)] in accordance with the provisions of GB/T 10610. This document does not specify the acceptance criteria for roughness. The acceptance criteria for the roughness (R_a or R_t) and tolerance of the hydroxyapatite coating shall be specified and documented.

The surface and cross-section of the hydroxyapatite coating shall be observed using a scanning electron microscope (SEM) or optical microscope. This document does not specify the acceptance criteria for this test. This test is intended to qualitatively characterize the coating porosity and surface condition.

NOTE: data from surface and cross-section observations of the hydroxyapatite coating are used to assist in evaluating process changes or comparing two different types of hydroxyapatite coatings.

5.7 Coating / Substrate Interface Adhesion Strength

The test of static tensile adhesion strength or static shear adhesion strength shall be performed in accordance with the practical application. The static tensile adhesion strength test shall be conducted in accordance with the provisions of GB/T 23101.4, and the static shear adhesion strength test shall be conducted in accordance with the provisions of YY/T 0988.12. If the practical application requires both tensile and shear resistance properties, both tests shall be conducted.

If the static tensile adhesion strength test is performed, the average tensile adhesion strength of the coating shall be no less than 15 MPa, and individual results shall be no less than 10 MPa.