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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Non-active surgical implants -- Osteosynthesis and joint
replacement implants -- Part 2: Particular requirements for joint
replacement implants
(English Translation)**

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1 Scope

This document specifies particular requirements for total and partial joint replacement implants, artificial ligaments, and bone cement (hereinafter referred to as the "implants"). This document specifies requirements regarding intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information supplied by the manufacturer. In this document, artificial ligaments and related fixation devices are included within the term "implants", hereinafter also referred to as the "implants".

This document is applicable to total and partial joint replacement implants, artificial ligaments, and bone cement.

NOTE: Some tests required to demonstrate compliance with this document are included in the Level 3 standard or its references.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through 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 3505 Geometrical product specifications (GPS) - Surface texture. Profile method - Terms, definitions and surface texture parameters (GB/T 3505-2009, ISO 4287.1997, IDT)

YY/T 0640-2016 Non-active surgical implants - General requirements

YY/T 0651.1 Implants for surgery - Wear of total hip-joint prostheses - Part 1>Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

YY/T 0651.2 Implants for surgery - Wear of total hip-joint prostheses - Part 2>Methods of measurement

YY/T 0809.4 Implants for surgery - Partial and total hip joint prostheses - Part 4>Determination of endurance properties and performance of stemmed femoral components

YY/T 0810.1 Joint replacements - Total knee-joint prostheses - Part 1>Determination of endurance properties of knee tibial trays

YY/T 1426.1 Implants for surgery - Wear of total knee-joint prostheses - Part 1>Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test

YY/T 1426.2 Implants for surgery - Wear of total knee-joint prostheses - Part 2>Methods of measurement

YY/T 1426.3 Implants for surgery - Wear of total knee-joint prostheses - Part 3>Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test

3 Terms and Definitions

The terms and definitions defined in YY/T 0640-2016, as well as the following terms and definitions, are applicable to this document.

3.1 Artificial Ligament

Implants used to strengthen or replace the body's natural ligaments, including their necessary fixation devices.

3.2 Joint Replacement Implants

Implants used to provide similar function to natural human joints and connect with the corresponding bone, including auxiliary implant components and materials.

3.3 Mean Centre

The position inside the sphere head that has the smallest average distance from a set of points evenly distributed on the surface of the sphere.

3.4 Radial Separation Value

The maximum difference between the average radius of the sphere and the distance from a point on the sphere to the mean centre.

NOTE: The unit is micrometers (μm).

4 Intended Performance

For the purposes of this document, the intended performance of the implant shall meet the requirements of Clause 4 of YY/T 0640-2016. Additionally, the design shall also consider the following issues.

- a) the intended minimum and maximum relative angular motion between the bones fixed by the joint replacement implants;
- b) the maximum intended loads (forces and moments) transmitted to the bony tissue fixed by the joint replacement implants;
- c) the dynamic response of the human body to the shape/stiffness of the implant;
- d) the intended wear of the articular surfaces;
- e) the suitability of the implant's dimensions and shape relative to the intended user population;
- f) the adhesion strength and durability of surface treatments or surface coatings.

NOTE 1: The indications and contraindications for using a specific implant are complex issues.

When selecting an implant for a specific patient, surgeons analyze and consider factors based on their personal judgment and experience.

NOTE 2: The lifespan of an implant depends on the interaction of a variety of factors, some of which are the responsibility of the manufacturer; some are the responsibility of the surgeon, such as the implantation technique; and some are related to the patient, such as the patient's biological and physiological response to the implant, the patient's medical condition, and the patient's behavioral characteristics, such as weight gain, lifting heavy objects, and high activity levels.

5.1 General

To achieve the intended performance, the manufacturer shall formulate design attributes in accordance with the requirements of Clause 5 of YY/T 0640-2016, and also consider the

following aspects.

- a) the adhesion strength and durability of surface treatments and surface coatings;
- b) wear on articular surfaces and other surfaces;
- c) the stability of the implant when the minimum and maximum relative movements between bones are permitted;
- d) avoidance of cutting or rubbing tissue while performing functions, except in cases of implantation and removal of implants;
- e) creep resistance and fracture characteristics, especially when related to ligaments.

NOTE 1: Methods for assessing wear on articular surfaces and other surfaces are described in standards such as YY/T 0651.2, YY/T 1426.1, YY/T 1426.2, and YY/T 1426.3.

NOTE 2: More specific requirements may appear in other standards, such as standards for hip replacement implants.

5.2 Surface Finishing of Metallic or Ceramic Implants Actively Connected to

Ultra-High Molecular Weight Polyethylene (UHMWPE)

For the surfaces of metallic or ceramic components that are actively connected to the UHMWPE in total joint replacements, the surface roughness (Ra) shall not exceed 0.1 μm (according to

7.2.2).

5.3 Surface Finishing of Metallic or Ceramic Implants for Partial Joint

Replacements

For the articular surfaces of metallic or ceramic components in partial joint replacements, the surface roughness (Ra) shall not exceed 0.5 μm (according to 7.2.2).

5.4 Convex Spherical Metallic or Ceramic Surfaces Actively Connected to

UHMWPE

For metallic or ceramic components that are actively connected to the UHMWPE in total joint replacements, if the articular surface is convex spherical, its surface roughness (Ra) shall not exceed 0.05 μm , and the radial separation value shall not exceed 10 μm (according to 7.2.2 and

7.2.3).