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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0924.2-2024

Replacing YY/T 0924.2-2014

Joint replacements - Components for partial and total knee joint prostheses - Part 2: Articulating surfaces made of metal, ceramic and plastics materials

关节置换植入器械 部分和全膝关节假体部件 第2部分：金属、陶瓷及塑料关节面

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting is required. This document is Part 2 of YY/T 0924 "Implantable Devices for Joint Replacement and Components of Total Knee Prosthesis". The following parts have been published.

1.Classification, definition and dimensioning;

2.Metal, ceramic and plastic joint surfaces. This document replaces YY/T 0924.2-2014 "Surgical implant parts and total knee prosthesis components Part

2.Metal, ceramic Compared with YY/T 0924.2-2014, the main technical changes are as follows:

--- Incorporated the amendments to ISO 7207-2.2011 AMD1.2016 AMD2.2020, the outer margins of the clauses involved Blank locations are marked with double vertical lines (). - Added reference to YY/T 0924.1 (see Chapter 2). - The surface roughness requirements have been changed (see 4.2,.2014 edition 3.2). This document is modified to adopt ISO 7207-2.2011 AMD1.2016 AMD2.2020 "Partial and total knee implants for surgery" Prosthetic components Part

2.Metal, ceramic and plastic articular surfaces. A new chapter "Terms and Definitions" has been added to this document. The technical differences between this document and ISO 7207-2.2011 AMD1.2016 AMD2.2020 and their reasons are as follows:

--- Regarding normative references, this document has been adjusted with technical differences to adapt to my country's technical conditions. The situation is reflected in Chapter 2 "Normative Reference Documents", and the specific adjustments are as follows: - Replaced ISO 4287 with GB/T 3505 which is equivalent to the international standard; - Replaced ISO 4288 with GB/T 10610 which is equivalent to the international standard; - ISO 7207-1 was replaced by YY/T 0924.1 which is modified to adopt the international

standard. The following editorial changes were made to this document.

--- Changed the name of the standard, using "joint replacement implants" instead of "surgical implants" to clarify the specific application areas of the standard. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document was prepared by the National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices, Orthopedic Implants Subcommittee (SAC/ TC110/SC1) is responsible for this. This document was drafted by: Tianjin Medical Device Quality Supervision and Inspection Center, National Medical Products Administration Medical Device Technical Review Center Center, National Medical Products Administration Medical Device Technical Review and Inspection Greater Bay Area Center, Dabao Medical Technology Co., Ltd., Suzhou Microport ARTICULAR MEDICAL TECHNOLOGY LIMITED. The main drafters of this document are. Li Nan, Li Wenjiao, Dong Shuangpeng, Wang Ying, Min Yue, Sun Jiayi, Zhang Kun, Lu Minqi, Zeng Da, and Yu Tianbai. This document was first published in.2014 and this is the first revision.

YY/T 0924 "Joint replacement implant components and total knee prosthesis components" is intended to consist of two parts.

1.Classification, definitions and dimensioning. The purpose is to give the knee joint bearing surface replacement of one or more compartments of the knee Classification of the femoral, tibial, and patellar components of the prosthesis and definition and dimensioning of the components.

2.Metal, ceramic and plastic joint surfaces. The purpose is to give partial and total knee joints classified according to YY/T 0924.1. Requirements for the surface roughness of the articular surface of joint prostheses. The purpose of this document is to provide guidance on the periodic validation of production processes. Joint replacement implants and total knee prostheses Components - Part

1 Scope

YY/T 0924.2 covers the bearing surfaces of a knee replacement, the metal, ceramic and polymer faces that slide against each other for the life of the implant. It is Part 2 of the Chinese knee prosthesis component series and sets the requirements for those articulating surfaces. The bearing couple determines the wear rate, and wear debris rather than mechanical failure is what drives most late revisions in knee arthroplasty, which is why the surfaces are specified separately from the components that carry them. It sits under the mandatory fundamental requirements of YY 0502 and alongside YY/T 0810.1 on tibial tray fatigue. For a manufacturer of knee systems seeking Chinese registration, this is the standard the bearing surface characterisation follows.

This document specifies the requirements for the surface roughness of the articular surfaces of partial and total knee prostheses classified as in YY/T 0924.1. This document is applicable to the evaluation of the surface roughness of metal, ceramic and plastic joint surfaces of joint replacement implant devices and total knee prosthesis components.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 3505 Product Geometry Specification (GPS) Surface Structure Profile Method Terminology, Definitions and Surface Structure Parameters (GB/T 3505-2009, ISO 4287.1997, IDT)

GB/T 10610 Geometric Product Specification (GPS) Rules and methods for evaluating surface structure by surface structure profile method (GB/T 10610-2009, ISO 4288.1996, IDT)

YY/T 0924.1 Surgical implant parts and total knee prosthesis components Part

1.Classification, definition and dimensioning (YY/T 0924.1-2014, ISO 7207-1.2007, MOD)

3 Terms and definitions

There are no terms or definitions that require definition in this document.

4 Surface roughness requirements

4.1 General The measurement of the surface roughness of knee prosthesis components shall follow the principles given in GB/T 3505 and the rules and procedures.

4.2 Knee prosthesis

4.2.1 Metal or ceramic femoral components When measuring in accordance with GB/T 10610, the measurement points of all articular surfaces of metal or ceramic femoral components should be distributed at characteristic positions. The surface roughness Ramax of the component should not be greater than 0.1μm, and the sampling length is 0.25mm. When analyzing a bicompartmental or tricompartmental knee prosthesis, the lateral and medial femoral condyles should be measured at the following locations.

a) Contact position with articular surface flexed at 0°;

b) contact position with the articular surface bent at 30°;

c) Contact position with the articular surface flexed 60° or more. When analyzing a three-compartment knee prosthesis, measurements should be taken at three evenly spaced locations on the femoral component where it contacts the patella.