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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1426.3-2017

Implants for surgery - Wear of total knee joint prostheses - Part 3: Loading and displacement parameters for displacement controlled wear testing machines and corresponding environmental conditions for test

外科植入物 全膝关节假体的磨损 第3部分：位移控制的磨损试验机的载荷和位移参数及相关的试验环境条件

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Foreword

YY/T 1426 "Surgical Implants Total Knee Prosthesis Wear" is divided into the following three parts.

--- Part 1. Load and displacement parameters of load-controlled wear testers and related test environmental conditions;

--- Part 2. Measurement methods;

--- Part 3. Load and displacement parameters of the wear tester for displacement control and related test environmental conditions. This part is the third part of YY/T 1426. This part is drafted in accordance with the rules given in GB/T 1.1-2009. This section uses the translation method equivalent to ISO 14243-3.2014 "Surgical implant total knee prosthesis wear Part 3. The load and displacement parameters of the wear-controlled wear tester and related test environmental conditions. The documents of our country that have a consistent correspondence with the international documents referenced in this part are as follows:

---YY/T 0924.1-2014 Surgical implant parts and total knee prosthesis parts - Part 1. Classification, definitions and dimensions Label (ISO 7207-1.2007, MOD) Please note that some of the contents of this document may involve patents. The issuing organization of this document is not responsible for identifying these patents. This part is proposed by the State Food and Drug Administration. This part is organized by the National Technical Committee

for Standardization of Surgical Implants and Orthopedic Devices, orthopedic implants subcommittee (SAC/TC110/ SC1). This section drafted by: Tianjin Medical Device Quality Supervision and Inspection Center, School of Mechanical Engineering, Xi'an Jiaotong University, China University of Mining and Technology material science and Engineering School. The main drafters of this section. Dong Shuangpeng, Zhang Shu, Wang Ling, Hou Yinhui, Zhang Dekun, Chen Kai. Surgical implant wear of the total knee prosthesis Part 3. Displacement controlled wear testing machine Load and displacement parameters and associated test environmental conditions

1 Scope

YY/T 1426.3 is Part 3 of the Chinese series on wear testing of total knee prostheses, and it governs the displacement-controlled variant of the test. It sets the loading and displacement parameters a wear testing machine has to apply and the environmental conditions the test has to run in, so that a knee prosthesis is worn on the bench under motion that represents walking. Wear debris is the main driver of long-term failure in knee replacement, which makes this test central to the durability evidence in a registration dossier. Part 1 covers the load-controlled variant and Part 2 the measurement of the resulting wear, so a laboratory generally needs more than one part of the series. For an orthopaedic manufacturer this is the protocol a Chinese reviewer expects the wear data to have been generated under.

This part of YY/T 1426 specifies the control of axial loading, buckling/extension angle motion control, front and rear displacement control and tibia Buckling/stretching between joint components during wear testing of total knee prosthesis on a partial rotational motion controlled knee wear tester Relative angular motion, loading mode, test speed and duration, specimen assembly and test environment requirements. The kinematics descriptions specified in this section may not apply to highly constrained knee prosthesis designs as they may be tested early It can cause damage to joint components and thus does not represent clinically expected performance.

1.6 Description. X

--- a percentage of a cycle, %; Y

--- humerus rotation, °. Figure

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article. Pieces. For undated references, the latest edition (including all amendments) applies to this document.

YY/T 1426.1-2016 Surgical implants - Total knee prosthesis wear - Part 1 . Load control wear test machine Load and displacement parameters and associated test environmental

conditions (

ISO 14243-1.2009, IDT) Surgical implants -- Total knee prosthesis wear -- Part 2 . Methods of measurement (ISO 14243-2. 2009, IDT) ISO 7207-

1 Surgical implant parts and total knee prosthetic parts - Part 1. Classification, definition and dimensioning
(Implantsforsurgery-Componentsforpartialandtotalknee-jointprostheses-Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Before and after (AP) displacement Anterior/Posterior (AP) displacement The amount of offset of the axial force axis relative to the buckling/extension axis measured in a direction perpendicular to the axial force axis and the buckling/extension axis.

Note. This displacement is specified when the total knee prosthesis is at the reference position (3.7), and the axial force axis is relative to the reference position of the total knee prosthesis. Set to a positive value (3.7).

3.2 Front and rear force APforce Perpendicular to the tibial axis and the flexion/extension axis, the shear force exerted by the tibial component on the femoral component, the line of action of the force passing through the axial direction Force axis.

Note. When the direction of action of the force is defined as positive along the tibial component from the back to the front.

3.3 Axial force axisforce The force of the knee prosthesis tibial component applied to the femoral component in a direction parallel to the axis of the tibia.

Note. The regulation is defined as positive when the direction of force is from bottom to top (see Figures 1 and 2). Description. 1

---buckling (femoral component); 2

---Tibial rotation; 3

---The displacement of the tibial component before and after; 4

---axial force. Figure

1 Symbolic rule of force and motion in the left knee of the total knee arthroplasty system Description. 1

---axial force axis; 2

---the humeral axis; 3

3.9 Provisions. Table

4 Changes in tibia rotation over time Percentage of time period /% Rotation angle/° 0 1.6 2 1.9 16 -1.2 40 1.6 88 -5.7 100

4 Principle

The total knee prosthesis is mounted on a test device that applies periodically varying buckling/period to the femoral and tibial component contact surfaces. The angle of extension, the angle of rotation of the tibia, the anteroposterior displacement and the axial force simulate the gait of a normal person. The tibial component is flexed/extended and rotated Movement of the femoral component under rotation, anterior and posterior displacement and axial force loading. The contact force/displacement effect of the load is axial force, buckling/stretching Rotation, front and rear displacement, and tibial rotation. All applied force/displacement actions follow a defined periodic variation law, and each force/motion action There is also a fixed relationship between them. The contact surfaces of the femoral and tibial components are immersed in a test medium that mimics human body lubricating fluid. Soak a control sample Calculate the creep of the test sample and/or by the axial force load in the liquid medium and with the same periodic variation as the test sample The quality change caused by liquid exchange. The test was carried out under controlled conditions simulating physiological conditions. 5 sample, lubricating fluid and sample volume

5.1 Liquid test medium The liquid test medium consists of the following parts.

--- Deionized water diluted protein calf serum solution of 20g/L;

--- Under normal circumstances, the liquid test medium needs to be filtered through 2μm filter membrane/paper;

--- In order to minimize microbial contamination, the liquid test medium should be stored frozen before the test. Can add bacteriostatic agents (such as azide sodium). The reagent may be a hazardous chemical;

--- The pH of the liquid test medium can be monitored regularly. If monitored, the test report should include the test results.

5.2 Test sample The size combination and design details of the selected test sample should be representative of the expected most unfavourable wear of the total knee system being tested. condition. Unless the physical characteristics of the implant system prove that it is not achievable, the tibial component should be supported on the dorsal articular surface (eg bone cement) Or machined humeral support for imitation of the inner surface). If the articular surface of the patella component is fixed to the tibial tray by a snap ring/fastening device, the workpiece Should be able to provide the same fixed conditions. If the normal backing or bone cement cannot be used due to the physical characteristics of the implant