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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1426.1-2016

**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**

外科植入物 全膝关节假体的磨损 第1部分：载荷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 per knee prosthesis wear" is divided into the following three parts. - Part 1. Load and displacement parameters of load control wear testing machines and associated test environmental conditions; - Part 2. Methods of measurement; Part 3. Load and displacement parameters of displacement control wear testing machines and associated test environmental conditions. This part is part 1 of YY/T 1426. This part is drafted in accordance with the rules given in GB/T 1.1-2009. This part uses the translation method equivalent to ISO 14243-1..2009 "Surgical implants for wear of the general knee prosthesis Part 1. The load and displacement parameters of the wear test machine and the relevant test environmental conditions ". In this part of the normative reference to the international documents have a consistent correspondence between the following documents. - YY/T 0924.1-2013 Surgical implants and total knee prostheses - Part 1. Classification, definitions and dimensions (ISO 7207-1..2007, MOD) - YY/T 1426.2-2016 Wear of surgical implants in the general knee joint Part 2. Methods of measurement (ISO 14243- 2..2009, IDT) Please note that some of the contents of this document may involve patents. The issuer of this document does not assume responsibility for the identification of these patents. This section is proposed by the State Food and Drug Administration. This part of the National Institute of Surgical Implants and Orthopedic Equipment Standardization Technical Committee of Materials and Orthopedic Implants Subcommittee (SAC/TC110/SC1). This part of the drafting unit. the State Food and Drug Administration Tianjin Medical Device Quality Supervision and Inspection Center, Xi'an Jiaotong University. This part of the main drafters. Zhang, Dong Shuangpeng, Li Libing, Wang Ling, Chen Xian. Peripheral prosthesis wear in surgical implants Part 1. Load of load test wear test machine And displacement parameters and associated experimental environmental conditions

1 Scope

YY/T 1426.1 is Part 1 of the Chinese series on wear testing of total knee prostheses and covers the load-controlled variant of the test. It specifies the flexion and extension angular motion, the loading pattern, the test speed and duration, and the joint and environmental conditions a wear testing machine has to reproduce, so that the prosthesis is worn under

motion and force representing gait. Wear debris from the tibial insert is the principal cause of long-term loosening in knee replacement, so this protocol underpins the durability evidence in any registration dossier. Part 2 covers how the resulting wear is measured and Part 3 the displacement-controlled variant. For an orthopaedic manufacturer entering China, this is the test regime a reviewer expects the submitted wear data to have followed.

This part of the YY/T 1426 specifies the flexion/extension angle between the joint parts under the total knee prosthesis wear test under load control Movement, loading method, test speed and duration, specimen assembly and test environment requirements.

2 Normative reference documents

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

ISO 7207-1 surgical implants and total knee prostheses - Part 1. Classification, definition and dimensioning

(Implantsforsurgery-Componentsforpartialandtotalknee-jointprostheses-Part 1.

Classification, definitionsanddesignationofdimensions ISO 14243-

2 Peripheral prosthesis for surgical implants - Part 2. Methods of measurement

(Implantsforsurgery- Wearoftotalknee-jointprostheses-Part 2. Methodsofmeasurement)

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Before and after displacement APdisplacement The offset of the axial force axis relative to the buckling/extension axis measured in the direction perpendicular to the axial force axis and the buckling/extension axis.

Note 1. A is the abbreviation of "anterior"; P is the abbreviation of "posterior".

Note 2. When the total knee joint is at the reference position (3.7), the displacement is set to zero, and when the axial force axis is relative to the reference position of the total knee joint Defined as a positive value (3.7), see Figure 1.

3.2 Before and after force APforce Perpendicular to the tibial axis and the flexion/extension axis, the force acting on the tibial plateau component, the force acting through the axial force axis.

Note. When the direction of action of the force along the tibial component from the forward, the definition is positive, see Figure 1.

3.3 Axial force axisforce The force applied to the tibial component of the knee prosthesis parallel to the tibial axis.

Note. When the direction of force from the bottom up when the provisions of the force is positive (see Figure 1 and Figure 2).

3.4 Axial force axis Axial force of the line, the line through the knee prosthesis tibial component from the tibial axis to the tibial lateral displacement of $0.07w \pm$

$0.01 w$, where w is the total width of the tibial component, see ISO 7207-1.

Note 1. See Figure 2.

Note 2. For an average width (i.e., 74 mm) tibial component, the

$0.07 w$ value is approximately equal to 5 mm.