ICS 11.040.40
CCS C35

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1426.2-2016

Implants for surgery - Wear of total knee-joint prostheses - Part 2: Methods of measurement

外科植入物 全膝关节假体的磨损 第2部分：测量方法

Issued on: January 26, 2016 **Implemented on: January 1, 2017**

Issued by: National Medical Products Administration

Table of Contents

Foreword

4 gravimetric method

1 Scope

YY/T 1426.2 is the part of the Chinese knee-wear series that says how the wear is measured once the test has been run. It specifies the method for assessing wear of the tibial component of a total knee prosthesis by gravimetric analysis, weighing the component before and after a wear test carried out under the other parts of the series. Weight loss is the accepted proxy for the volume of debris a joint will shed in the body, and the measurement has to be corrected for fluid absorption or the result is meaningless. The standard carries Amendment 1 of 2023. It is a companion document rather than a standalone one: a laboratory running knee wear tests needs it alongside Part 1 or Part 3, and a Chinese reviewer will expect the wear figures in a dossier to have been derived by this method.

This part of YY/T 1426 specifies the use of weight analysis to evaluate the total knee after total knee prosthesis wear test in accordance with Part

1 The method of wear of tibial parts of joint prosthesis.

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 14243-

1 Surgical implants - Wear of the general knee prosthesis - Part 1. Load and wear of the

load - controlled wear test machine. Shift parameters and associated environmental conditions (Implantsforsurgery-Wearoftotalknee-jointprostheses-Part 1. Loadinganddisplacementparametersforwear-testingmachineswithloadcontrolandcorresponding environmentalconditionsfortests

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Wear wear Due to the relative movement between the prosthetic component components and the load caused by the loss of component material.

4 Weight analysis

4.1 Principles The test sample is soaked in the lubricating fluid and repeatedly removed from the lubricating fluid, washed, dried and weighed until the liquid absorption rate reaches Stability value. The test sample was mounted on a knee joint simulator for a wear test to measure the quality loss of the test sample due to wear. The control samples were soaked in the same lubricating medium medium with no or no load and no relative motion, so that the control sample was drawn And the same treatment procedure is used to achieve the purpose of the control.

4.2 Reagents and materials

4.2.1 Liquid test media, according to ISO 14243-1.

4.2.2 Control samples according to ISO 14243-1.

4.2.3 isopropanol.

4.3.1 Balance. The range meets the mass range of the test sample with an accuracy of ±

0.1 mg.

5 Test Report 3

YY/T 1426 "Surgical implants per knee prosthesis wear" is divided into 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 2 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 14243-2..2009 "Surgical implants of the knee joint prosthesis wear Part 2. Quantity method ". In this part of the normative reference to the international documents

have a consistent correspondence between the following documents. - YY/T 1426.1-2016 Surgical implants for wear of total knee prostheses Part 1. Wear test for wear control Load and displacement parameters of the machine and associated test environmental conditions (ISO 14243-1..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 section is organized by the National Committee for the Standardization of Surgical Implants and Orthopedic Instruments 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. Jiao Yongzhe, Dong Shuangpeng, Wang Ling, Hou Yinhui. Peripheral prosthesis wear in surgical implants Part 2. Methods of measurement