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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0809.13-2020

Implants for surgery - Partial and total hip joint prostheses - Part 13: Determination of resistance to torque of head fixation of stemmed femoral components

外科植入物 部分和全髋关节假体 第13部分：带柄股骨部件头部固定抗扭转力矩的测定

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Table of Contents

Foreword

YY/T 0809 "Surgical Implant Parts and Total Hip Joint Prostheses" is expected to be divided into the following parts.

1.Classification and dimensioning;

2.Metal, ceramic and plastic joint surfaces;

4.Fatigue performance test and performance requirements of shank femoral components;

6.Neck fatigue performance test and performance requirements of the femoral component with handle;

8.Fatigue performance of shank femoral components with torque effect;

10.Determination of the static resistance of the combined femoral head;

12.Test method for acetabular cup deformation;

13.Determination of the fixed anti-torsion moment of the head of the shank femoral component. This part is part 13 of YY/T 0809. This section was drafted in accordance with the rules given in GB/T 1.1-2009. This part uses the redrafting method to modify and adopt ISO 7206-13.2016 ``Surgical Implant Parts and Total Hip Joint Prostheses Part

13 Minutes. Determination of the anti-torsion torque of the head of the shank femoral component. Compared with ISO 7206-13.2016, this part has the following technical differences.

---Regarding normative reference documents, this standard has made adjustments with

technical differences to adapt to my country's technical conditions and adjustments. The situation is collectively reflected in Chapter 2 "Normative Reference Documents", and the specific adjustments are as follows: - Replace ISO 7500-1 with GB/T 16825.1 equivalent to the international standard; - Replace ISO 7206-1 with YY/T 0809.1 equivalent to the international standard; - Replace ISO 7206-10 with YY/T 0809.10 modified to adopt international standards; - Figure 1 and Figure 2 swap the sequence. - The brand name was deleted in 6.3.3. Please note that certain contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents. This part was proposed by the State Drug Administration. This part is organized by the Orthopedic Implant Sub-Technical Committee of the National Standardization Technical Committee for Surgical Implants and Orthopedic Devices (SAC/TC110/ SC1) Centralized. Drafting organizations of this section. Tianjin Medical Device Quality Supervision and Inspection Center, Trauson Medical Devices (China) Co., Ltd., Shanghai University School of Electrical Engineering and Automation, Beijing Natong Technology Group Co., Ltd. The main drafters of this section. Dong Shuangpeng, Li Wenjiao, Chen Changsheng, Wang Jian, Hua Zikai, Cai Peng, Li Renyao, Zhao Wenwen. Surgical implant parts and total hip prostheses Part

1 Scope

YY/T 0809.13 is the bench test for the taper junction of a hip prosthesis. It specifies a method for determining the torque required to loosen the fixation of the femoral head on the stem, for designs in which the ball is not intended to rotate relative to the neck, under defined laboratory conditions. That junction is where the modular hip has historically given trouble: a head that can turn on its taper fretting and generating debris is the failure the test exists to exclude. It is Part 13 of the YY/T 0809 series, the Chinese adoption of the international hip prosthesis test methods, and the version in circulation carries amendment 1 of 2025. For a manufacturer of modular hip systems seeking Chinese registration, this is the method behind the taper fixation data, alongside the mandatory fundamental requirements in YY 0118.

This part of YY/T 0809 specifies that the fixation of the hip joint prosthesis femoral ball head is loosened under specific laboratory conditions. (In hip prostheses, the ball head is expected to be unable to rotate relative to the neck) The method of torque required. This part is applicable to the femoral components of partial or total hip prostheses, in which the femoral ball head and the femoral neck/stem (hereinafter referred to as the cone) are connected Over-cone locking or other ways to fix together, in which the femoral ball head and cone are independent parts, they are made of metal or non-metallic materials production. This section does not include the method of inspecting the sample; the inspection of the sample should be negotiated between the testing laboratory and the sample provider.

2 Normative references

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

GB/T 16825.1 Inspection of static uniaxial testing machine Part

1.Inspection and calibration of force measuring system of tensile and (or) compression testing machine Standard (GB/T 16825.1-2008, ISO 7500-1.2004, IDT)

YY/T 0809.1 Surgical implant parts and total hip joint prostheses. Part

3 Terms and definitions

The terms and definitions defined in YY/T 0809.1 and YY/T 0809.10 apply to this document.

4 Principle

Apply a static torque to the femoral ball head/cone assembly of the hip prosthesis and increase the torque until it reaches the gap between the femoral ball head and cone. The connection fails or the selected maximum torque is reached (without failure).

5 Equipment

5.1 The testing machine, in accordance with the requirements of GB/T 16825.1, should have the following characteristics.

---Axial pressure can be applied through the axis of the femoral ball head/cone for assembly, and the full scale accuracy is 1%;

---Axial force can be applied to a specific point on the lever arm of the cone unit, or the cone unit can be directly applied without the lever arm Torque is applied, and the full scale accuracy is 1%;

--- There is a monitoring device that can record the load value and angular displacement value applied to the sample, with a tolerance of ±0.5°.

5.2 Cone unit, including a cone that is assembled with the femoral ball head in actual use, or a replica of the cone, which is the same as the cone Size and made of the same material, using the same manufacturing process and the same specifications.

5.3 The loading tooling should be able to withstand the expected load, and its design can make the line of action of the external torque and the femoral ball head/cone assembly center The heart lines are collinear, as shown in Figure 1. Figure

1 Schematic diagram of the test device with suggested dynamic and motion boundary

conditions

6 Steps

6.1 Specimen and sample size In order to determine the torque that loosens the fixation of the femoral ball head in the hip prosthesis, at least the cone unit of each ball head should be tested 5 pieces. Each specimen shall contain a femoral ball head and the femoral neck intended to be fixed to it. The sample can be a real implant or a substitute sample composition.

6.2 Assembly (installation) of test piece Assemble the femoral ball head and cone unit according to YY/T 0809.10.

6.3 Femoral ball head fixation

6.3.1 Optional method 1, process two parallel planes on the ball head near the equator, and the distance between these two planes and the center of the ball head is perpendicular Basically the same, as shown in Figure 2. Figure

2 An example of preparing a femoral ball head that is locked and fixed with parallel planes The two planes facilitate the use of a flat wrench to fix the femoral ball head to resist axial torque. The perpendicular distance between the two parallel planes should be at the femur Within the range of 30% to 70% of the average diameter of the ball head. The remaining wall thickness of the ball head on the plane should be at least 2.0mm.

Note. For 28mm femoral ball head, a vertical distance of 19.0mm±0.5mm is suitable.

6.3.2 Optional method two, you can bond the femoral ball head into a metal ball socket, the ball socket should be able to cover at least 140 ° spherical head hemisphere. The separation torque of the bonded part should be greater than the expected separation torque of the femoral ball head/cone assembly. If the bonding interface is expected at the femoral ball head Before the rotation is broken, it must be recorded in the test report. A sample should be added for testing.

Note. Epoxy adhesives have been found to be suitable for bonding the ball head to the tooling.

6.3.3 Optional method three, use pouring resin to embed the ball head in the embedding tooling. The separation torque of the embedding medium/femoral ball head should be greater than the expected separation torque of the femoral ball head/cone assembly. If the interface is on the ball head Destruction before rotation is expected, it should be recorded in the test report. A sample should be added for testing.

Note. Pouring resin has been found to be suitable for fixing the ball head.