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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0810.1-2024

Joint replacements - Total knee-joint prostheses - Part 1: Determination of endurance properties of knee tibial trays

关节置换植入器械 全膝关节假体 第1部分：胫骨托疲劳性能的测定

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Foreword

This document was drafted in accordance with the rules provided in GB/T 1.1-2020 Directives for Standardization - Part

1.Rules for the Structure and Drafting of Standardizing Documents. This document is Part 1 of YY/T 0810 Joint Replacements - Total Knee-joint Prostheses. YY/T 0810 has issued the following part.

1.Determination of Endurance Properties of Knee Tibial Trays. This document serves as a replacement for YY/T 0810.1-2010 Implants for Surgery - Total Knee-joint Prostheses - Part

1.Determination of Endurance Properties of Knee Tibial Trays. In comparison with YY/T 0810.1-2010, apart from editorial modifications, the main technical changes are as follows:

---The basis for dynamic calibration is modified, and GB/T 16825.1-2022 is used to replace ISO 4965 [see

1 Scope

YY/T 0810.1 is the fatigue test for the tibial tray, the metal platform that carries the bearing insert on the shin side of a knee replacement. It specifies the method for determining the endurance properties of knee tibial trays under defined laboratory loading. The tray is the component where a knee replacement fails mechanically rather than by wear: a tray that cracks under years of cyclic load takes the whole construct with it, and the failure appears late enough that only a bench test can find it before a patient does. It is Part 1 of the Chinese total knee prosthesis test method series, sitting alongside YY/T 0924.2 on bearing

surfaces and under the mandatory requirements of YY 0502. For a manufacturer of knee systems seeking Chinese registration, this is the method behind the tray fatigue data.

This document describes the test method for determining the endurance properties of knee tibial trays that support and protect plastic articular surfaces in knee prostheses under specific laboratory conditions. This document applies to knee tibial trays that cover the mediolateral tibia. This document does not apply to tibial components made of plastic materials only. This document does not cover the test and reporting methods of the final state of specimens, which are determined by the test laboratory and the specimen provider through negotiation.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 16825.1-2022 Metallic Materials - Calibration and Verification of Static Uniaxial Testing Machines - Part

1.Tension / compression Testing Machines - Calibration and Verification of the Force-measuring System (ISO 7500-1.2018, IDT)

YY/T 0924.1-2014 Implants for Surgery - Components for Partial and Total Knee Joint Prostheses - Part

3 Terms and Definitions

The terms and definitions defined in YY/T 0924.1 and the following are applicable to this document.

3.1 anteroposterior centerline A straight line passing through the center of the knee tibial tray shank and parallel to the sagittal plane and perpendicular to the line of action of the force. NOTE. the shank or other protrusion on the lower surface of the knee tibial tray may also be called the keel.

3.2 mediolateral centerline A straight line passing through the center of the knee tibial tray shank and parallel to the coronal or frontal plane and perpendicular to the line of action of the force. NOTE. the shank or other protrusion on the lower surface of the knee tibial tray may also be called the keel.

3.3 ML moment arm dm

1 The vertical distance between the anteroposterior centerline of the tibial component and

the axis of load application. NOTE. if the loading point is inside the anteroposterior centerline, then, the distance is a positive value.

3.4 AP moment arm dap The vertical distance between the mediolateral centerline of the tibial component and the axis of load application. NOTE. if the loading point is behind the mediolateral centerline, then, the distance is a positive value.

4 Principle

The specimen is fixed on the test equipment, so that one condyle of the knee tibial tray extends out to become a cantilever structure. Through a gasket, apply cyclic load to the unsupported condyle. When the specimen fails or the set number of cycles is reached, stop loading. Check the specimen for defects caused by the load.

5 Equipment

5.1 Testing machine with the following characteristics.

a) Sinusoidal dynamic loading waveform at a specific frequency;

5.1

b) of Version 2010];

---The definitions of anteroposterior centerline (see 3.1;

3.1 of Version 2010) and mediolateral centerline (see 3.2;

3.2 of Version 2010) are modified;

---The requirements for gaskets are modified (see 5.3;

5.3 of Version 2010);

---The requirements for test samples and test conditions are added (see Chapter 6);

---The requirements for the loading frequency of the testing machine are modified (see 7.7;

6.7 of Version 2010). This document modifies and adopts ISO 14879-1.2020 Implants for surgery - Total knee joint prostheses - Part

1.Determination of endurance properties of knee tibia trays. The technical differences between this document and ISO 14879-1.2020 and the causes for the differences are as follows:

---In terms of Normative References, this document makes adjustments with technical differences to adapt to the technical conditions of China. The adjustments are intensively reflected in Chapter 2 "Normative References". The specific adjustments are as follows: YY/T 0924.1-2014, which modifies and adopts international standard, is used to replace

ISO 7207-1.2007; GB/T 16825.1-2022, which identically adopts international standard, is used to replace ISO 7500-1.2018. This document makes the following editorial modifications. Joint Replacements - Total Knee-joint Prostheses - Part 1. Determination of Endurance Properties of Knee Tibial Trays