

ICS 11.060.10
CCS C33

YY

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

YY/T 1983-2025

**Dentistry - Zirconia dental implants - Dynamic fatigue loading
test**

牙科学 氧化锆牙种植体 动态疲劳试验

Issued on: October 30, 2025

Implemented on: November 1, 2026

Issued by: National Medical Products Administration

Table of Contents

- 1 Scope
- 2 Normative references
- 3 Terms and Definitions
- 4 Basic Principles

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Technical Committee on Standardization of Dental Materials and Instruments (SAC/TC99). This document was drafted by: the Oral Medical Device Testing Center of Peking University School of Stomatology, Peking University School of Stomatology, Beijing Forestry University. Huazhi Medical Equipment (Beijing) Co., Ltd., Weihai Weigao Jielikang Biomaterials Co., Ltd., Northeastern University, Sichuan University, Shanghai Jiao Tong University The Ninth People's Hospital Affiliated to the Medical School and Hangzhou Erran Technology Co., Ltd. The main drafters of this document are. Han Jianmin, Guo Chuanbin, Li Nan, Bai Wei, Liu Wen, Zhang Zutai, Li Xinchang, Sun Fei, Yuan Tun, Liu Xin, and Sui Baiyan. Lu Hua and Zhao Wuyuan. Zirconia dental implants Dynamic fatigue test

1 Scope

YY/T 1983 is the fatigue test for ceramic dental implants. It describes the dynamic fatigue test method for zirconia dental implants and their prosthetic components: the cyclic loading regime that stands in for years of chewing and reveals whether a ceramic implant will survive in service. Zirconia behaves differently from titanium under cyclic load, which is why it gets a dedicated method rather than being folded into the general dental implant standards, and why the test covers the restorative components together with the fixture. For a manufacturer of metal-free implant systems seeking registration in China, this is the method the mechanical test report has to follow, and for a testing laboratory it is the protocol a Chinese reviewer will expect to see named in the report.

This document describes the dynamic fatigue performance testing method for zirconia dental implants and their restorative components. This document applies to the

determination of fatigue performance of zirconia dental implants and their restorative components.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies; for undated references, the latest version (including all revisions) applies. This document.

GB/T 9937 Terminology in Dentistry

GB/T 40005-2021 Weibull Statistical Analysis Method for Strength Data of Fine Ceramics

YY/T 0521-2018 Dental Implants - Dynamic Fatigue Testing of Intraosseous Dental Implants

YY/T 1715-2020 Yttrium-stabilized tetragonal zirconia (Y-TZP) ceramic materials for surgical implants

3 Terms and Definitions

The terms and definitions defined in GB/T 9937, YY/T 0521-2018 and YY/T 1715-2020 apply to this document.

4 Basic Principles

4.1 Finished Product Testing This trial should ideally select representative final products for testing. For example, if the manufacturer specifies that zirconia dental implants require pre-operative evaluation by a clinician... If sterilization is required, the implants should be sterilized according to the manufacturer's instructions before the experiment.

4.2 Assembly of Dental Implant Systems Dental implants generally need to be used in conjunction with other components to achieve their intended purpose. For example, a dental implant system typically consists of a tooth implanted into the bone. The implant consists of the superstructure that restores the missing soft and hard tissues, and/or the abutment connecting the two. When conducting this experiment, it is advisable to use... Use the components recommended by the manufacturer and assemble according to the instructions. If the implant components are connected by screws, these screws should be installed according to the manufacturer's specifications. The recommended method is to use the tools (screwdriver, torque wrench) compatible with the dental implant system to tighten the screws to the specified torque. If implantation is needed... If the components of the body are fixed in place by adhesive, it is advisable to use the adhesive and bonding method recommended by the manufacturer for fixing before testing and recording the results.

4.3 Worst-case test If a dental implant or a component thereof can be available in different sizes and/or shapes, then it is advisable to select within the recommended range. Conduct experiments under the worst-case conditions. The choice of the worst-case conditions should be based on sufficient justification and recorded. For instructions on how to choose the worst-case scenario, see [link to relevant documentation]. Appendix B of YY/T 0521-2018.

chinastandards.org - PREVIEW