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

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Dentistry - Tissue punches

牙科学 软组织环切刀

(English Translation)

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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.

This document is modified to adopt ISO 23445:2021 "Dental Science - Soft Tissue Circumcision Knife".

The technical differences between this document and ISO 23445:2021, and the reasons therefor, are as follows.

---Added a description of the scope of application (see Chapter 1);

---ISO 1942 has been replaced with the normatively referenced GB/T 9937 (see Chapter 3) to adapt to my country's technical conditions and increase operability.

Actual nature;

---ISO 1797 (see Chapter 3, 6.3.4) has been replaced with the normatively referenced YY/T 0967 to adapt to my country's technical conditions, and has been improved.

Increase operability;

---ISO 16443 (see Chapter 3) has been replaced with the normatively referenced YY/T 1619 to adapt to my country's technical conditions and add [further details needed].

Operability;

---A symbol for the diameter of the central guide post has been added (see Chapter 4);

---ISO 21850-1 (see 6.1) has been replaced with the normatively referenced YY/T 1952.1 to adapt to my country's technical conditions and add [further details needed].

Operability;

---The clause "The manufacturer should confirm whether the accuracy of the measuring device is suitable" (see 7.2) has been removed to better suit actual testing conditions and improve operability.

Actual nature;

---ISO 17664 (see 7.3) has been replaced with the normatively referenced YY/T 0802 to adapt to my country's technical conditions and increase operability.

Actual nature;

---ISO 6508-1 (see 7.4) has been replaced with the normatively referenced GB/T 230.1 to adapt to my country's technical conditions and increase operability.

Actual nature;

---ISO 6507-1 (see 7.4) has been replaced with the normatively referenced GB/T 4340.1 to adapt to my country's technical conditions and increase operability.

Actual nature;

---ISO 13504 (see 8.1, 8.2, 8.3) has been replaced with the normatively referenced YY/T 1486 to adapt to my country's technical conditions, and has been improved.

Increase operability;

---The AB distance in Figure 3 has been corrected according to the description in 7.5 (see Figure 3).

The following editorial changes have been made to this document.

---The URLs referenced in the ISO and IEC terminology databases have been removed;

---Added illustrations of Figure 2D4 and the central guide post in the left view;

---Added a note to the illustration of Figure 3 in 7.5 (see 7.5) to clarify the function of Figure 3;

---Figure 3 has been changed from "AB" to "AB"; point B has been moved forward to ensure its fixed position is secure; point B has been added according to YY/T 0874.

The diagram shows a distance of 3mm from the end of the rod.

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 was prepared by the National Technical Committee on Standardization of Dental Materials and Instruments, Subcommittee on Dental Equipment and Instruments (SAC/TC99) SC1) is under the jurisdiction of the relevant authorities.

Introduction

A soft tissue circumcission blade is a dental implant instrument used in conjunction with a curved handpiece for the implantation of dental implants in oral surgery.

During the process, holes are made or circumferential cuts are made in the gingival tissue and removed, etc.

This document provides guidance on quality control for this type of product.

Dental soft tissue circumcission knife

1 Scope

This document specifies the performance requirements, marking and labeling information for soft tissue circumferential excision tools used with dental handpieces, and describes the corresponding test...

Verification method.

This document applies to soft tissue circumcission knives used in oral surgical implantation procedures to make holes or circumcise and remove gingival tissue.

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 to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB/T 230.1 Metallic materials-Rockwell hardness test-Part 1: Test methods (GB/T 230.1-2018, ISO 6508-1.

2016, MOD)

GB/T 4340.1 Metallic materials - Vickers hardness test - Part 1: Test methods (GB/T 4340.1-2009, ISO 6507-1:2005, MOD) GB/T 9937 Terminology in Dentistry (GB/T 9937-2020, ISO 1942:2009, MOD) YY/T 0802 Handling of Medical Devices - Information provided by medical device manufacturers (YY/T 0802-2020, ISO 17664.

2017, MOD)

YY/T 0874-2013 Test methods for dental rotating instruments (ISO 8325:2004, IDT) YY/T 0967 Rods for dental rotary and reciprocating instruments (YY/T 0967-2022, ISO 1797-2017, MOD) YY/T 1486 General Requirements for Instruments and Related Auxiliary Instruments for Dental Implants (YY/T 1486-2016) ISO 13504:2012, IDT YY/T 1619 Terminology for Dental Implant Systems and Related Processes (YY/T 1619-2018, ISO 16443:2014, IDT) YY/T 1952.1 Dental Science - Materials for Dental Instruments - Part 1: Stainless Steel (YY/T 1952.1-2024, ISO 21850-1.

2020, MOD)

3 Terms and Definitions

The terms and definitions defined in GB/T 9937, YY/T 0967, and YY/T 1619, as well as the following terms and definitions, apply to this document.

Soft tissue circumcision knife tissue punches an instrument used to remove a circular piece of soft tissue.

[Source. YY/T 1619-2018, 3.3.8]

4 Symbols

The following symbols apply to this document.

D1.Outer diameter of the working part.