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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
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Dentistry - Trephine burs

牙科学 环钻

(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 20569:2018 "Dental Science - Tremming".

The technical differences between this document and ISO 20569:2018, and the reasons therefor, are as follows.

---The scope of application has been expanded (see Chapter 1) to better suit my country's technological conditions and increase operability;

---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 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;

---ISO 1797 (see Chapter 3, 5.3.5) 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 7153-1 (see 5.1) has been replaced with the normatively referenced YY/T 0294.1 to adapt to my country's technical conditions and increase operability.

Actual nature;

--- Added normative reference YY/T 1952.1 (see 5.1) to better align with the dental standards system;

---ISO 13504 (see 5.1, 7.1~7.3) has been replaced by the normatively referenced YY/T 1486 to adapt to my country's technical conditions, and has been improved.

Increase operability;

---ISO 17664 (see 6.3) has been replaced with the normatively referenced YY/T 0802 to adapt to my country's technical conditions and increase operability.

Actual nature;

---ISO 6507-1 (see 6.4) has been replaced with the normatively referenced GB/T 4340.1 to adapt to my country's technical conditions and increase operability.

Acting.

The following editorial changes have been made to this document.

---In section 3.2, L3 was changed from "length of the operating section" to "length of the operating section and the working section";

---Added a note for 5.3.3;

---5.3.3 Change "Length of the operation section" in the title and content to "L3";

---Added the corresponding chapter/section number for the test methods in 5.3.4;

---In Figure 3 of section 5.7, "0.08" is changed to "0.1", "AB" is changed to "AB", and "10" is changed to " ≥ 10 ";

---Added note 6.6 and Appendix A;

---The preface to ISO 20569:2018 has been removed.

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 dental trephine is a dental instrument used for dental implants.

Dental trephine

1 Scope

This document specifies the requirements for dental trephine drills used in oral implant surgeries (such as bone harvesting or implant removal), and provides a classification and description.

The corresponding test methods are described, and the requirements for marking, labeling, and instructions for use are also specified.

This document applies to dental trephine drills used in dental implant surgery.

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 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 0294.1 Surgical Instrument Materials - Part 1: Metallic Materials (YY/T 0294.1-2024, ISO 7153-1.

2016, 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)

3.1 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.

3.1.1

trephinebur

Rotating instruments used with dental handpieces for preparation, bone harvesting, or implant removal during oral implant surgery.