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

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Dentistry - Filling instrument with contra angle

牙科学 反角充填器

(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 19715:2017 "Dental science - Reverse angle fillings".

The technical differences between this document and ISO 19715:2017, and the reasons therefor, are as follows.

---Statements that expand 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 6508-1 (see 6.2) 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 6.2) 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 17664 (see 5.7, 6.4) has been replaced with the normatively referenced YY/T 0802 to adapt to my country's technical conditions and add [something related to compliance/standards].

Operability;

---The definition of reverse angle has been changed to reflect current industry practices (see 3.2);

---The definition of the reverse angle filler has been changed to reflect current industry practices (see 3.3);

---The description of the workpiece dimensions has been changed to a recommended description to reflect current industry practices (see 5.2);

---The surface roughness requirement has been changed; the phrase "the working end of the filler should be surface polished" has been removed because that description pertains to the manufacturer.

Process requirements (see 5.4);

---The wording of the hardness test has been changed to reflect current industry practices (see 6.2).

The following editorial changes have also been made to this document.

---The title of version 5.4 has been changed;

---Note 6.1 has been deleted;

---Added note 6.2;

--- Replace YY/T 0294.1 with ISO 7153-1 as reference information for test methods (see 5.3);

---YY/T 1952.1 has been added as informative reference information for test methods (see 5.3).

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

In dentistry, filling instruments come into contact with patients depending on their intended use. Therefore, special attention must be paid to their tolerance to repeated treatments.

Ergonomics also needs to be considered, therefore, a unique reverse angle design was adopted.

Dental reverse angle filling device

1 Scope

This document specifies the requirements and test methods for inverted corner fillers, which are used to repair surfaces using polymer-based repair materials and cement.

Complex teeth. This document also specifies requirements for design, dimensions, and marking.

This document applies to reverse-angle fillings used to restore teeth using polymer-based restorative materials and cement.

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)

3 Terms and Definitions

The terms and definitions defined in GB/T 9937 and the following terms and definitions apply to this document.

Filling instrument

A passive, handheld dental instrument used to shape and use polymer-based restorative materials and cement during dental restorations.

contraangle

Connect the shank to the working end (3.4) and compensate for the first bend by the angle of the second bend of the rod so that the working end is close to the axis of the rod.

The working end (3.4) is close to the same axis as the handle axis, and the rod part forms a filler (3.1) at an angle (3.2).

workingend

The filler (3.1) is used in the foremost area of the work.