



SLOVENSKI STANDARD
oSIST prEN ISO 7551:2022
01-januar-2022

Zobozdravstvo - Vpojna sredstva (ISO/DIS 7551:2021)

Dentistry - Absorbent points (ISO/DIS 7551:2021)

Zahnheilkunde - Absorbierende Spitzen (ISO/DIS 7551:2021)

Médecine bucco-dentaire - Cones absorbants (ISO/DIS 7551:2021)

Ta slovenski standard je istoveten z: prEN ISO 7551

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ICS:

11.060.10 Zobotehnični materiali Dental materials

oSIST prEN ISO 7551:2022

en,fr,de

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Dentistry — Absorbent points

Médecine bucco-dentaire — Cones absorbants

ICS: 11.060.10

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 Appearance.....	2
4.2 Length.....	2
4.3 Size designation and taper.....	2
4.3.1 Standard absorbent points.....	3
4.3.2 Variable taper absorbent points.....	4
4.3.3 Auxiliary absorbent points.....	4
4.4 Absorption.....	4
4.5 Disintegration.....	4
4.6 Sterility.....	4
4.7 Color-coding.....	4
5 Procurement of samples	5
6 Measurement and test methods	5
6.1 Test conditions.....	5
6.2 Visual examination.....	5
6.3 Length.....	5
6.3.1 Apparatus.....	5
6.3.2 Method.....	5
6.4 Size Designation.....	5
6.4.1 Apparatus.....	5
6.4.2 Method.....	5
6.4.3 Taper.....	6
6.5 Absorption.....	6
6.5.1 Apparatus.....	6
6.5.2 Materials.....	6
6.5.3 Procedure.....	6
6.5.4 Interpretation of results.....	7
7 Packaging, marking and instructions and information to be supplied by the manufacturer	7
7.1 Packaging.....	7
7.2 Labelling.....	7
7.3 Declaration of components.....	8
Bibliography	9

ISO/DIS 7551:2021(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and Restorative Materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 7551:1996), which has been technically revised.

The main changes compared to the previous edition are as follows:

- update of format
- addition of points other than standard taper points
- alignment of the sizes of the absorbent points specified in this international standard now correspond to the sizes for obturating points specified in ISO 6877 and instruments from the ISO 6360 series
- removal of Fig 2.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The following should be taken into account when using this document: specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this document but it is recommended that, for the assessment of such biological risks, reference be made to ISO 7405 and ISO 10993-1.

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Dentistry — Absorbent points

1 Scope

This document specifies requirements and test methods for absorbent points used in endodontic procedures. The requirements apply to absorbent points which have been sterilized once in a manner approved by the manufacturer. Sterility is not included in this document, and any claim that the product is sterile is the responsibility of the manufacturer (see [Table 2](#)). [Clause 7](#) specifies the labelling needed, including the instructions for use.

Absorbent points are marketed sterilized or non-sterilized. This document covers the physical attributes expected of such products as supplied.

Sterility is not included in this document, and any claim that the product is sterile is the responsibility of the manufacturer (see [Table 2](#)). [Clause 7](#) specifies the labelling needed, including the instructions for use.

2 Normative references

The following document, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3630-1, *Dentistry — Endodontic instruments — Part 1: General requirements*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements* [oSIST prEN ISO 7551:2022](https://standards.iteh.ai/catalog/standards/sist/03cef3f8-dd3f-4677-9d73-6e8164d4d79b/osist-pren-iso-7551-2022)

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 3630-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org>

3.1

absorbent point

elongated preformed cones or cylinders of paper or polymer materials for absorption of liquids from a root canal

3.2

tip

distal end of an *absorbent point* ([3.1](#))

3.3

unit pack

smallest pack distributed which contains one or more *absorbent points* ([3.1](#)) of one or more sizes

ISO/DIS 7551:2021(E)

3.4 size designation

numerical indication, "000", of the projected tip diameter, measured in hundredths of a millimetre

3.5 taper

percentage increase in diameter along the length of the absorbent point (3.1)

EXAMPLE 02 taper represents a 2 % increase in diameter along the length of the point.

3.6 standard absorbent point

absorbent point (3.1) having a uniform 02 taper over the first 16 mm

3.7 greater taper absorbent point

absorbent point (3.1) having a uniform taper greater than 02 over the first 16 mm

3.8 variable taper absorbent point

absorbent point (3.1) which has a taper that varies over the first 16 mm

3.9 auxiliary absorbent point

absorbent point (3.1) excepting standard absorbent point (3.6), greater taper absorbent point (3.7) and variable taper absorbent point (3.8)

3.10 neck

portion of an absorbent point (3.1) for grasping while inserting the opposite end for to dry the root canal

4 Requirements

4.1 Appearance

Throughout the length, the absorbent point shall be smooth and uniform in appearance, free of extraneous matter or fibres projecting from the point.

Test according to 6.2.

4.2 Length

Unless otherwise stated by the manufacturer, the overall length shall be not less than (28 ± 1) mm. Test according to 6.3.

4.3 Size designation and taper

The designation of the size of a standard absorbent point is comprised of the nominal size designation expressed as a three-digit number in accordance with Table 1 and the specified colour or its abbreviation.

The dimensions of standard absorbent points shall comply with Table 1 and Figure 1. Within the dimensions specified, variations in shape and design are permitted.

Testing for compliance shall be carried out in accordance with ISO 3630-1, and in accordance with 6.2 and 6.3 of this document. The dimensions of the points shall be as shown in Table 1.

The tip of absorbent points shall be rounded, conical or blunt. The neck may be continuously tapered or cylindrical, or a combination of both.