STN	Stomatológia Absorpčné čapíky (ISO 7551: 2023)	51: 2023) STN EN ISO 7551	
		66 5244	

Dentistry - Endodontic absorbent points (ISO 7551:2023)

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/23

Obsahuje: EN ISO 7551:2023, ISO 7551:2023

Oznámením tejto normy sa ruší STN EN ISO 7551 (66 5244) z júna 2001

137158

STN EN ISO 7551: 2023

EUROPEAN STANDARD

EN ISO 7551

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2023

ICS 11.060.10

Supersedes EN ISO 7551:1998

English Version

Dentistry - Endodontic absorbent points (ISO 7551:2023)

Médecine bucco-dentaire - Cônes absorbants utilisés en endodontie (ISO 7551:2023)

Zahnheilkunde - Absorbierende Spitzen (ISO 7551:2023)

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EN ISO 7551:2023 (E)

Contents	Page
European foreword	3

EN ISO 7551:2023 (E)

European foreword

This document (EN ISO 7551:2023) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2023, and conflicting national standards shall be withdrawn at the latest by November 2023.

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Endorsement notice

The text of ISO 7551:2023 has been approved by CEN as EN ISO 7551:2023 without any modification.

INTERNATIONAL STANDARD

ISO 7551

Second edition 2023-05

Dentistry — Endodontic absorbent points

Médecine bucco-dentaire — Cônes absorbants utilisés en endodontie



STN EN ISO 7551: 2023

ISO 7551:2023(E)



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Published in Switzerland

ISO 7551:2023(E)

Contents			Page	
Fore	eword		iv	
Intr	oductio	on	v	
1	Scor	oe	1	
2	Nor	native references	1	
3		ns and definitions		
	Requirements			
4	кеq 4.1	Appearance		
	4.2	Length		
	4.3	General		
	4.4			
	4.5	Colour-coding		
	4.6	Taper	5	
	4.7	Absorption		
	4.8	Disintegration	5	
5	Pro	curement of samples	5	
6	Mea	Measurement and test methods		
	6.1	Test conditions	5	
	6.2	Visual examination	6	
	6.3	Length		
		6.3.1 Apparatus		
		6.3.2 Method		
	6.4	Taper and nominal size measurements		
		6.4.1 Apparatus 6.4.2 Method for standard and greater taper points		
		6.4.3 Method for variable taper absorbent points		
	6.5	Absorption		
	0.5	6.5.1 Apparatus		
		6.5.2 Material		
		6.5.3 Method		
		6.5.4 Interpretation of results		
7	Product information			
	7.1			
	7.2	8 8		
	7.3	7.3 Labelling		
Bibl	iogran	hv	12	

ISO 7551:2023(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 document 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).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 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 are as follows:

- the format has been updated;
- absorbent points other than standard taper absorbent points have been added;
- <u>Table 2</u> has been added for the dimensions of greater taper absorbent points;
- the sizes of the absorbent points specified in this document have been aligned with the sizes for obturating points specified in ISO 6877 and for instruments from the ISO 6360 series;
- the nomenclature of "numbering system" has been changed to "nominal size designation" of the tip;
- Figure 2 has been removed.

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.

ISO 7551:2023(E)

Introduction

The following information 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.

Dentistry — **Endodontic absorbent points**

1 Scope

This document specifies the requirements and test methods for sterilized absorbent points used in endodontic procedures. Absorbent points are marketed sterilized or non-sterilized. The requirements apply to absorbent points which have been sterilized once in a manner approved by the manufacturer. This document specifies numerical systems and a colour-coding system for designating the sizes of absorbent points.

<u>Clause 7</u> specifies the labelling and packaging needed, including the instructions for use. A claim by the manufacturer that the contents of the unopened pack are sterile is the responsibility of the manufacturer (see <u>Table 2</u>). This document does not specify requirements or test methods for sterility.

NOTE 1 Reference to applicable national regulations can be made.

Reference is made to internationally accepted pharmacopoeia.

NOTE 2 National requirements can apply.

Standards on methods of validating sterilization processes are also available: ISO 11137-1, ISO 11137-2 and ISO 11137-3.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, Dentistry — Vocabulary

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

ISO 6360-1, Dentistry — Number coding system for rotary instruments — Part 1: General characteristics

ISO 8601-1, Date and time — Representations for information interchange — Part 1: Basic rules

ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

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

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