



SLOVENSKI STANDARD
oSIST prEN ISO 3630-5:2019
01-julij-2019

Zobozdravstvo - Instrumenti za zobni kanal - 5. del: Instrumenti za oblikovanje in čiščenje (ISO/DIS 3630-5:2019)

Dentistry - Endodontic instruments - Part 5: Shaping and cleaning instruments (ISO/DIS 3630-5:2019)

Zahnheilkunde - Endodontische Instrumente - Teil 5: Form- und Reinigungsinstrumente (ISO/DIS 3630-5:2019)

Médecine bucco-dentaire - Instruments d'endodontie - Partie 5: Instruments de mise en forme et de nettoyage (ISO/DIS 3630-5:2019)

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Part 5: Shaping and cleaning instruments

*Médecine bucco-dentaire — Instruments d'endodontie —**Partie 5: Instruments de mise en forme et de nettoyage*

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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).

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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 on 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/106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This second edition cancels and replaces the first edition (ISO 3630-5:2011), which has been technically revised.

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

- harmonization of d_0 , d_3 and d_{16} with other 3630 documents.

A list of all parts in the ISO 3630- series can be found on the ISO website.

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

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this document. However, in assessing possible biological or toxicological hazards, it is recommended that reference be made to ISO 10993-1 and ISO 7405.

Attention is drawn to ISO 6360 (all parts), which specifies a 15-digit number for the identification of dental rotary instruments of all types.

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Dentistry — Endodontic instruments —

Part 5: Shaping and cleaning instruments

1 Scope

This document specifies requirements and test methods for hand-held or mechanically operated shaping and cleaning instruments used to perform root canal procedures not cited in the other parts of the 3630 series.

This document specifies requirements for size, marking, product designation, safety considerations, labelling and packaging.

2 Normative references

The following referenced documents are indispensable for the application 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 3630-1:2019, *Dentistry — Endodontic instruments — Part 1: General requirements*

3 Terms and definitions

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

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

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

4 Classification

For the purposes of this document, shaping and cleaning instruments are classified into five types, as specified in ISO 3630-1:2019, Clause 4.

5 Requirements

5.1 Material

The materials used for the working part, the shank and the handle of shaping and cleaning instruments are left to the discretion of the manufacturer but shall meet the requirements of ISO 3630-1:2019, 5.7.

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5.2 Dimensions

5.2.1 General

The dimensions for the nominal diameter and taper of shaping and cleaning instruments shall meet the requirements of ISO 3630-1:2019, Clause 5.

The allowable tolerance for the identified diameters of Types 2, 3, 4, and 5 shall be less than 50 % of the difference between the preceding size and the next larger size instrument of the available brand sizes.

5.2.2 Diameter

The diameter of the shaping and cleaning instrument shall be as specified in ISO 3630-1.

5.2.3 Length

The length of the shaping and cleaning instrument shall be as specified in ISO 3630-1 and shall be measured as specified in ISO 3630-1:2019, 7.3.

5.2.4 For Type 1

Working part length shall be at least 16 mm. Operative part length and overall length shall be left to the discretion of the manufacturer. The manufacturer shall specify operative end length, which shall be within 0,5 mm of the length specified. When provided by the manufacturer, the actual overall length shall be within 1,0 mm of the stated length.

5.2.5 For Types 2, 3, 4 and 5

Working part length, operative part length, and overall length shall be left to the discretion of the manufacturer. The manufacturer shall specify working part length as a minimum; operative part length shall be within 0,5 mm of the length specified. When provided by the manufacturer, the actual overall length shall be within 1,0 mm of the stated length.

5.3 Mechanical

5.3.1 Resistance to fracture by twisting and angular deflection

When tested in accordance with ISO 3630-1:2019, 7.4, the shaping and cleaning instrument shall not fracture at less than the minimum value specified for the resistance to fracture in twisting and angular deflection, given as follows:

- a) for Type 1, standard instruments, in [Table 1](#);
- b) for Type 2, tapered instruments, in [Table 2](#) and [Table 3](#);
- c) for Type 3, shaped instruments, in [Table 1](#);
- d) for Type 4, non-tapered instruments, in [Table 1](#);
- e) for Type 5, non-uniform tapered instruments, in [Table 2](#) and [Table 3](#).

5.3.2 Stiffness

The stiffness is tested as resistance to bending.

When tested as specified in ISO 3630-1:2019, 7.5, the shaping and cleaning instrument shall not fracture and the maximum value given shall not be exceeded, as follows:

- a) for Type 1, standard instruments, in [Table 4](#);