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Dentistry — Endodontic instruments —

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).

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).

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 4, *Dental instruments*, 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 3630-5:2011), which has been technically revised.

The main change compared to the previous editions is as follows: d_0 and d_3 have been harmonized with the other parts of ISO 3630.

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.

Dentistry — Endodontic instruments —

Part 5:
Shaping and cleaning instruments

1 Scope

This document specifies requirements and test methods for hand-held and mechanically operated instruments used for shaping and cleaning root canals, and which are not specified in other parts of the ISO 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, *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:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Classification

For the purposes of this document, shaping and cleaning instruments are classified into five classes, 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.

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 Classes 2, 3, 4, and 5 shall be less than 75 % 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.

5.2.4 For Class 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 Classes 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

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 Class 1 (standard) instruments in Table 1;

b) for Class 2 (taper) instruments in Table 2 and Table 3;

c) for Class 3 (non-taper) instruments in Table 1;

d) for Class 4 (non-uniform taper) instruments in Table 2 and Table 3;

e) for Class 5 (shape) instruments in Table 1.

Table 1 — Resistance to fracture by twisting and angular deflection (applicable to Class 1, Class 3 and Class 5 instruments)

Nominal size, d_0 mm	Resistance to fracture (torque) mN·m, minimum			Angular deflection °, minimum	
Instrument	**K File**	**H File**	**K Reamer**	**K File and K Reamer**	**H File**
06	0,34	0,34	0,34	360	180
08	0,50	0,50	0,50	360	180
10	0,60	0,60	0,60	360	180
15	0,80	0,80	0,80	360	180
20	1,76	1,18	1,18	360	180
25	2,94	1,96	1,96	360	180
30	4,42	3,43	3,43	360	180
35	6,36	4,91	4,91	360	180
40	9,81	6,37	6,87	360	120
45	11,78	8,82	9,32	360	120
50	16,68	11,78	11,78	360	120

Table 2 — Resistance to fracture by twisting (applicable to Class 2 and Class 4 instruments)

Diameter of instrument at test location, d_3 mm	Resistance to fracture (torque) mN·m, minimum		
Instrument	**K File**	**H File**	**K Reamer**
<0,124	0,34	n/a[a]	0,34
0,124 to <0,164	0,59	0,59	0,59
0,164 to <0,214	0,79	0,79	0,79
0,214 to <0,264	1,77	1,18	1,18
0,264 to <0,314	2,94	1,96	1,96
0,314 to <0,364	4,42	3,43	3,43
0,364 to <0,414	6,38	4,91	4,91
0,414 to <0,464	9,81	6,38	6,87
0,464 to <0,514	11,78	8,83	9,32
0,514 to <0,564	16,68	11,78	11,78

[a] n/a = not applicable.