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Dentistry - Endodontic instruments - Part 1: General requirements (ISO/DIS 3630-1:2018)

Zahnheilkunde - Endodontische Instrumente - Teil 1: Allgemeine Anforderungen (ISO/DIS 3630-1:2018)

Médecine bucco-dentaire - Instruments d'endodontie - Partie 1: Exigences générales (ISO/DIS 3630-1:2018)

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Part 1: General requirements

Médecine bucco-dentaire — Instruments d'endodontie —

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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 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 [or Project Committee] ISO/TC [or ISO/PC] ###, [name of committee], Subcommittee SC ##, [name of subcommittee].

This third edition cancels and replaces the second edition (ISO 3630-1:2008), which has been technically revised.

This reorganization of ISO 3630 is intended to present the requirements and test methods for endodontic instruments in an orderly manner.

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

— title change of ISO 3630- series to "Endodontic instruments";

— addition of requirements for current use of Nickel-Titanium;

— clarification of option for the handle shape for the manufacturer;

— addition of new identification symbols in Figure 10.

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

Introduction

This document defines general requirements and test methods for endodontic instruments. Subsequent parts provide the specific requirements and test methods, if applicable, for six areas of endodontics. These parts are: enlargers, compactors, auxiliary instruments, shaping and cleaning instruments, number coding system and ultrasonic inserts.

With current use of Nickel-Titanium alloys for manufacture of endodontic instruments a need for adequate expertise in their safe use is recommended. This document does not attempt to provide information for proper use of any instruments.

The sizes of the root canal obturating points (cones) specified in ISO 6877 have to be aligned with the corresponding sizes for endodontic instruments specified in ISO 3630.

Dentistry — Endodontic instruments —

Part 1:
General requirements

1 Scope

This document specifies general requirements and test methods for endodontic instruments used for endodontic purposes, e. g. enlargers, compactors, accessory instruments, shaping and cleaning instruments, and numbering system. In addition, it covers general size designations, colour-coding, packaging, and identification symbols.

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 554, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 1797, *Dentistry — Shanks for rotary and oscillating instruments*

ISO 1942, *Dentistry — Vocabulary*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 4288, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture*

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

ISO 6360-2, *Dentistry — Number coding system for rotary instruments — Part 2: Shapes*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following 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

3.1 General

3.1.1
endodontic instrument
dental instrument designed to explore, shape, clean and/or fill a root canal system

3.1.2
standard instrument
endodontic instrument (3.1.1) having a uniform taper of 0,02 mm per millimetre of length of the working part throughout the range of available sizes

Note 1 to entry: The nominal sizes of endodontic instruments are listed in Table 1.

3.1.3
non-standard instrument
endodontic instrument (3.1.1), which has a tip diameter and/or shape other than that of a standard endodontic instrument

3.1.4
taper instrument
endodontic instrument (3.1.1) of which the sizes are determined by the tip sizes and have uniform tapers of the working part other than 0,02 mm per millimetre of length

3.1.5
non-taper instrument
endodontic instrument (3.1.1) having a cylindrical shape along its long axis

3.1.6
non-uniform taper instrument
endodontic instrument (3.1.1) having more than one taper along the working part

3.1.7
shape instrument
endodontic instrument (3.1.1) having a contoured working part with continuously varying profile

3.1.8
flexible instrument
endodontic instrument (3.1.1) of which the mean value, when tested according to 7.5, is 65 % or less of the value listed in the appropriate bending or stiffness table of referenced specifications

3.1.9
tip part of the instrument
part of the *endodontic instrument* (3.1.1), which is intended as the point, the shape of which is at the discretion of the manufacturer

3.1.10
guiding tip instrument
non-cutting *endodontic instrument* (3.1.1) having a tip which guides access within root canal systems

3.1.11
working part
that part of the *endodontic instrument* (3.1.1) which has a cutting surface

3.1.12
shaft
that part of the *endodontic instrument* (3.1.1) between the handle or shank and the working part

3.1.13
handle
that part of the *endodontic instrument* (3.1.1) which is held by the user's fingers for manipulation of the instrument in the root canal

3.1.14
shank
that part of a rotary, oscillating or reciprocating *endodontic instrument* (3.1.1) which is designed to fit into the chuck of a handpiece

3.1.15
operative part
that part of the *endodontic instrument* (3.1.1) from the tip to the handle or shank

3.1.16
diameter
dd_n
diameter of the *endodontic instrument* (3.1.1) at the subscripted millimetre distance from the tip indicated by [n].

EXAMPLE d_3 is the diameter at 3 mm from the tip.

3.1.17
length
l_n
length of the *endodontic instrument* (3.1.1) at the subscripted millimetre distance from the tip indicated by [n] and l_t as described in 3.2

EXAMPLE l_3 is the length 3 mm away from the tip.

3.2 Symbols

For the purposes of this document the following symbols apply.

D diameter of the projection of the working part at the tip end (reference size);

d_s diameter of the shank (the subscript indicates the location on the shank in *s* mm from the tip);

l_s minimum length of the shank;

l_t length of operative part, measured from the tip.

4 Classification

For the purposes of this document, endodontic instruments are classified as follows:

Standard instrument

— Type 1: standard instrument (taper = 02);

Non-standard instrument

— Type 2: taper instrument (taper other than 02);

NOTE Some manufacturers may designate taper as a percentage, e.g., ‘2%’.

— Type 3: non-taper instrument (zero taper);

— Type 4: non-uniform taper instrument (more than one taper); and

— Type 5: shape instrument (arc shape).