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Third edition 2019-08

Dentistry — Endodontic instruments —

Part 1: **General requirements**

Médecine bucco-dentaire — Instruments d'endodontie — Partie 1: Exigences générales



ISO 3630-1:2019(E)

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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 ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

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

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

- reorganization with the intention of presenting the requirements and test methods for endodontic instruments in an orderly manner;
- change of the main element of the title of the ISO 3630 series to "Endodontic instruments";
- addition of requirements for the current use of Nickel-Titanium;
- clarification of the option for the handle shape for the manufacturer:
- addition of the new identification symbols in Figure 10.

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.

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Introduction

This document specifies general requirements and test methods for endodontic instruments. Other parts of the ISO 3630 series provide the specific requirements and test methods for six areas of endodontics (enlargers, compactors, auxiliary instruments, shaping and cleaning instruments, numeric 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 endodontic obturating points (cones) specified in ISO 6877 should be aligned with the corresponding sizes for endodontic instruments specified in all parts of the ISO 3630 series.