
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

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 3630-5 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

ISO 3630 consists of the following parts, under the general title *Dentistry — Endodontic instruments*:

- *Part 1: General requirements and test methods*
- *Part 2: Enlargers*
- *Part 3: Condensers, pluggers and spreaders*
- *Part 4: Auxiliary instruments*
- *Part 5: Shaping and cleaning instruments*

Introduction

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this part of ISO 3630. 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.

Dentistry — Endodontic instruments —

Part 5: Shaping and cleaning instruments

1 Scope

This part of ISO 3630 specifies requirements and test methods for hand-held or mechanically operated shaping and cleaning instruments used to perform root canal procedures not cited in ISO 3630-1, ISO 3630-2, ISO 3630-3 or ISO 3630-4.

This part of ISO 3630 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 3630-1:2008, *Dentistry — Root-canal instruments — Part 1: General requirements and test methods*

3 Terms and definitions

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

4 Classification

For the purposes of this document, shaping and cleaning instruments are classified into five types, as specified in ISO 3630-1:2008, 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 3630-1:2008, 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 3630-1:2008, 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.