

**ISO TC 106/SC 4 N**

Date: 2005-02-17

**ISO/CD 3630-1.2**

ISO TC 106/SC 4/WG 9

Secretariat: DIN

## **Dentistry — Root-canal instruments — Part 1: General requirements**

*Art dentaire — Instruments pour canaux radiculaires — Partie 1: Exigences générales*

### **Warning**

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

**GOLD STANDARD EXHIBIT 2050**  
*US ENDODONTICS v. GOLD STANDARD*  
CASE IPR2015-00632

Document type: International Standard  
Document subtype:  
Document stage: (30) Committee  
Document language: E

U:\KEL\ISO\106\SC4\WG09\3630-1\2ndCD3630-1\ISO\_3630-1\_(E).doc STD Version 2.2



**Copyright notice**

This ISO document is a working draft or committee draft and is copyright-protected by ISO. While the reproduction of working drafts or committee drafts in any form for use by participants in the ISO standards development process is permitted without prior permission from ISO, neither this document nor any extract from it may be reproduced, stored or transmitted in any form for any other purpose without prior written permission from ISO.

Requests for permission to reproduce this document for the purpose of selling it should be addressed as shown below or to ISO's member body in the country of the requester:

[Indicate the full address, telephone number, fax number, telex number, and electronic mail address, as appropriate, of the Copyright Manager of the ISO member body responsible for the secretariat of the TC or SC within the framework of which the working document has been prepared.]

Reproduction for sales purposes may be subject to royalty payments or a licensing agreement.

Violators may be prosecuted.

<b>Contents</b>	<b>Page</b>
Foreword .....	v
Introduction.....	vi
<b>1 Scope .....</b>	<b>1</b>
<b>2 Normative references .....</b>	<b>1</b>
<b>3 Terms, definitions and symbols.....</b>	<b>2</b>
<b>3.1 Terms and definitions .....</b>	<b>2</b>
<b>3.2 Symbols.....</b>	<b>3</b>
<b>4 Classification .....</b>	<b>3</b>
<b>5 Requirements.....</b>	<b>3</b>
<b>5.1 General .....</b>	<b>3</b>
<b>5.2 Standard sized (Type 1) instruments .....</b>	<b>4</b>
<b>5.3 Taper-sized (Type 2) instruments.....</b>	<b>6</b>
<b>5.4 Shape-sized (Type 3) instruments .....</b>	<b>7</b>
<b>5.5 Non-tapered sized (Type 4) instruments.....</b>	<b>8</b>
<b>5.6 Non-uniform taper-sized (Type 5) instruments .....</b>	<b>9</b>
<b>5.7 Material .....</b>	<b>10</b>
<b>5.8 Dimensions .....</b>	<b>10</b>
<b>5.9 Mechanical requirements .....</b>	<b>10</b>
<b>5.10 Chemical requirements.....</b>	<b>11</b>
<b>6 Sampling.....</b>	<b>11</b>
<b>7 Testing.....</b>	<b>11</b>
<b>7.1 Visual inspection .....</b>	<b>11</b>
<b>7.2 Test conditions .....</b>	<b>11</b>
<b>7.3 Measurement of dimensions .....</b>	<b>12</b>
<b>7.4 Resistance to fracture by twisting and angular deflection .....</b>	<b>12</b>
<b>7.5 Stiffness.....</b>	<b>14</b>
<b>7.6 Handle and shank security .....</b>	<b>15</b>
<b>7.7 Corrosion test .....</b>	<b>15</b>
<b>7.8 Heat effects of sterilization.....</b>	<b>16</b>
<b>8 Designation, marking and identification .....</b>	<b>17</b>
<b>8.1 General .....</b>	<b>17</b>
<b>8.2 Identification symbols.....</b>	<b>17</b>
<b>9 Packaging.....</b>	<b>17</b>
<b>10 Manufacturer's instructions for use .....</b>	<b>17</b>
<b>11 Labelling.....</b>	<b>17</b>
Bibliography.....	19

**Figures**

Figure 1 — Type 1: Standard-sized instrument: taper = 2 % — Dimensions, locations ..... 4

Figure 2 — Tip length and angle ..... 6

Figure 3 — Type 2: Taper-sized instrument: taper other than 2 % – Dimensions, locations ..... 7

Figure 4 — Type 3: Shape-sized instrument: arc shape – Dimensions, locations ..... 8

Figure 5 — Type 4: Non-tapered instrument: zero taper – Dimensions, locations..... 8

Figure 6 — Apparatus for torque test ..... 13

Figure 7 — Details of test chuck ..... 13

Figure 8 — Apparatus for bending test..... 14

Figure 9 — Identification symbols for root-canal instruments..... 17

**Tables**

Table 1 — Standard-sized instrument dimensions, size designation, and colour designation ..... 5

## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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 3630-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This second/third/... edition cancels and replaces the first/second/... edition (ISO 3630-1:1992), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

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

- *Part 1: General requirements*
- *Part 2: Enlargers*
- *Part 3: Condensers, pluggers and spreaders*

The following parts are under preparation:

- *Part 4: Auxilliary instruments*
- *Part 5: Shaping and cleaning instruments*

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.