INTERNATIONAL STANDARD

ISO 13397-1

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Periodontal curettes, dental scalers and excavators —

Part 1: General requirements

Curettes parodontales, instruments dentaires pour détartrage et excavateurs dentaires —
Partie 1: Prescriptions générales

Reference number
ISO 13397-1:1995(E)

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.

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.

International Standard ISO 13397-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

ISO 13397 consists of the following parts, under the general title *Periodontal curettes, dental scalers and excavators*:

— *Part 1: General requirements*

— *Part 2: Dental curettes — Gr-type*

— *Part 3: Dental scalers — H-type*

— *Part 4: Dental excavators*

It is anticipated that additional types of instruments will form the subject of future parts.

Annex A of this part of ISO 13397 is for information only.

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Periodontal curettes, dental scalers and excavators —

Part 1:
General requirements

1 Scope

This part of ISO 13397 specifies the general material and performance requirements for periodontal curettes, dental scalers and excavators.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 13397. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 13397 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942-3:1989, *Dental vocabulary — Part 3: Dental instruments.*

ISO 6507-2:1983, *Metallic materials — Hardness test — Vickers test — Part 2: HV 0,2 to less than HV 5.*

ISO 7153-1:1991, *Surgical instruments — Metallic materials — Part 1: Stainless steel.*

ISO 13402:1995, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure.*

3 Definitions

For the purposes of this part of ISO 13397, the definitions given in ISO 1942-3 apply.

4 Classification

Periodontal curettes, dental scalers and excavators specified in all parts of ISO 13397 are classified according to the Vickers hardness of the working end:

class 1: 600 HV1 - 700 HV1
class 2: 550 HV1 - 620 HV1

5 Material

5.1 Material of working end

The working end shall be made of martensitic stainless steel complying with ISO 7153-1 or other materials providing the instrument made therefrom meets the requirements of clause 6.

5.2 Material of handle

The material of the handle, selected at the discretion of the manufacturer, shall meet the requirements of clause 6.

6 Requirements

6.1 Surface finish

6.1.1 All surfaces

All surfaces shall be visibly free from pores, crevices, grinding marks, residual scales, acid, grease and residual grinding and polishing materials, when inspected using normal vision.

6.1.2 Satin finish

Satin finish shall be both uniform and smooth, and it shall reduce glare.

6.1.3 Mirror finish

Mirror finish shall be ground to remove all surface imperfections and polished to remove grind marks, resulting in a highly reflective surface.

6.2 Vickers hardness of working end

The Vickers hardness of the finished instrument, when tested in accordance with ISO 6507-2, shall be within the range of class 1 or class 2. The manufacturer shall state the appropriate (hardness) class for each instrument pattern or range of instruments in the documentation.

6.3 Resistance against corrosion

When tested in accordance with 7.2 or 7.3, there shall be no visible signs of corrosion.

With the exception of serrated martensitic stainless steel handles, any blemish shall be considered as evidence of corrosion.

6.4 Resistance against thermal exposure

When tested in accordance with 7.4, there shall be no alteration of its physical appearance. The Vickers hardness after thermal exposure shall still be within the stipulated hardness range.

6.5 Union of working end and handle

The union between the working end and the handle of the instrument, previously tested in accordance with 7.1, shall not become loosened under tensile load when tested in accordance with 7.5.1 and under torque when tested in accordance with 7.5.2.

6.6 Design and dimensions

The instrument shall have the design and dimensions specified in the appropriate part of ISO 13397.

Annex A provides details of one method of measurement applicable to most types of dental hand instrument.

7 Test methods

7.1 Test sequence and cycles

Carry out the autoclave test or the boiling water test and the thermal test in one operation for five cycles.

After completion of the tests rub the instrument(s) vigorously with a cloth to remove any blemishes.

7.2 Autoclave test

Carry out the autoclave test as specified in ISO 13402.

7.3 Boiling water test

Carry out the boiling water test as specified in ISO 13402.

7.4 Thermal test

Carry out the thermal test as specified in ISO 13402.

7.5 Test for union of working end and handle

7.5.1 Test under tensile load

Subject the union between the working end and the handle to a tensile force of 600 N, applied in the direction parallel to the centreline of the handle, for a duration of at least 5 s.

7.5.2 Test under torque

Subject the union between the working end and the handle to a torque of 400 N·cm for a duration of at least 5 s.

Annex A
(informative)

Measurement of dimensions

A.1 General

This method of measurement is applicable to most types of dental hand instrument and is based on the use of an optical projector. Dimensions are measured parallel, and at right angles, to the centreline of the instrument and are constructed from a datum point at its working end. Although this is the preferred method, it is by no means the only technique available.

A.2 Apparatus

A.2.1 Optical projector (shadowgraph) fitted with × 10 magnifying lens and micrometer stage.

A.2.2 Glass specimen slide and plasticine, or

A.2.3 Mechanical holding device (e.g. light machine vice), or

A.2.4 V-block.

A.3 Procedure

A.3.1 Preparation for measurement

A.3.1.1 Support or hold the dental instrument using one of the devices in A.2.2, A.2.3 or A.2.4.

A.3.1.2 Place the supported instrument on the micrometer stage of the projector (A.2.1) and ensure that the following requirements are met:

a) the working end of the instrument projects beyond the holding device;

b) the instrument is securely held;

c) there is an unobstructed view of the working end.

A.3.1.3 Ensure that the dental instrument is parallel to the micrometer stage by focussing on, and traversing the length of, the handle. If the handle remains in focus over the traversed distance, then the instrument is ready for measurement.

If the handle does not remain in focus, repeat A.3.1.2 and A.3.1.3 until the handle remains in focus through the field of traverse.

A.3.1.4 Align the centreline of the dental instrument with the vertical and horizontal cross-wires on the projector screen.

A.3.2 Horizontal and vertical measurements

A.3.2.1 Refer to the illustration, table of dimensions and table of measurement points related to the instrument to be measured and, using the micrometer stage, bring the appropriate point of the projected image to either the vertical or horizontal cross-wire, whichever is appropriate to the datum measuring point of interest.

A.3.2.2 Zero the micrometer and move the micrometer stage to the final measurement position and record the measurement.

A.3.2.3 Realign the instrument (A.3.1.4) and repeat steps A.3.2.1 and A.3.2.2 for the remaining dimensions.

A.3.3 Angular measurements

A.3.3.1 Refer to the illustration, table of dimensions and table of measurement points related to the instrument to be measured and, using the micrometer stage, bring the appropriate point of the projected image to either the vertical or horizontal cross-wire, whichever is appropriate.

A.3.3.2 Rotate the bezel of the projector screen to the datum measuring point and note the angular reading.

A.3.3.3 Rotate the bezel to the final measurement position, subtract the initial angular reading from the final reading and record the measured angle.

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