

BRITISH STANDARD

**BS EN ISO
13397-1 : 1996**

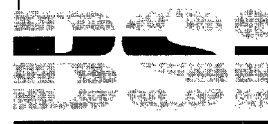
Periodontal curettes, dental scalers and excavators

Part 1. General requirements

The European Standard EN ISO 13397-1 : 1995 has the status of a
British Standard

ICS 11.060.20

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/52, Dental instruments, upon which the following bodies were represented:

British Dental Association
 British Dental Trade Association
 British Endodontic Society
 British Society for Restorative Dentistry
 British Society for the Study of Prosthetic Dentistry
 Department of Health
 Ministry of Defence

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 June 1996

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Amendments issued since publication

Amd. No.	Date	Text affected

The following BSI references relate to the work on this standard:
 Committee reference CH/52
 Draft for comment 94/504196 DC

ISBN 0 580 25683 9

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National foreword

This British Standard has been prepared by Technical Committee CH/52 and is the English language version of EN ISO 13397-1 : 1995 *Periodontal curettes, dental scalers and excavators — Part 1 : General requirements*, published by the European Committee for Standardization (CEN). It is identical with ISO 13397-1 : 1995 published by the International Organization for Standardization (ISO). EN ISO 13397-1 was produced as a result of international discussion in which the United Kingdom took an active part.

BS EN ISO 13397-1 : 1996 supersedes BS 2965 : 1970 which is withdrawn.

Cross-references

Publication referred to	Corresponding British Standard
EN 21942-3 : 1993	BS EN 21942 <i>Dental vocabulary</i>
(ISO 1942-3 : 1989)	Part 3 : 1994 <i>Dental instruments</i>
ISO 7153-1 : 1991	BS 5194 <i>Surgical instruments</i>
	Part 1 : 1991 <i>Specification for stainless steel</i>

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EUROPEAN STANDARD
 NORME EUROPÉENNE
 EUROPÄISCHE NORM

EN ISO 13397-1

December 1995

ICS 11.060.20

Descriptors: Dentistry, dental equipment, dental instruments, classification, specifications, material specifications, performance, tests, generalities

English version

Periodontal cures, dental scalers and excavators — Part 1: General requirements

(ISO 13397-1 : 1995)

<p>Cures parodontales, instruments dentaires pour détartrage et excavateurs dentaires — Partie 1: Prescriptions générale (ISO 13397-1 : 1995)</p>	<p>Parodontalküretten, zahnärztliche Schaber und Exkavatoren — Teil 1: Allgemeine Anforderungen (ISO 13397-1 : 1995)</p>
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Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

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Ref. No. EN ISO 13397-1 : 1995 E

Foreword

The text of the International Standard ISO 13397-1 : 1995 has been prepared by Technical Committee ISO/TC 106, Dentistry, in collaboration with CEN/TC 55, Dentistry.

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

- Part 1: *General requirements*
- Part 2: *Periodontal curettes — G-type (dimensions)*
- Part 3: *Dental scalers — H-type (dimensions)*
- 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 1996, and conflicting national standards shall be withdrawn at the latest by June 1996.

In accordance with the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

NOTE. Normative references to international publications are listed in annex ZA (normative).

Periodontal cures, dental scalers and excavators —

Part 1: General requirements

1 Scope

This part of ISO 13397 specifies the general material and performance requirements for periodontal cures, 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 cures, 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.



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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 $\times 10$ 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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Annex ZA (normative)**Normative references to international publications with their relevant European publications**

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 1942-3	1989	<i>Dental vocabulary — Part 3: Dental instruments</i>	EN 21942-3	1993

List of references

See national foreword.



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