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Dentistry — Spoons and bone curettes

Médecine bucco-dentaire — Cuillères et curettes à os

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Foreword

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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).

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For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry,* Subcommittee SC 4, *Dental instruments.*

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.

Dentistry — Spoons and bone curettes

1 Scope

This document specifies requirements and test methods for spoons and bone curettes used in dentistry for oral surgical procedures.

It specifies shapes and dimensions as well as information for marking.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1101, *Geometrical product specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out*

ISO 1942, *Dentistry — Vocabulary*

ISO 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

ISO 6508-1, *Metallic materials — Rockwell hardness test — Part 1: Test method*

ISO 7153-1, *Surgical instruments — Materials — Part 1: Metals*

ISO 13504, *Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 21850-1, *Dentistry — Materials for dental instruments — Part 1: Stainless steel*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 13504 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
spoons and bone curettes
hand-guided dental instruments for removing pathologically changed hard and soft tissue in the area of the jawbones

3.2
sharp spoon according to Hemingway
special instrument design of a sharp double-ended spoon having an oval shape of the working end where the spoons have a lateral inverse orientation of 180°

Note 1 to entry: Sharp spoons are used for revision of tooth alveoli and for smoothing of sharp bone parts after extraction of tooth.

3.3
bone curette according to Lucas
special instrument design of a sharp double-ended bone curette having a pear-shaped working end where the working ends have a lateral inverse orientation of 180°

4 Classification

Spoons and bone curettes are classified into the following types according to the width of the working end:

— Type 1: small; S

— Type 2: medium; M

— Type 3: large; L

— Type 4: extra-large; XL

5 Requirements

5.1 Dimensions

The maximum overall length of spoons and bone curettes shall be 173 mm.

The general design of spoons and bone curettes is left to the manufacturer unless a specific design is described in this document.

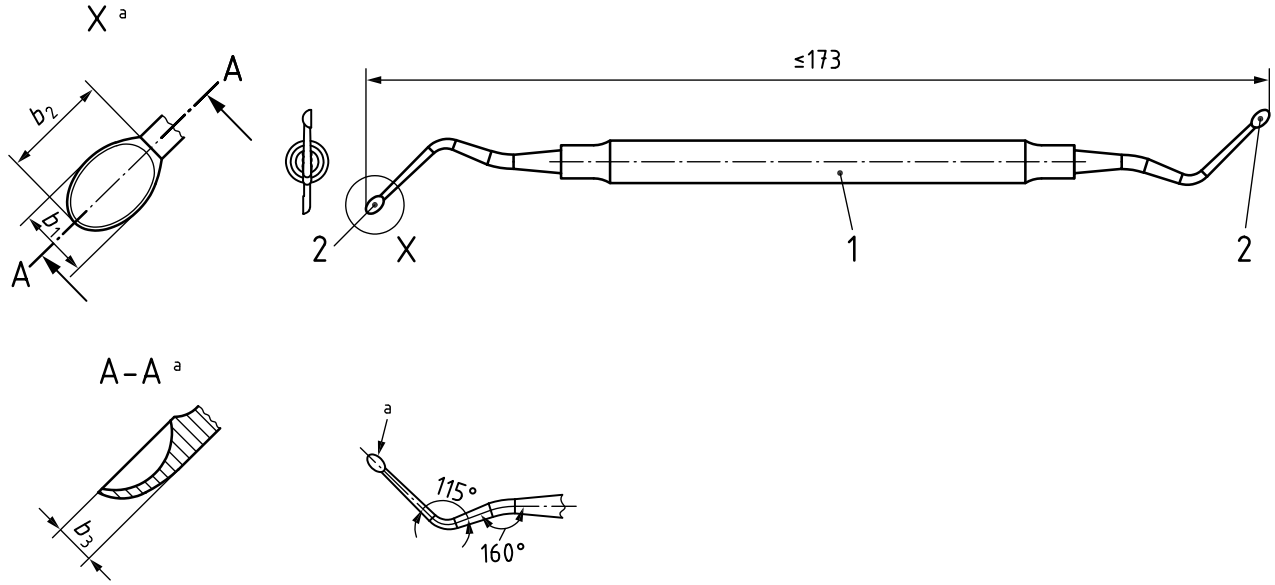
Spoons and bone curette can consist of one part or also from three parts (two inserts and a handle).

Spoons according to Hemingway shall have the dimensions given in Figure 1 and Table 1. The minimum dimension from the tip of the spoon to the first bend shall be 17 mm.

Bone curettes according to Lucas shall have the dimensions given in Figure 2 and Table 2.

Dimensions without tolerances shall be in accordance with ISO 2768-1. Tolerances of form, orientation and location shall be in accordance with ISO 1101, if not specified otherwise in this document.

Dimensions in millimetres

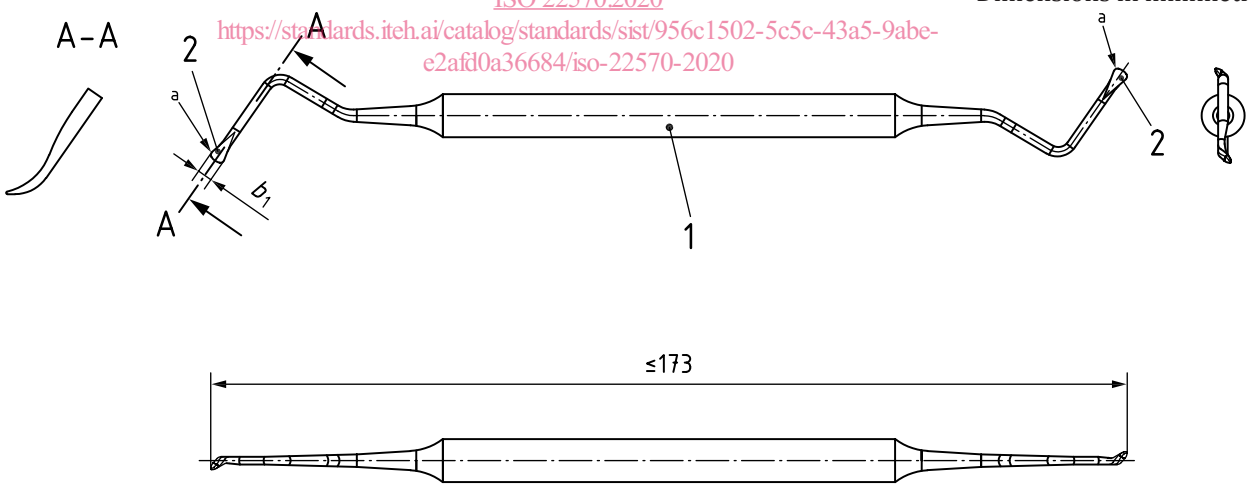


Key

1 handle
2 spoon
a Sharpened.

Figure 1 — Sharp spoons according to Hemingway

Dimensions in millimetres



Key

1 handle
2 curette
a Sharpened.

Figure 2 — Bone curettes according to Lucas

Table 1 — Dimensions for sharp spoons according to Hemingway

Dimensions in millimetres

Designation	Breadth b_1 Tolerance ±0,15	Length b_2 Tolerance ±0,2	Height b_3 Tolerance ±0,2
Type 1: S	2,0	3,5	1,5
Type 2: M	2,5	4,5	2,0
Type 3: L	3,0	5,0	2,2
Type 4: XL	3,5	5,5	2,4

Table 2 — Dimensions for bone curettes according to Lucas

Dimensions in millimetres

Designation	b_1 Tolerance ±0,15
Type 1: S	2,0
Type 2: M	2,5
Type 3: L	3,0
Type 4: XL	3,5

5.2 Materials

The material used for spoons and bone curettes is at the discretion of the manufacturer provided the requirements of this document are satisfied. If stainless steel is used, it shall be in accordance with ISO 7153-1 or ISO 21850-1.

The material of the handle is at the manufacturer's discretion providing it complies with 5.6.

Test in accordance with 6.3.

5.3 Handle

The shape of the handle for spoons and bone curettes is at the manufacturer's discretion.

5.4 Working end

The shape of the working end of a sharp spoon according to Hemmingway shall be oval. See Figure 1.

The shape of the working end of a bone curette according to Lucas shall be pear-shaped. See Figure 2.

The labial surface forms the cutting edge at the transition to the rounded back surface. The cutting edge shall extend at least up to the point of the greatest width (see cross-section A-A in Figure 1 and Figure 2).

The working end shall have a hardness of 42 HRC to 58 HRC.

Test in accordance with ISO 6508-1, Scale C.

Alternatively, a Vickers hardness test in accordance with ISO 6507-1 can be performed. The measured values thus determined shall be converted into Rockwell values.

NOTE ISO 18265:2013, Table 1 contains practical conversion values. 1 HRC is added to the value thus calculated (empirical values with stainless steel).

5.5 Surface finish

The surfaces of the spoons and bone curettes shall be free from defects and residues.

The surface finish of the working ends and the shafts shall be polished. The degree of gloss is at the manufacturer's discretion.

For reasons of hygiene, a surface that facilitates reprocessing of spoons and bone curettes should be selected for the handle surface.

Test in accordance with 6.1.

5.6 Resistance to reprocessing

The spoons and bone curettes shall withstand 100 reprocessing cycles, as defined by the instructions for use accordance with ISO 17664, without deterioration in performance or signs of corrosion.

If the manufacturer states a lower number of permitted reprocessing cycles, then this number shall be used in place of the 100 stated above.

The reprocessing cycle shall include the recommended methods for cleaning, disinfection and sterilization.

Test in accordance with 6.3.

6 Measurement and test methods

6.1 Visual inspection

Carry out visual inspection with normal visual acuity and without magnification.

6.2 Dimensions

Measure the dimensions using a measuring device that is accurate to 1/10 of the tolerance to be measured.

EXAMPLE Suitable measuring devices are Vernier callipers and micrometres in accordance with ISO 3611.

6.3 Resistance to reprocessing

Carry out 100 reprocessing cycles with the spoons and bone curettes, as specified in the instruction for use, in accordance with ISO 17664. The reprocessing cycle shall include the manufacturer's recommended methods of cleaning, disinfection and sterilization.

If the manufacturer has specified a maximum number of cycles less than 100, this number shall be used for the test.

Visually inspect the instrument for any signs of corrosion or distortion. Repeat the hardness test and check that the results are still compliant.

NOTE Discolorations due to water stains are not signs of corrosion.

7 Marking, labelling and instructions for use

7.1 Marking on the instrument

Spoons and bone curettes shall be marked as follows:

a) name of the manufacturer and/or trade name;