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Dentistry — Intraoral spatulas

Médecine bucco-dentaire — Spatules intraorales

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Foreword

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

Dentistry — Intraoral spatulas

1 Scope

This International Standard specifies requirements and their test methods for metallic and non-metallic intraoral spatulas used to introduce and model filling materials into a tooth cavity, including single use disposable items.

NOTE This includes instruments used for placement and contouring of non-metallic direct restorative materials.

It also specifies requirements for their marking and labelling.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

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

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

3 Terms and definitions

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

3.1
intraoral spatula
hand-held dental instrument with a flat blade used to introduce filling materials into tooth cavities and to model the contours of the filling surfaces, which could be made from metallic or non-metallic materials

3.2
non-metallic intraoral spatula
intraoral spatula (3.1) made from plastics or ceramic materials

4 Classification

Spatula blades for intraoral spatulas are classified into the following types depending on their design and material properties (e.g. shape, function, bending):

— Type 1: oval, cutting, rigid;

— Type 2: rectangular, flat, flexible.

5 Requirements

5.1 Dimensions

Metallic intraoral spatulas shall have the dimensions indicated in Figure 1 and Table 1.

The width of the spatula blade, *b*, shall be within a range of 1,4 mm to 3,2 mm.

The minimum thickness of the intraoral spatula blade shall be 0,2 mm.

The degree of taper of the blade will be at the discretion of the manufacturer.

Spatulas with dimensions other than listed are acceptable provided that they meet the functional needs for placement of filling materials.

Test in accordance with 6.2.

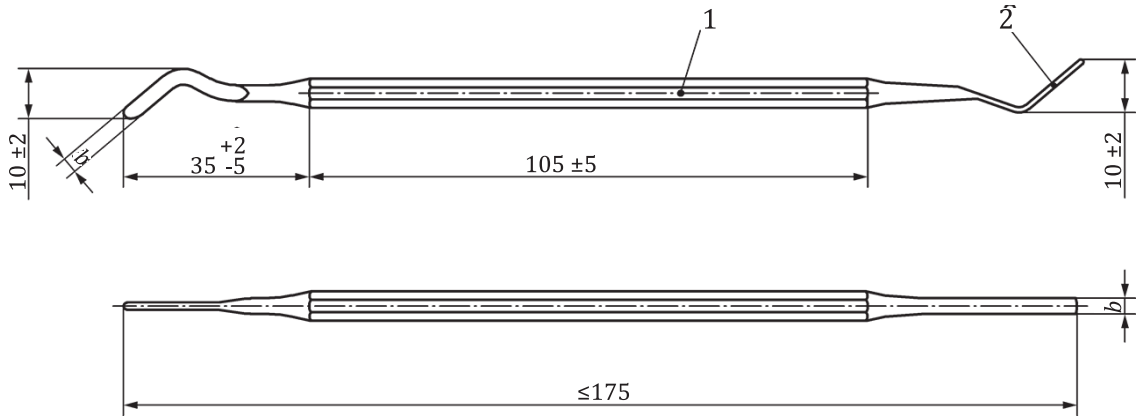
Table 1 — Dimensions for intraoral spatulas

Dimensions in millimetres

Overall length[a] max.	**Handle length** ±5	**Length of spatula blade** ±2	**Length of shaft and spatula blade** + 2 - 5	**Height of spatula blade** ±2
175	105	13,5	35	10

[a] Thus, during reprocessing, the intraoral spatula fits into a dental tray.

Dimensions in millimetres



Key

1 handle area, used for marking

2 spatula blade

Figure 1 — Intraoral spatulas

5.2 Material

Metallic intraoral spatulas shall consist of martensitic and precipitation hardening corrosion-resistant steel with the material numbers 4021-420-00-1 (X20Cr13; 1.4021), 4034-420-00-1 (X46Cr13; 1.4034) or 4040-420-00-1 (X68Cr17, 1.4040).

Examples of additional suitable stainless steels can be found in ISO 7153-1.

Non-metallic materials are at the discretion of the manufacturer.

5.3 Handle

The shape of the handle (e.g. circular, octagonal) is left to the discretion of the manufacturer.

5.4 Spatula blade

The spatula blade shall have a hardness of 42 HRC to 60 HRC or a Vickers hardness of 410 HV 1 to 700 HV 1, respectively.

Test in accordance with ISO 6508-1, scale C, or ISO 6507-1.

5.5 Combination of handle and blade

Removable blades shall be securely fixed to the handle. The extraction force shall be >10 N.

5.6 Surface

The surface and shape of the cross sectional profile is designed at the discretion of the manufacturer.

The surfaces of the intraoral spatula shall be free of defects and residues.

The surfaces of the working ends and of the shafts shall be smooth. No remaining signs of machined surface finish shall be seen.

Coatings may be added to the working tip of metal intraoral spatulas to increase lubricity and provide contrast in the oral cavity.

Test in accordance with 6.1.

5.7 Resistance to reprocessing

The metallic intraoral spatula shall withstand 100 reprocessing cycles, as defined by the manufacturer's instructions, in accordance with ISO 17664 without deterioration in performance or showing signs of corrosion.

Non-metallic intraoral spatulas shall withstand the same reprocessing procedures as metallic intraoral spatulas, unless

a) the intraoral spatula is designated as single-use disposable item, and

b) the manufacturer has specified a maximum number of cycles less than 100; this number shall be used for the test.

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

Test in accordance with 6.3.

6 Test methods

6.1 Visual examination

Perform the visual examination with normal visual acuity and without any magnification.

6.2 Dimensions

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

NOTE Examples of suitable measuring devices are vernier calipers and micrometers in accordance with ISO 3611.

6.3 Test of resistance to reprocessing

Carry out 100 reprocessing cycles with the intraoral spatula, as defined by the manufacturer's instructions, in accordance with ISO 17664.

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

The intraoral spatula shall show no signs of deterioration, distortion or corrosion.

NOTE Discolorations due to water stains are no signs of corrosion.

7 Marking

Intraoral spatulas shall be marked as follows:

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

b) the model number (reference number);

c) the lot number (batch designation).

Bibliography

[1] ISO 3611, *Geometrical product specifications (GPS) — Dimensional measuring equipment: Micrometers for external measurements — Design and metrological characteristics*

[2] ISO 4049, *Dentistry — Polymer-based restorative materials*

[3] ISO 7153-1,[1)] *Surgical instruments — Materials — Part 1: Metals*

1) To be published.

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