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## Dentistry — Intraoral spatulas

*Médecine bucco-dentaire — Spatules intraorales*



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## 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.

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](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.