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**Dentistry — Oral surgical scalpel  
handle**

*Médecine bucco-dentaire — Manche de bistouri pour chirurgie buccale*

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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)).

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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](http://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](http://www.iso.org/members.html).

## Introduction

Oral surgical scalpel handles are dental instruments used in conjunction with detachable blades for oral surgical procedures such as cutting and/or removal of soft oral tissues.

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# Dentistry — Oral surgical scalpel handle

## 1 Scope

This document specifies requirements and their test methods for multiple use of oral surgical scalpel handles used in conjunction with detachable blades for oral surgical procedures such as cutting and/or removal of soft oral tissues.

It also specifies the requirements for marking and labelling of oral surgical scalpel handles.

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

ISO 7740:1985, *Instruments for surgery — Scalpels with detachable blades — Fitting dimensions*

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

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 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 <https://www.electropedia.org/>

### 3.1

#### **oral surgical scalpel handle**

handle of a handheld dental instrument where a detachable blade, which is used for oral surgery, is connected

#### 3.1.1

##### **straight type**

<oral surgical scalpel handle> scalpel handle with no angulation between axis of *fitting feature* (3.3) and handle

Note 1 to entry: See Type 1, [Figure 1](#).

### 3.1.2

#### **angulated type**

<oral surgical scalpel handle> scalpel handle with angulation between axis of *fitting feature* (3.3) and handle where proximal point of fitting feature is connected to shank of scalpel handle

Note 1 to entry: See Type 2, [Figure 2](#).

### 3.1.3

#### **reverse angled type**

<oral surgical scalpel handle> scalpel handle with offset angulation between axis of *fitting feature* (3.3) and handle where distal point of fitting feature is connected to shank of scalpel handle

Note 1 to entry: See Type 3, [Figure 3](#).

### 3.2

#### **working end**

part of the oral surgical scalpel handle consisting of a *fitting feature* (3.3) and a shank connected to the handle

### 3.3

#### **fitting feature**

most frontal area of the instrument on which the detachable blade is fitted

#### 3.3.1

##### **proximal point**

point farthest from the cutting edge of the blade

#### 3.3.2

##### **distal point**

point closest to the cutting edge of the blade

### 3.4

#### **shank**

part of the *working end* (3.2) that connects the *fitting feature* (3.3) to the handle

### 3.5

#### **handle**

area used for holding the instrument during operation

## 4 Classification

For the purposes of this document, scalpel handles are classified according to the shape of the scalpel into the following three types:

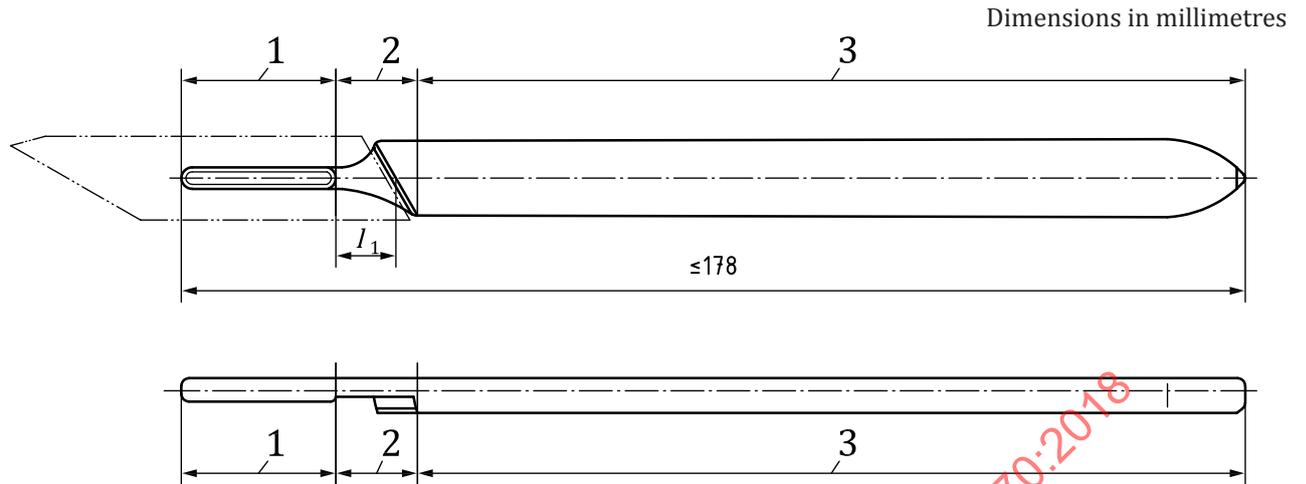
- Type 1: Straight type;
- Type 2: Angled type;
- Type 3: Reverse angled type.

## 5 Requirements

### 5.1 Shape

The shape of the connection between the shank and the handle for each type of the scalpel handle is left to the discretion of the manufacturer.

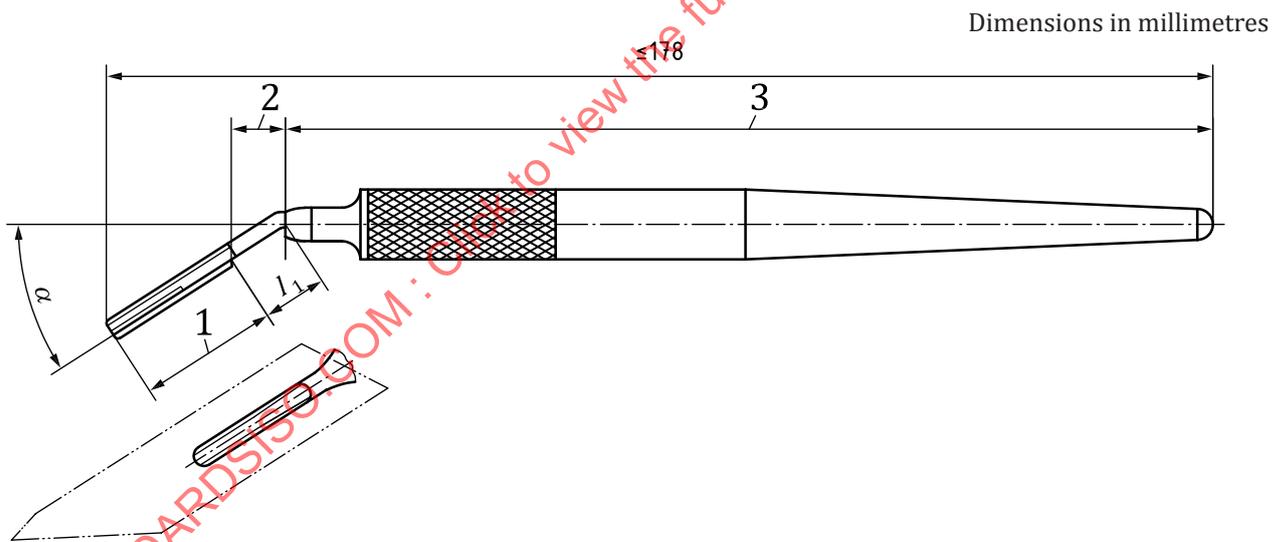
Examples of scalpel handles are shown in [Figure 1](#), [Figure 2](#) and [Figure 3](#).



**Key**

- 1 fitting feature
- 2 shank
- 3 handle

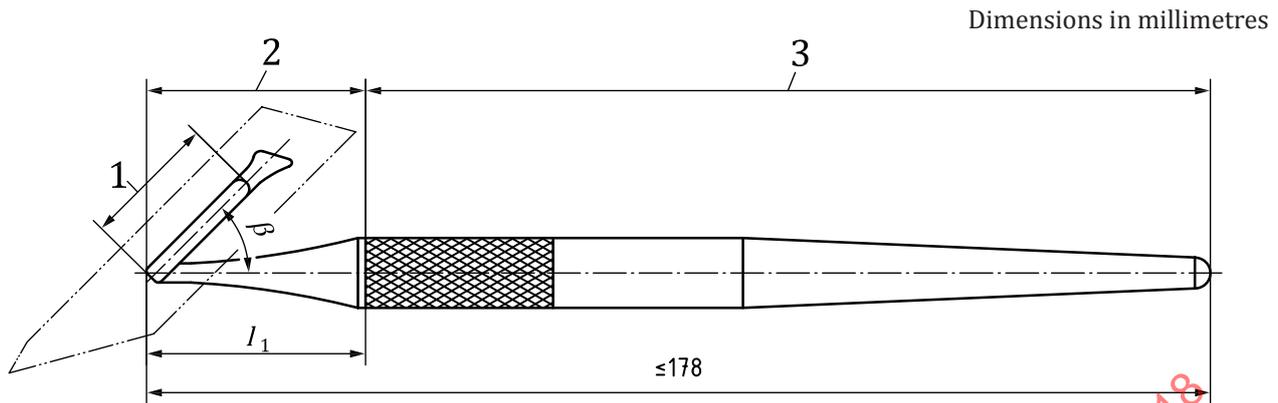
**Figure 1 — Type 1: Straight oral surgical scalpel handle**



**Key**

- 1 fitting feature
- 2 shank
- 3 handle
- $\alpha$  angle between midline of handle and midline of shank/fitting feature

**Figure 2 — Type 2: Angled oral surgical scalpel handle**



**Key**

- 1 fitting feature
- 2 shank
- 3 handle
- $\beta$  angle between midline of handle/shank and midline of fitting feature

**Figure 3 — Type 3: Reverse angled oral surgical scalpel handle**

**5.2 Dimensions**

**5.2.1 Maximum overall length**

The maximum overall length of the instrument shall be 178 mm.

**5.2.2 Dimensions of fitting feature**

The dimensions of fitting feature of the scalpel handle shall be in accordance with the ISO 7740:1985, 2.1 when tested according to 5.1.

**5.2.3 Dimensions of the shank**

The length of the shank for Type 1 straight scalpel handle shall be in accordance with ISO 7740:1985, 2.1 when tested according to 6.1.

The length of the shank for Type 2 angled scalpel handle shall be greater than 4,50 mm when tested according to 6.1.

The length of the shank for Type 3 reverse angled scalpel handle shall be greater than  $22,31 \cos \beta$ .

**5.2.4 Angle between the handle and the working tip**

The angle  $\alpha$  in Figure 2 shall be greater than  $0^\circ$  but less than or equal to  $90^\circ$ . The angle  $\beta$  in Figure 3 shall be greater than or equal to  $20^\circ$  but less than or equal to  $90^\circ$ .

**5.3 Materials**

The materials of the scalpel handles shall be in accordance with ISO 7153-1.

**5.4 Surface finish**

The surfaces of the instruments shall be free of visible surface defects when tested according to 6.2.

## 5.5 Resistance to reprocessing

There shall be no visible signs of deterioration when tested in accordance with 6.3.

## 5.6 Hardness

The hardness of the scalpel handles shall be equal or greater than 220 HV1 or 16 HRC.

Test in accordance with 6.4.

## 5.7 Security of attachment

There shall be no axial, lateral or rotational movement of the blade when it is attached to the handle.

Test in accordance with 6.5.

# 6 Measurement and test methods

## 6.1 Measurement of dimensions

Measuring devices with the appropriate accuracy shall be used for measurements of dimensions.

Carry out measurements without the detachable scalpel blade in place.

## 6.2 Test on surface finish

Perform visual examination with normal visual acuity without any magnification.

## 6.3 Test on resistance to reprocessing

Carry out 100 reprocessing cycles as specified in the manufacturer's instructions. If the manufacturer defines the maximum number of reprocessing cycles less than 100, this number shall be used. Inspect the surfaces in accordance with 5.2 for signs of rust, pitting or any other surface defects.

## 6.4 Hardness test

Test the Vickers hardness and Rockwell hardness in accordance with ISO 6507-1 and ISO 6508-1, Class C, respectively

## 6.5 Security of attachment

Secure the blade to the handle. Clamp blade and apply moderate lateral, axial and rotational finger pressure to the handle. Visually observe for any signs of movement.

# 7 Marking, labelling and instructions for use

## 7.1 Marking on the scalpel handle

Each scalpel handle shall be permanently marked with the following information:

— name of manufacturer and/or brand name.