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Dentistry — Oral surgical scalpel handle

Médecine bucco-dentaire — Manche de bistouri pour chirurgie buccale

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Foreword

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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.

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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.

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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.

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