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Dentistry — Tissue punches

Médecine bucco-dentaire — Bistouris circulaires

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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).

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).

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

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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.

Introduction

Tissue punches are dental implant instruments used in conjunction with angled dental handpieces for surgical dental implant procedures such as cutting holes or notches in and removing of gingival tissue.

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Dentistry — Tissue punches

1 Scope

This document specifies requirements and their test methods for tissue punches used with a handpiece in dentistry especially for oral surgical implant procedures, such as cutting holes or notches in and removing of gingival tissue. It also specifies the requirements for their marking and labelling.

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 1797, *Dentistry — Shanks for rotary and oscillating instruments*

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 8325:2004, *Dentistry — Test methods for rotary instruments*

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

ISO 16443, *Dentistry — Vocabulary for dental implants systems and related procedure*

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 1797, ISO 1942, ISO 16443 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

tissue punch

instrument for removal of a disk of soft tissue

[SOURCE: ISO 16443:2014, 3.3.8]

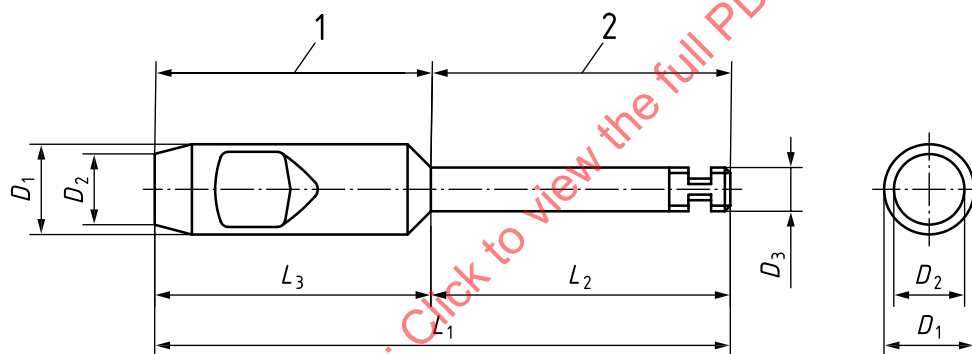
4 Symbols

D_1	outer diameter of working part
D_2	inner diameter of working part
D_3	diameter of shank
L_1	overall length
L_2	length of shank
L_3	length of working part

5 Classification

For the purpose of this document, tissue punches shall be classified according to the purposes of use into following types:

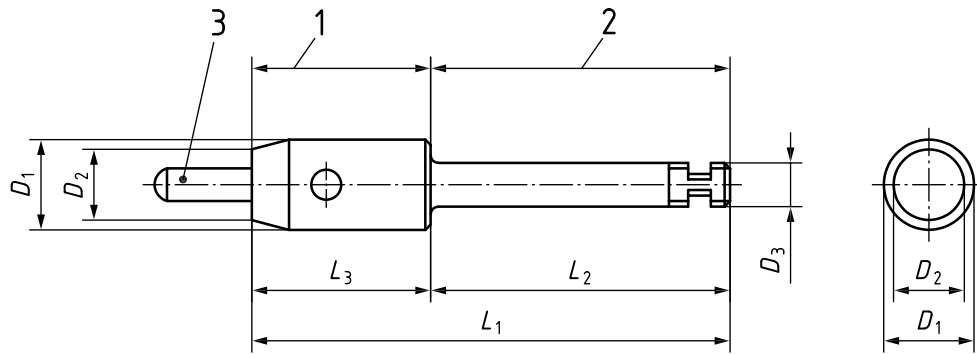
- Type 1: hollow (see [Figure 1](#))
- Type 2: centre-guided (see [Figure 2](#))



Key

- 1 working part
- 2 shank

Figure 1 — Tissue punch type 1: Hollow

**Key**

- 1 working part
- 2 shank
- 3 centre-guide

Figure 2 — Tissue punch type 2: Centre-guided**6 Requirements****6.1 Selection of metals**

The metals of the tissue punch shall be in accordance with ISO 21850-1.

6.2 Surface finish

Surface treatment shall be left to the discretion of the manufacturer. The surfaces of the tissue punch shall be free of visible surface defects when tested in accordance with 7.1.

6.3 Dimensions**6.3.1 Diameter of the working part and centre-guide**

Inner diameter of the working part (D_2) shall be specified, and shall be within $\pm 0,1$ mm of the manufacturer's stated value when measured in accordance with 7.2.

For type 2, the diameter of centre-guide shall be specified, and shall be within $\pm 0,1$ mm of the manufacturer's stated value when measured in accordance with 7.2.

6.3.2 Length of the working part

The length of the working part shall be within $\pm 0,5$ mm of the manufacturer's stated value when measured in accordance with 7.2.

6.3.3 Overall length

The maximum overall length shall be left to the discretion of the manufacturers.

6.3.4 Dimensions of the shank

The dimensions of the shank shall be in accordance with ISO 1797 when measured in accordance with 7.2.