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Dentistry — Tissue punches

Médecine bucco-dentaire — Bistouris circulaires

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Foreword

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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).

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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.

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.

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

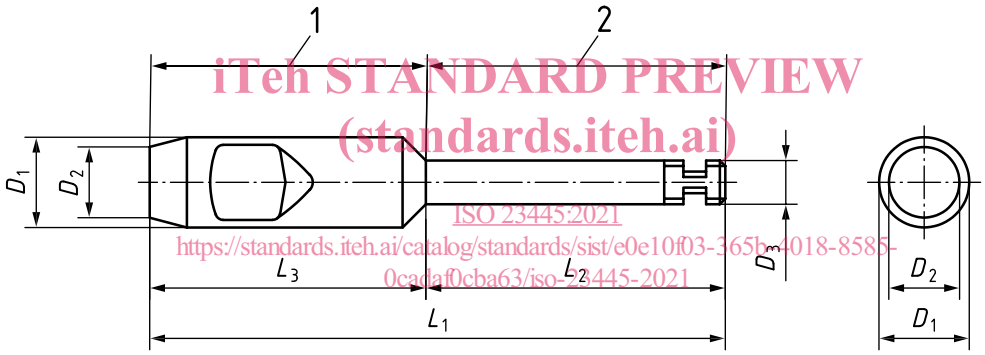
L_3 length of working part

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)

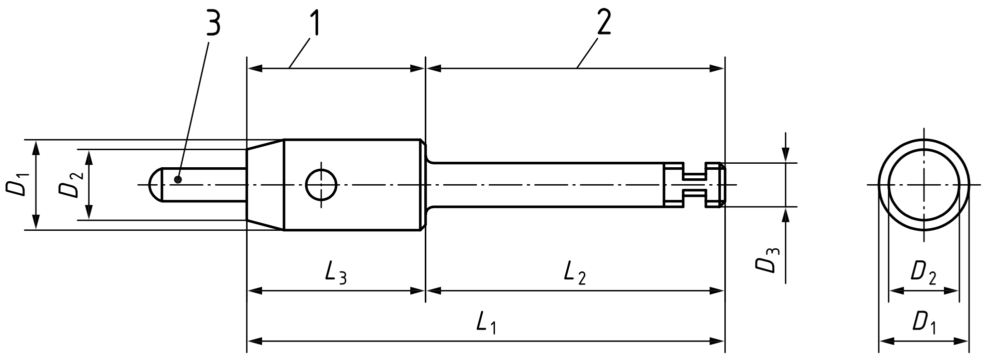


Key

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 ±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 ±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 ±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.

6.4 Resistance to reprocessing

There shall be no signs of deterioration in performance or corrosion when tested in accordance with 7.3.

6.5 Hardness

The hardness of the tissue punch shall be equal or greater than 400 HV2 or 41 HRC when tested with 7.4.

6.6 Run-out

The total indicated run-out shall not exceed 0,1 mm, when tested in accordance of 7.5.

7 Measurement and test methods

7.1 Visual inspection

Perform visual examination with normal visual acuity without any magnification.

7.2 Dimensions

Measure the dimensions in accordance with ISO 8325:2004, 4.1 to 4.3, and 5.1, 5.2, 5.4, 5.5 and 5.6, as appropriate. The manufacturer shall validate that the accuracy of the measuring device is applicable. The accuracy of measurement device shall be 1/10 of the required tolerance.

7.3 Resistance to reprocessing

Carry out 100 reprocessing cycles as specified in the manufacturer's instructions. The reprocessing cycle shall include the manufacturer's recommended methods for cleaning, disinfection and sterilization in accordance with ISO 17664.

If the manufacturer defines the maximum number of reprocessing cycles less than 100, this number shall be used.

Assess visually for any signs of deterioration of the surface, e.g. signs of rust, pitting or any other surface defects, including marking. Repeat the tests for 6.5 and 6.6.

Inspect the surfaces in accordance with 7.1.

7.4 Hardness

Test the hardness in accordance with either ISO 6507-1 or ISO 6508-1.

7.5 Run-out

Determine the run-out by guiding the shank of the instrument, placing a comparator at 1 mm from the tip of the working part and rotating it over 360°. The shank shall be supported at least by 10 mm. Record the minimum and maximum value. The difference of both extrema is defined as the runout.