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Dentistry — Trephine burs

Médecine bucco-dentaire — Fraises-trépans

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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.

Introduction

Dental trephine burs are dental instruments used in dental implantology.

Dentistry — Trephine burs

1 Scope

This document specifies requirements and their test methods for trephine burs used in dentistry especially for oral implantology procedures such as collecting bone and/or removing an implant. It also specifies 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 7153-1, *Surgical instruments — Materials — Part 1: Metals*

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*

3 Terms, definitions and symbols

3.1 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 https://www.electropedia.org/

3.1.1
trephine bur
rotary instrument used together with a handpiece in oral implantology procedures such as preparing and collecting bone cores or removing implants

3.2 Symbols

D_1 outer diameter of working part

D_2 inner diameter of working part

D_3 diameter of shank

D_4 diameter of the operative part

L_1 overall length

L_2 length of shank

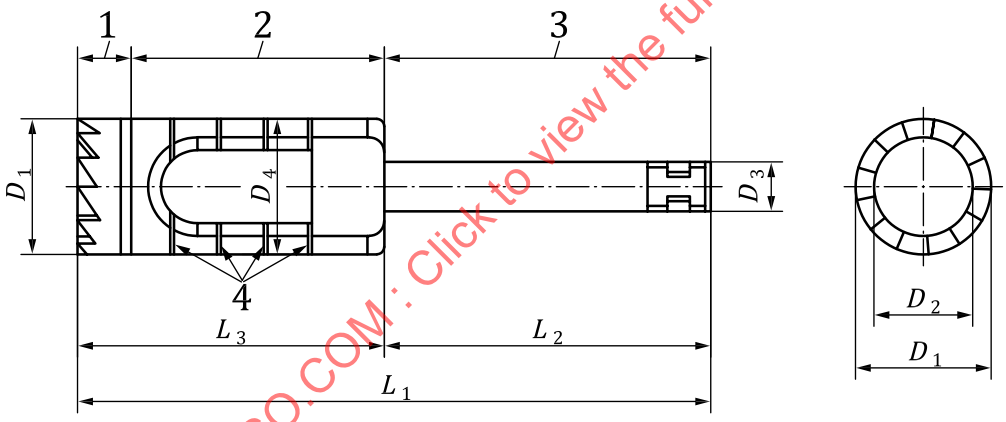
L_3 length of operative part

4 Classifications

For the purposes of this document, trephine burs shall be classified according to the purposes of use into the following types:

— Type 1: for bone collection (Figure 1);

— Type 2: for implant removal (Figure 2).



Key

1 working part with teeth

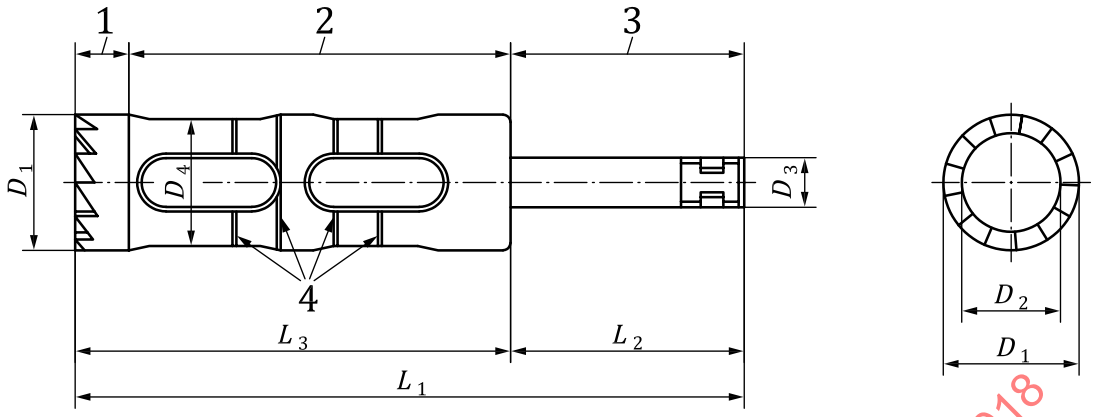
2 operative part

3 shank

4 marking lines

The design and number of lateral openings are left to the discretion of the manufacturer. They should be designed in such a way not to decrease the resistance nor the performance of the trephine bur.

Figure 1 — Trephine burs Type 1 for bone collection



Key

1 working part with teeth
2 operative part
3 shank
4 marking lines

The design and number of lateral openings are left to the discretion of the manufacturer. They should be designed in such a way not to decrease the resistance nor the performance of the trephine bur.

Figure 2 — Trephine bur Type 2 for implant removal

5 Requirements

5.1 Selection of metals

The metals of the trephine bur shall be in accordance with ISO 7153-1 and ISO 13504.

5.2 Surface finish

Surface treatment shall be left to the discretion of the manufacturer. The surfaces of the trephine bur shall be free of visible surface defects when tested in accordance with 6.1.

5.3 Dimensions

5.3.1 Number of teeth

The number of teeth shall be left to the discretion of the manufacturer.

5.3.2 Diameter of the working part and wall thickness

Outer diameter of the working part (D_1) shall be specified for Type 1, where it shall be between 2 mm to 16 mm.

Inner diameter of the working part (D_2) shall be specified for Type 2, where it shall be between 2 mm to 15 mm.

Values shall be within ±0,05 mm of manufacturer's stated value when measured in accordance with 6.2.

For both Type 1 and Type 2, diameter of working part (D_1) shall be greater than the diameter of operative part (D_4). For Type 1, working part shall be tapered to match the diameter of operative part (D_4).

The wall thickness of the trephine bur is left to the discretion of the manufacturer, but shall be designed to withstand a torque of 80 Ncm, tested in accordance with 6.6.

5.3.3 Length of the operative part

The length of the operative part for Type 2 is left to the discretion of the manufacturer but shall be designed in such a way to allow a safe removal of the implant. The minimum operative length shall be marked onto the bur as a digit on a marking line.

The length of the working part shall be within ±0,5 mm of manufacturer's stated value when measured in accordance with 6.2.

5.3.4 Overall length

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

5.3.5 Dimensions of the shank

The dimensions of the shank shall be in accordance with ISO 1797 when measured in accordance with 6.2.

5.4 Marking lines on the operative part

5.4.1 General

Marking lines shall be marked from the tip of the working part at intervals, in order to indicate the depth of introduction of the trephine bur into osseous tissue. The length from the working tip to the marking line shall be measured in accordance with 6.2. It shall be within ±0,1 mm of the manufacturer's stated dimensions, measuring from the tip of working part to one of the two marking lines, whichever nearer to the tip.

5.4.2 Thickness of scale line

The fine scale line or markings used in single dimension shall be visible without magnification.

5.5 Resistance to reprocessing

There shall be no signs of deterioration in performance or corrosion when tested in accordance with 6.3.

5.6 Vickers hardness

The hardness of the trephine bur shall be equal or greater than 500 HV2 when tested in accordance with 6.4.

5.7 Run-out

The total indicated run-out shall not exceed 0,1 mm as indicated by Figure 3.

Dimensions in millimetres

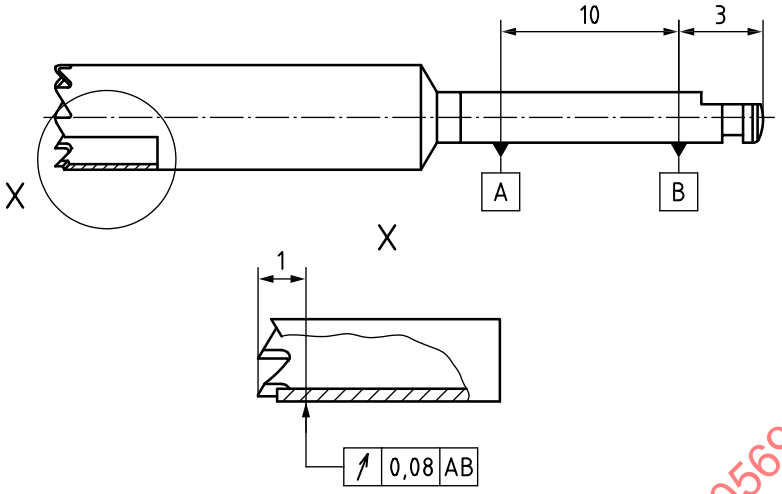


Figure 3 — Location of run-out test on trephine bur

Testing shall be carried out in accordance with 6.5.

5.8 Resistance to torque

The instrument shall not fracture or exhibit any sign of deformation under a torque of 80 Ncm when tested in accordance with 6.6.

Testing shall be carried out after the reprocessing and in accordance with 6.6.

6 Measurement and test methods

6.1 Visual inspection

Perform visual examination with normal visual acuity without any magnification.

6.2 Dimensions and number of teeth

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.

Determine the number of teeth by visual inspection.

6.3 Resistance to reprocessing

Carry out 10 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 a maximum number of reprocessing cycles less than 10, 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 5.6, 5.7 and 5.8.

Inspect the surfaces in accordance with 6.1.