
Dentistry — Trephine burs

Médecine bucco-dentaire — Fraises-trépan

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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).

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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*.

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.

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Dentistry — Trepine 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

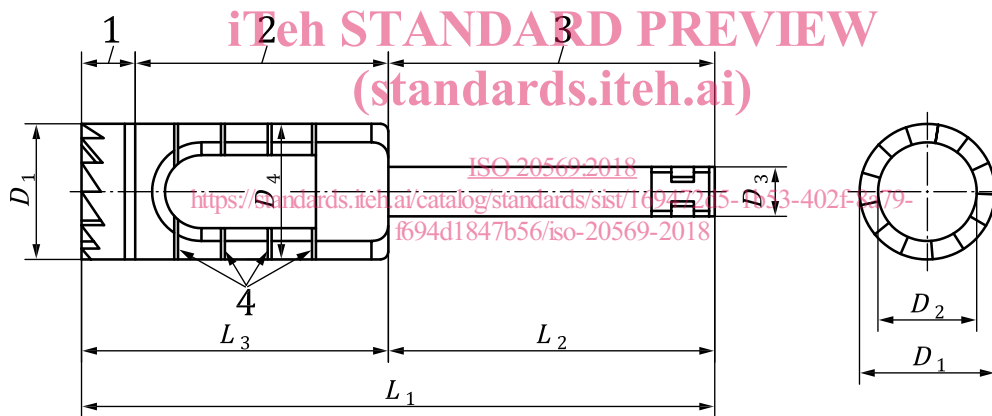
3.2 Symbols

- 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).

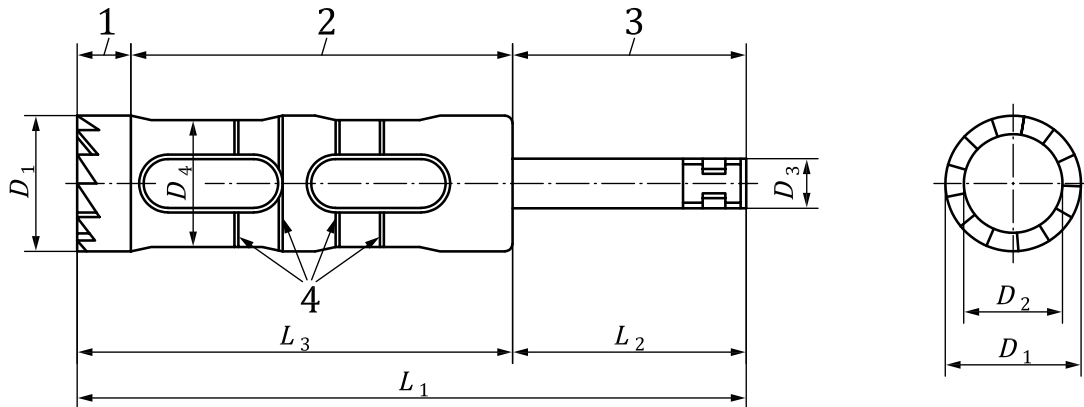


Key

- 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

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5 Requirements [\(standards.iteh.ai\)](https://standards.iteh.ai)

5.1 Selection of metals [ISO 20569:2018](https://standards.iteh.ai)

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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 $\pm 0,05$ 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](#).