INTERNATIONAL STANDARD

ISO 23445

> First edition 2021-04

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Reference number ISO 23445:2021(E)



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Published in Switzerland

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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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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

aes are atal impla. 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.

This document is a previous general ded by tills

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]

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