



SLOVENSKI STANDARD
oSIST prEN ISO 24466:2022
01-april-2022

Zobozdravstvo - Označevanje delov in dimenzij telesa implantata ali enodelnega implantata (ISO/DIS 24466:2022)

Dentistry - Designations for the parts and dimensions of an implant body or a monopart implant (ISO/DIS 24466:2022)

Zahnheilkunde – Bezeichnungen für die Teile und Maße eines Implantatkörpers (ISO/DIS 24466:2022)

Médecine bucco-dentaire - Désignations pour les parts et les mesures des corps d'implant (ISO/DIS 24466:2022)

Ta slovenski standard je istoveten z: prEN ISO 24466

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ICS:

11.060.15 Zobni implantati Dental implants

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DRAFT INTERNATIONAL STANDARD

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Dentistry — Designations for the parts and dimensions of an implant body or a monopart implant

Médecine bucco-dentaire — Désignations pour les parts et les mesures des corps d'implant

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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 8, *Dental implants*.

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.

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Introduction

The terms and designations used by the manufacturers of dental implants for the individual system parts are not uniform.

As a first step all manufacturers of dental implants should use ISO 16443 in order to designate system parts in a uniform manner.

This document was developed to clarify the remaining issues for the application of these designations.

Specific labelling instructions are given by national regulations.

General international labelling specifications for medical devices (including dental implants) are given by the following documents:

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 20417, *Medical devices — Information to be provided by the manufacturer*

However, no international information on the clinician's specific labelling requirements is available. This information is given in several professional guidelines, which are sometimes contradictory.

This document specifies the general labelling information required by the clinician for the selection of a suitable dental implant for the surgical procedure.

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Dentistry — Designations for the parts and dimensions of an implant body or a monopart implant

1 Scope

This document designates the terms for the parts of an implant body or a monopart implant that are used in oral implantology as well as determination of the dimensions and their data on the packaging of a dental implant.

General terms and dimensions, two for diameters (bone diameter, platform diameter) and four for lengths (implanted length, total length, outmost length, transmucosal length), are shown and explained in examples.

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 1942, *Dentistry — Vocabulary*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in 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

bone diameter

d

largest diameter of implant body that is intended for insertion into the bone

Note 1 to entry: This includes the retention elements (e.g. outer thread flanks).

3.2

bone level implant

dental implant intended for insertion into bone so that its occlusal end is level with the surface of the adjacent crestal bone

3.3

conical implant

dental implant with a conical implanted length and having a largest and a smallest diameter

3.4

implant apex

apical end of implant body

ISO/DIS 24466:2022(E)**3.5****internal threaded connection**

internal implant connection for a screw intended to secure the seated abutment or primary prosthetic component in position

3.6

length

3.6.1**implanted length**

l

length of implant body that is intended for insertion into the bone

3.6.2

overall length

L_o

<monopart implant> complete length of dental implant including implanted length, transmucosal length, abutment length and prosthesis retention area (if present)

3.6.3**total length**

L

largest length of implant body and transmucosal length

3.6.4**transmucosal length**

largest length of transmucosal area

3.7**platform diameter**

D

largest diameter of implant connective platform

3.8**retention area**

portion of the tissue interface surface of a dental implant which is intended to come into contact with bone

Note 1 to entry: The retention area is often similar to a thread.

3.9**tissue level implant**

dental implant with a retention area and a transmucosal area

3.10**transmucosal area**

area of dental implant body or monopart dental implant that is intended for contact with soft tissues

4 Multipart implant**4.1 Multipart implant with internal connection**

The designations of the parts of an implant body with an internal connection for a multipart implant are shown in [Figure 1](#) and [Figure 2](#). There are many techniques for connecting the implant abutment and body:

- a) threaded,
- b) friction fit;