# INTERNATIONAL STANDARD

ISO 16443

NORME INTERNATIONALE

First edition Première édition 2014-07-15

# Dentistry — Vocabulary for dental implants systems and related procedure

Médecine bucco-dentaire — Vocabulaire des systèmes d'implants dentaires et procédures associées

# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 16443:2014 https://standards.iteh.ai/catalog/standards/sist/e5b21e01-96a2-4562-bb84



# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 16443:2014
https://standards.iteh.ai/catalog/standards/sist/e5b21e01-96a2-4562-bb84-b36905241d20/iso-16443-2014



# COPYRIGHT PROTECTED DOCUMENT DOCUMENT PROTÉGÉ PAR COPYRIGHT

© ISO 2014

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie, l'affichage sur l'internet ou sur un Intranet, sans autorisation écrite préalable. Les demandes d'autorisation peuvent être adressées à l'ISO à l'adresse ci-après ou au comité membre de l'ISO dans le pays du demandeur.

ISO copyright office Case postale 56 • CH-1211 Geneva 20 Tel. + 41 22 749 01 11 Fax + 41 22 749 09 47 E-mail copyright@iso.org Web www.iso.org

Published in Switzerland/Publié en Suisse

Cor	itent	ts	Page
Fore	word		iv
Intro	ductio	on	v
1	Scor	pe	1
2	Normative references		1
3		ns and definitions related on medical devices used in oral implantology  Dental implant  Dental implant system  Ancillary devices used in oral implantology	
4	Terms and definitions related to clinical and surgical concepts used in oral implantology. 8		
Bibli	ograp	hy	12

# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 16443:2014
https://standards.iteh.ai/catalog/standards/sist/e5b21e01-96a2-4562-bb84-b36905241d20/iso-16443-2014

# **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. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 3, *Terminology*.

ISO is now publishing all its standards using a processing system that allows the production of International Standards as XML files. With this new system, the terms and definitions from terminologies and vocabularies are stored in the Online Browsing Platform (OBP) (www.iso.org/obp) where they can be browsed free of charge by members of the public (but not downloaded).

# Introduction

This terminology international standard has been prepared and is presented accordingly with recommendations provided in

ISO 704, Terminology work — Principles and methods,

ISO 860, Terminology work — Harmonization of concepts and terms,

ISO 1087-1, Terminology work — Vocabulary — Part 1: Theory and application, and

ISO 10241-1, Terminological entries in standards — Part 1: General requirements and examples of presentation.

Accordingly to ISO directives, ISO 704 and ISO 1087, this standard has been prepared and is presented in a systematic approach. The systematic approach presents the advantage of being independent from language, therefore allowing the same logical numbering in any language.

# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 16443:2014
https://standards.iteh.ai/catalog/standards/sist/e5b21e01-96a2-4562-bb84-b36905241d20/iso-16443-2014

# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 16443:2014
https://standards.iteh.ai/catalog/standards/sist/e5b21e01-96a2-4562-bb84-b36905241d20/iso-16443-2014

# Dentistry — Vocabulary for dental implants systems and related procedure

# 1 Scope

This International Standard specifies terms and definitions for dental implants and for instruments, accessories, and the most commonly used clinical terms related to implant systems and procedures in dentistry. Grafting materials and membranes are excluded from this International Standard.

The following devices are also excluded from the scope of this International Standard.

Device specially designed to be placed within, through or upon the bones of the cranio-facial complex, the primary purpose of which is to provide anchorage for an epithesis (to replace for example: ears, noses and parts of eyes and orbital regions):

- epithesis implant;
- craniofacial implant;
- maxillofacial implant.

Device specially designed to be placed within, through or upon the bones of the cranio-facial complex, the primary purpose of which is to provide anchorage for an orthodontic appliance:

orthodontic implant<sup>1)</sup>.

# 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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

NOTE Except for the following terminological entries that supersede ISO 1942:2009, the terms and definitions given in ISO 1942 apply for the purpose of this document.

# 3 Terms and definitions related on medical devices used in oral implantology

For the purposes of this document, the following terms and definitions apply.

# 3.1 Dental implant

#### 3.1.1

# dental implant

device especially designed to be placed within, through or upon the bones of the cranio-facial complex, the primary purposes of which are to support and/or to resist displacement of a dental prosthesis

#### 3.1.1.1

# endosseous dental implant

endosteal implant (DEPRECATED)

dental implant (3.1.1) placed partially or entirely within the bone

<sup>1)</sup> This definition supersedes the one given in ISO 1942.

#### 3.1.1.2

#### interim endosseous dental implant

provisional implant

endosseous dental implant (3.1.1.1) for temporary usage

#### 3.1.1.3

#### transendodontic implant

# endodontic endosseous implant

transradicular implant (DEPRECATED)

rod, specially made to be inserted longitudinally either through a root canal or through a root segment which extends through the apex into the surrounding bone to stabilize a tooth

#### 3.1.1.4

# intramucosal implant

#### oral mucosal insert

submucosal implant (DEPRECATED)

button implant (DEPRECATED)

dental implant (3.1.1) placed in the soft tissue lining of the oral cavity

#### 3.1.1.5

#### ramus endosseous implant

ramus endosteal implant (DEPRECATED)

dental implant (3.1.1) placed within the ramus of the mandible

#### 3.1.1.6

# frame implant

ramus frame endosteal implant (DEPRECATED)

One-piece implant consisting of a number of mandibular subperiosteal and/or endosseous components linked with an intra-oral structure

#### 3.1.1.7

#### subperiosteal dental implant

subperiosteal implant abutment (DEPRECATED)

dental implant (3.1.1) that is placed beneath the periosteum and overlying the bony cortex

# 3.1.1.8

# transmandibular implant

dental implant (3.1.1) consisting of a plate and posts designed so that the posts can be placed to extend vertically from the inferior border of the mandible through the plate, bone and mucosa and into the oral cavity in the anterior region

# 3.1.1.9

## zvgoma implant

dental implant (3.1.1) intended to be partially inserted into or on the zygomatic bone

# 3.2 Dental implant system

#### 3.2.1

#### dental implant system

implant kit

implant system

integrated system of components, specific equipment and ancillary instruments necessary for the clinical and laboratory procedures required for the placement of the *dental implant* (3.1.1) and the construction and insertion of an implant-supported dental prosthesis

#### 3.2.2

#### implant component

element of a dental implant system (3.2.1)

#### 3.2.3

# dental implant assembly

assembly of dental *implant components* (3.2.2) as recommended by the manufacturer(s) to serve the purposes of a *dental implant* (3.1.1)

#### 3.2.4

## implant body

dental implant body

implant fixture (DEPRECATED)

endosteal implant body (DEPRECATED)

primary single component or portion of a *dental implant* (3.1.1) which is intended to remain within the hard and soft tissues and can be totally or partially submerged by soft tissue

#### 3.2.4.1

## implant body endosseous zone

portion of the *implant body* (3.2.4) which is intended for intra-bone positioning

#### 3.2.5

#### transmucosal component

part of a dental implant system (3.2.1) that passes through the mucosa

#### 3.2.6

#### tissue interface surface

# implant contact surface

surface of an *implant body* (3.2.4) or *implant component* (3.2.2) intended to contact the patient's tissues

#### 3.2.7

# tissue interface surface treatment

modification of a dental *implant component* (3.2.2) surface by subtraction or addition of material

#### 3.2.7.1

#### implant component coating

implant component (3.2.2) surface treatment by addition 65b21e01-96a2-4562-bb84-

#### 3.2.8

#### connecting interface

# implant connective platform

portion of a dental *implant body* (3.2.4) or *implant component* (3.2.2) intended to connect with another *implant component* (3.2.2)

#### 3.2.8.1

#### platform switching design

connecting interface (3.2.8) designed to allow the use of *implant abutments* (3.2.10) with diameters less than that of the *implant body* (3.2.4)

#### 3.2.9

# anti-rotation feature

design of the *connecting interface* (3.2.8), that prevents rotation of the connected *implant component* (3.2.2) around the central long axis of the *implant body* (3.2.4)

#### 3.2.9.1

#### external anti-rotation feature

anti-rotation feature (3.2.9) extending outside the implant body (3.2.4)

#### 3.2.9.2

#### internal anti-rotation feature

anti-rotation feature (3.2.9) shaped within the implant body (3.2.4)

# ISO 16443:2014(E/F)

#### 3.2.10

#### implant abutment

*implant component* (3.2.2) connected to the *implant body* (3.2.4) or *implant connecting part* (3.2.11), which serves as an abutment

#### 3.2.10.1

## straight implant abutment

# non-angulated implant abutment

#### non-angled implant abutment

*implant abutment* (3.2.10) having central long axis coincident with that of the *implant body* (3.2.4)

#### 3.2.10.2

#### angulated implant abutment

#### angled abutment

*implant abutment* (3.2.10) having a principal long axis divergent from the central long axis of the *implant body* (3.2.4)

#### 3.2.10.3

#### castable implant abutment

castable abutment

prefabricated *implant abutment* (3.2.10) intended to be customized and used for casting

#### 3.2.10.4

# partially castable implant abutment

partially castable abutment

UCLA abutment (DEPRECATED)

prefabricated *implant abutment* (3.2.10) intended to be customized and cast except for the *connecting interface* (3.2.8)

### 3.2.10.5

#### preparable abutment

milling abutment

*implant abutment* (3.2.10) intended to be customized in its shape or form by a milling process

#### 3.2.10.6

#### **CAD/CAM abutment**

patient specific *implant abutment* (3.2.10) designed and fabricated using the CAD/CAM process

#### 3.2.10.7

# implant ball abutment

ball abutment

implant abutment that serves as a prosthetic attachment

#### 3.2.10.8

#### implant magnetic abutment

magnetic abutment

implant abutment (3.2.10) that serves as a magnetic prosthetic attachment

#### 3.2.11

## implant connecting part

dental implant connecting part

implant component (3.2.2) used between the implant body (3.2.4) and the implant abutment (3.2.10)

#### 3.2.12

### monopart implant

monotype implant

one-piece implant

1-piece implant

endosseous dental implant (3.1.1.1) made in one piece that consists of the implant body (3.2.4) part and an implant abutment (3.2.10)

#### 3.2.13

#### two part implant

two piece implant

2-piece implant

endosseous dental implant (3.1.1.1) consisting of an implant body (3.2.4) to which is connected an implant abutment (3.2.10) or a dental prosthesis

#### 3.2.14

### multi-part implant

two parts implant (3.2.13) with the addition of one or more implant connecting parts (3.2.11)

#### 3 2 15

#### implant cover screw

cover screw

*implant component* (3.2.2) used in phase one or placement surgery to prevent tissue growth within the *connecting interface* (3.2.8) of an *implant body* (3.2.4)

#### 3.2.16

#### transmucosal healing component

transmucosal forming component

implant healing abutment

*implant component* (3.2.2) that projects into the oral cavity and is used for a limited time to guide healing of the surrounding soft tissues

#### 3.2.17

# abutment screw Ch STANDARD PREVIEW

centre screw (DEPRECATED)

implant component (3.2.2) used to attach an implant abutment (3.2.10) to an implant body (3.2.4)

#### 3.2.18

#### prosthetic screw

ISO 16443:2014

horizontal screw

occlusal screw standards.iteh.ai/catalog/standards/sist/e5b21e01-96a2-4562-bb84

*implant component* (3.2.2) screw which fixes the *implant superstructure* (4.23.1) to the *implant body* (3.2.4), *implant connecting part* (3.2.11) or *implant abutment* (3.2.10)

#### 3.2.19

#### implant connecting part screw

*implant component* (3.2.2) which fixes an *implant connecting part* (3.2.11) to an *implant body* (3.2.4)

#### 3.2.20

implant analogue GB

implant analog US

#### implant laboratory replica

*implant component* (3.2.2) intended for inclusion in a working model or cast to replicate the *connecting interface* (3.2.8) of an *implant body* (3.2.4) or *implant component* (3.2.2) for laboratory procedures

#### 3.2.21

implant impression coping

implant impression cap

implant transfer post

#### implant impression post

 $implant\ component\ (3.2.2)$  used to transfer the position of the  $connecting\ interface\ (3.2.8)$  to the working cast/model by means of an impression

#### 3.2.22

#### abutment analog

*implant component* (3.2.2) directly connected to the *implant laboratory replica* (3.2.20) and used only for the preparation of the *implant superstructure* (4.23.1) in the dental laboratory and not intended for clinical use

# 3.3 Ancillary devices used in oral implantology

#### 3.3.1

# implant screwdriver

tool for tightening and/or removing (loosening) screws that connect *implant components* (3.2.2) and/or dental prosthesis

#### 3.3.2

#### bone thread cutter

bone tap

bone thread former

instrument for preparation of athread in the prepared *implant osteotomy site* (4.6)

#### 3.3.3

# profile drill

stepped drill

calibrated rotary instrument for preparation of the *implant osteotomy site* (4.6) in various shapes and lengths, so as to precisely fit the *implant body* (3.2.4)

#### 3.3.4

# implant insertion preassembled device

insertion transfer device

fixture mount (DEPRECATED)

device to which an *implant body* (3.2.4) may be temporarily secured to facilitate its placement in the prepared osteotomy site

#### 3.3.5

# holding bar

holding key

device designed to hold the *implant body* (3.2.4) in the planned position during placement

# 3.3.6

#### pilot drill

rotary instrument used to prepare a preliminary hole for the *implant osteotomy site* (4.6)

#### 3.3.7

#### abutment finisher

crown base finisher

finishing instrument for planned removal of oxide layers on the *implant abutment* (3.2.10)

#### 3.3.8

# tissue punch

rotary tissue punch soft tissue trepan

central knife

instrument for removal of a disc of soft tissue

# 3.3.9

#### ratchet wrench

force transferring instrument, used for preparation of the implant osteotomy site or the insertion of the *implant body* (3.2.4) or as a holder for the *implant screwdriver* (3.3.1)

#### 3.3.10

#### torque wrench

ratchet wrench (3.3.9) with a measurable torque and/or torque limitation