SLOVENSKI STANDARD
oSIST prEN ISO 22683:2021

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Zobozdravstvo - Preskus prilagodljivosti med telesom implantata in nosilcem vsadka v sistemih zobnih vsadkov (ISO/DIS 22683:2021)

Dentistry - Adaptability test between implant body and implant abutment in dental implant systems (ISO/DIS 22683:2021)

Zahnheilkunde - Passungsprüfung zwischen Implantatkörper und Implantatabutment bei dentalen Implantatsystemen (ISO/DIS 22683:2021)

Médecine bucco-dentaire - Essai de compatibilité entre le corps d'implant et le pilier implantaire pour les systèmes d'implants dentaires (ISO/DIS 22683:2021)

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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.

Introduction

The adaptation between an implant body and an implant abutment is an important physical property as it affects the quality of fit between them and therefore resistance to loosening. Also, correct adaptation between these components can influence the vertical positioning of the final prostheses, the accuracy of the occlusion which it provides, and its physical behaviour under load. The test is currently carried out when evaluating the physical properties of dental implant systems but there is currently no international standard available, resulting in variance in method and the requirements of adaptations.

Dentistry — Adaptability test between implant body and implant abutment in dental implant systems

1 Scope

This document specifies a test method to evaluate the adaptability between an implant body and an implant abutment in a dental implant system.

This document may be applicable to the implant systems which do not have a friction-fit between implant body and implant abutment but incorporate an anti-rotational feature between these components. It is not acceptable to use analog or replica components to evaluate adaptability of dental implant systems.

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 14801, *Dentistry — Implants — Dynamic loading test for endosseous dental implants*

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
rotational angle between implant body and implant abutment
angle on a plane at right angles to the central long axis of the implant body described by the rotation between fully clockwise and fully counter-clockwise of a seated implant abutment without use of abutment screw, cement or friction and rotated clockwise or counter-clockwise

3.2
adaptability between implant body and implant abutment
adequate fit between an implant body and an implant abutment in terms of the *rotational angle between implant body and implant abutment* (3.1)

3.3
dental implant systems
integrated system of components which consists of implant bodies and implant abutments

[SOURCE: ISO 16443:2014, 3.2.1, modified — specific equipment and ancillary instruments have been deleted]

4 Test methods

4.1 General

Due to machining tolerance, most dental implant systems which have anti-rotational structure (i.e. hexagonal anti-rotational structure) have rotational clearance angle between implant body and implant abutment to facilitate clinical procedure.

However, if this rotational clearance angle is too large then loosening of the dental prosthesis can occur. Such loosening can be clinically detrimental and thus must be mitigated.

Testing shall be performed on specimens that are representative of the finished devices (i.e. implant bodies and implant abutment that have undergone the same manufacturing process and sterilization as the devices that are to be marketed). However, if there is evidence the sterilization method has no significant effect on the properties of all the materials of specimens being tested, then sterilization is not necessary.

4.2 Apparatus

Rotatable testing device which is composed of two parts. A goniometer and a jig to hold the implant body and implant abutment, as in Figure 1.

The goniometer must be capable of measuring to an accuracy of 0.5 degrees.

The jig for the implant body and implant abutment shall not deform the implant body and implant abutment.

NOTE The implant body can be embedded using a material in reference to ISO 14801.

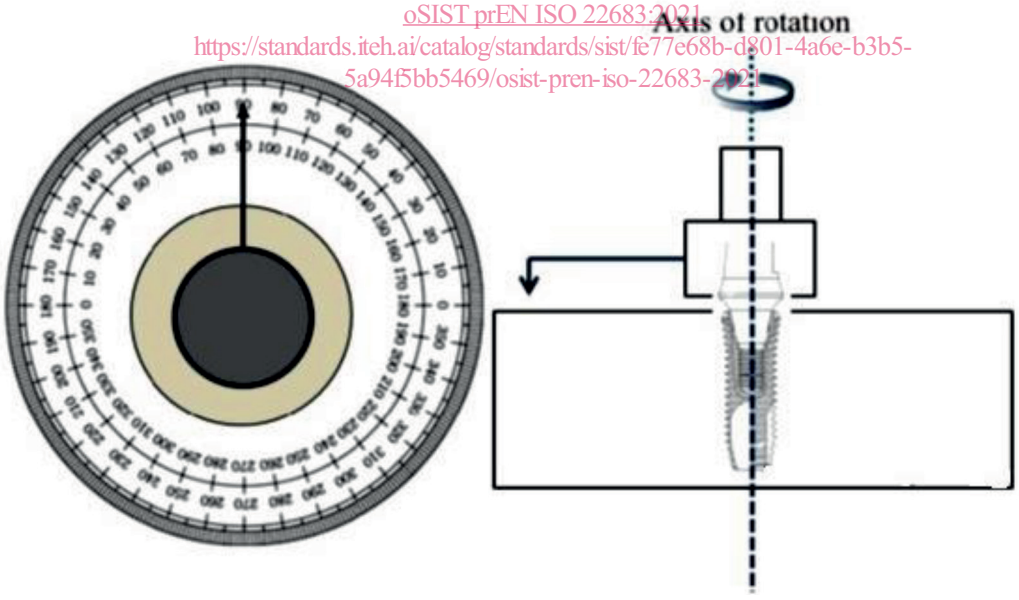

Figure 1 — Example of the testing devices to measure the rotational angle between implant body and implant abutment

4.3 Sampling

Five implant body and implant abutment assemblies recommended by the manufacturer for use together shall be procured for this test.