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Dentistry — Torque transmitter for handpieces used for implantation

Médecine bucco-dentaire

ICS: 11.060.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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Foreword

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 17509 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

Introduction

Based on ISO 13504, *Dentistry – General requirements for instruments and related accessories used in dental implant placement and treatment*, this International Standard describes accessories that are inserted into dental handpieces and that impart rotational forces from a dental handpiece to dental implants or their connecting parts.

Dentistry — Torque transmitter for handpieces used for implantation

1 Scope

This International Standard specifies requirements for torque transmitters and rotary instruments to be used in oral implantology in conjunction with a dental handpiece as an accessory in the placement of dental implants and the further manipulation of connecting parts in the craniofacial area.

This International Standard applies to torque transmitters used for placement and for removal in the oral cavity of the patient which are be connected to power-driven systems, but does not apply to the power-driven systems themselves.

This International Standard does not include the dental implant nor parts that would be connected to it.

With regard to safety, this International Standard gives requirements for classification, intended performance, performance attributes, material selection, performance evaluation, manufacture, reprocessing and information to be supplied by the manufacturer.

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*

ISO 1797-1, *Dentistry — Shanks — Part 1: Shanks made of metals*

ISO 3274, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Nominal characteristics of contact (stylus) instruments*

ISO 4288, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture*

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 13504:2012, *Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment*

ISO 16443, *Dentistry — Vocabulary of oral Implantology*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 13504, ISO 16443 and the following apply.

3.1
accessory used in dental implant placement and treatment
non surgically invasive device used with a transient usage in direct or indirect contact to the human body to be used in the placement of dental implants and the further manipulation of connecting parts

3.2
torque transmitter
screw bit
non-invasive surgically device designed to transmit a rotary movement from a dental handpiece to a dental implant or a dental implant connecting parts

4 Classification

Torque transmitters are classified according ISO 13504 clause 4.1 – 4.3 as given in Table 1.

Table 1 — Classification of torque transmitter

ISO 13504:2012, Clause	Classification requirements	Selection	Description
4.1	Intended usage	Type 1	Energized or motor driven instrument
4.2	Tissue contact	Class 2	Soft tissue
4.3	Reprocessing	Group 1	Multiple use

5 Intended performance

ISO 13504:2012, Clause 5 a) and 5 b) and IEC 62366 apply.

6 Performance attributes

ISO 13504:2012, Clause 6 applies.

Torque transmitters as shown in Figure 1 shall be designed to transmit a rotary movement safely and without visible sign of disturbance to applicable dental implants or dental implant connecting parts.

The dimensions and tolerances of the shank shall be in accordance with ISO 1797-1, Type 1 shank and the shape and dimensions of the head is at the discretion of the manufacturer.

Torque transmitters connected to an appropriate dental handpiece shall be designed to transmit a torque of at least 1, 0 Nm for the insertion of dental implants.

Test in accordance with 12.2.

NOTE The measure detail is a limiting value on technical data and not a medical statement.

The construction of torque transmitters shall provide for their safe and reliable operation in connection with dental handpieces in accordance with IEC 62366.

The surface roughness, as determined by the methods described in ISO 3274 and ISO 4288, shall be as specified in Figure 1.

Dimensions in millimetres

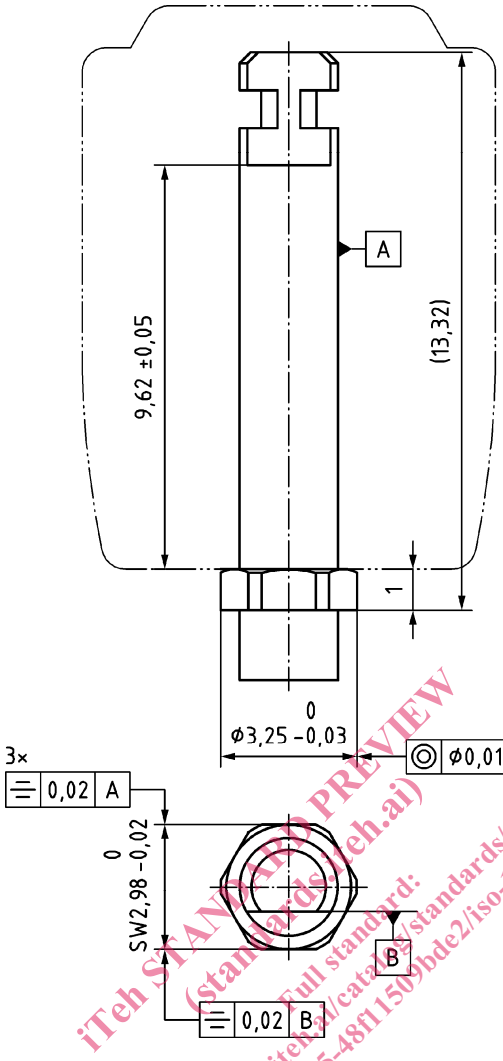

Figure 1 – Torque transmitter

7 Material selection

ISO 13504:2012, Clause 7 applies.

7.1 Material

The manufacturer of the torque transmitter shall be use a material as specified in Annex A in ISO 13504:2012.

7.2 Hardness

The hardness for shanks made from steel as determined by the method specified in ISO 6507-1 shall be not less than 500 HV 5.

8 Performance evaluation

ISO 13504:2012, Clause 8 applies.

9 Manufacturing

ISO 13504:2012, Clause 9 applies.