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Dentistry — Magnetic attachments

Médecine bucco-dentaire — Attaches magnétiques

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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).

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 (see 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 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 2, *Prosthodontic materials*. This second edition cancels and replaces the first edition (ISO 13017:2012), which has been technically revised. It also incorporates the Amendment ISO 13017:2012/Amd.1:2015. The main changes compared to the previous edition are as follows:

— addition of ISO 14233 to Clause 2;

— addition of lead as a hazardous element;

— addition of the cleaning method of test specimens prepared for retentive force;

— change of the device for retentive force to a single shaft type;

— change of Figure 3 to the single shaft type device;

— specification of the performance of the device with respect to moving friction force and modification of specimen tables;

— change of a cross-head speed in measuring retentive force from 5,0 mm min^{-1} to 2,0 mm min^{-1};

— addition of materials for fixing a specimen on the table such as cyanoacrylate adhesive and self-curing acrylic resin;

— deletion of the description of the adhesive double sided tape to fix a specimen on the table;

— specification of the procedures to fix a specimen on the table;

— addition of detailed method of measuring retentive force;

— addition of explaining the calculation method of retentive force;

— addition of a figure that shows a retentive force curve as Figure 4;

— specification of quantitative analyses in the static immersion test using definition of determination limit and detection limit;

— addition of “quantity” to labelling.

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 early practical uses of permanent magnets were as navigational compasses. Magnets have since become firmly integrated into today's modern electronic device technology. The development of magnetic technology has generated rare earth magnets. Their excellent magnetic character properties permit predictable clinical applications and use. Dental magnetic attachments are one of the products composed of rare earth magnets, providing retention, support and stabilization of dental and maxillofacial appliances.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document, but for the assessment of possible biological or toxicological hazards, reference can be made to ISO 10993-1 and ISO 7405.

Dentistry — Magnetic attachments

1 Scope

This document specifies requirements and test methods for assessing the applicability of dental magnetic attachments that provide retention, support and stabilization of removable prostheses (crowns and bridges, partial dentures and overdentures), superstructures of dental implants and orthodontic or maxillofacial prostheses including obturators.

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 3585, *Borosilicate glass 3.3 — Properties*

ISO 5832-1, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel*

ISO 10271, *Dentistry — Corrosion test methods for metallic materials*

ISO 14233, *Dentistry — Polymer-based die materials*

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

ISO 22674, *Dentistry — Metallic materials for fixed and removable restorations and appliances*

IEC 60404-8-1, *Magnetic materials — Part 8-1: Specifications for individual materials — Magnetically hard materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 10271 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

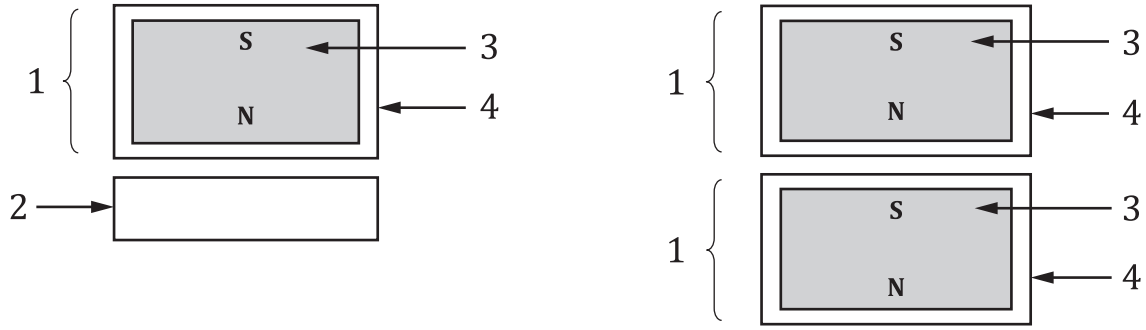
— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
magnetic attachment
device to provide retention of a prosthesis mainly utilizing magnetic attraction

3.1.1
open magnetic circuit attachment
magnetic attachment (3.1) wherein a magnetized permanent magnet is working by itself with no high permeability material

Note 1 to entry: The magnet is encased within a corrosion-resistant metal or alloy cover of titanium, titanium alloy or stainless steel to prevent corrosion of the magnet. The attachment uses either a magnet and a ferromagnetic alloy *keeper* (3.3) or two magnets as retentive coupling components.

See Figure 1.



a) Combination of a magnet and a keeper **b) Combination of two magnets**

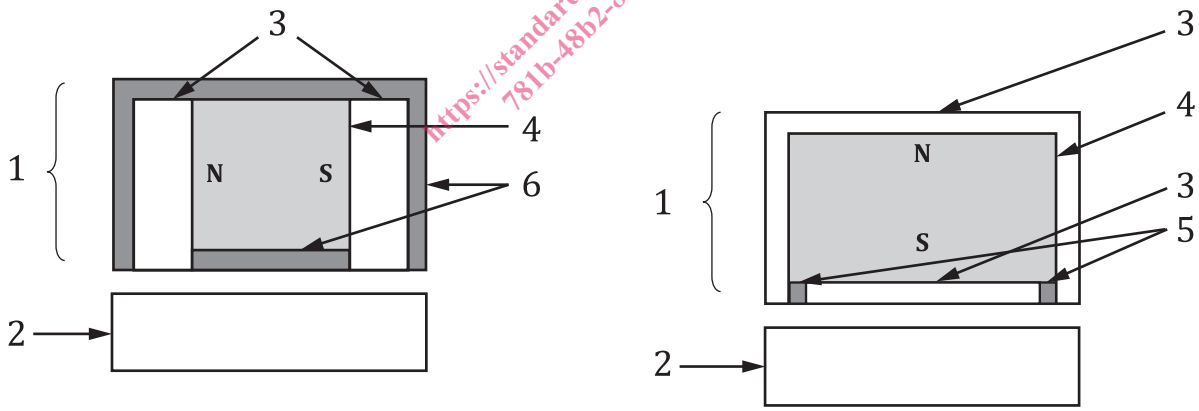
Key

1 magnet
2 keeper
3 magnet core
4 cover

Figure 1 — Schematic diagrams of open magnetic circuit attachment

3.1.2
closed magnetic circuit attachment
magnetic attachment (3.1) wherein the external flux path of a permanent magnet is confined within a high permeability material

Note 1 to entry: The attachment consists of a combination of a *magnetic assembly* (3.2) and a *keeper* (3.3). Some examples are the sandwich type and the cup-yoke type. See Figure 2.



a) Sandwich type **b) Cup-yoke type**

Key

1 magnetic assembly
2 keeper
3 yoke
4 magnet core
5 spacer
6 cover

Figure 2 — Schematic diagrams of closed magnetic circuit attachment

3.2
magnetic assembly
assembly composed of a small magnet which is sealed within ferromagnetic yokes and a non-magnetic spacer, completing a closed magnetic circuit with a *keeper* (3.3)

Note 1 to entry: The closed magnetic circuit is a complete circulating path for magnetic flux through the yoke and keeper, which are made of ferromagnetic materials. This circuit can enhance the retentive force and reduce the magnetic flux leakage.

3.3
keeper
ferromagnetic alloy component fixed to an abutment to retain a prosthesis mainly

Note 1 to entry: The keeper is placed across the poles of a magnet or a *magnetic assembly* (3.2) to complete the magnetic circuit.

3.4
yoke
ferromagnetic alloy component connected to a permanent magnet and used for concentrating magnetic flux

4 Requirements

4.1 Material

4.1.1 Magnet core

A magnet that is classified by principal constituents in accordance with IEC 60404-8-1 shall be used as the magnet core.

4.1.2 Components other than the magnet core

A material whose chemical composition is declared by the manufacturer shall be used for components of the dental magnetic attachment, other than the magnet core.

4.1.3 Reported chemical composition

For the magnet core, the principal constituents in accordance with IEC 60404-8-1 shall be stated [see Clause 7, a)].

For the materials of the dental magnetic attachment other than the magnet core, all constituent element names that are present in excess of 1,0 % (mass fraction) shall be stated [see Clause 7, a)] by reference to the manufacturer's composition report. The manufacturer shall disclose the chemical composition of an appropriate lot production, if users request it.

4.2 Hazardous elements

4.2.1 Recognized hazardous elements

For the purpose of this document, the elements nickel, cadmium, beryllium and lead are designated hazardous elements.

4.2.2 Permitted limits for the hazardous elements cadmium, beryllium and lead

Materials of dental magnetic attachments shall not contain more than 0,02 % (mass fraction) cadmium, beryllium or lead as determined by ISO 22674.

4.2.3 Manufacturer's reported nickel content and permitted deviation

If the materials of the dental magnetic attachment other than the magnet core contain more than 0,1 % (mass fraction) nickel, the contents shall be given to an accuracy of 0,1 % (mass fraction) in the literature which accompanies the package [see Clause 7, f)] and on the package, label or insert [see 8.2, e)]. The mass fraction as determined by ISO 22674 shall not exceed the value stated in Clause 7, f) and 8.2, e).

4.3 Risk analysis

Risk analysis should be carried out and documented according to ISO 14971.

4.4 Magnetic flux leakage

If the average maximum magnetic flux density 5 mm from the surface of the magnetic attachment is over 40mT[5], when tested in accordance with 6.2, this value shall be stated in the literature accompanying the package [see Clause 7, b)].

4.5 Retentive force

The retentive force of the dental magnetic attachment shall not be less than 85 % of the value stated in the literature accompanying the package [see Clause 7, d)] when tested in accordance with 6.3.

4.6 Corrosion resistance

4.6.1 Released ions

The total metal ions released from the magnet or the magnetic assembly and from the keeper into the specified solution (see 6.4.1.3) at (37 ± 1) °C in a time period of 7 d ± 1 h shall not exceed 200 µg/cm^2 in accordance with ISO 22674 when tested in accordance with 6.4.1.

4.6.2 Breakdown potential

Breakdown potentials of the magnet or the magnetic assembly and the keeper shall be equal to, or higher than, that of wrought stainless steel in accordance with ISO 5832-1 when tested in accordance with 6.4.2.

5 Preparation of test specimens

5.1 Retentive force

Clean the mating face on the magnet or the magnetic assembly and the keeper using a cotton bud which has been soaked in acetone, ethanol or methanol just before measurement (see 6.3.4). Dry with oil- and water-free compressed air as appropriate.

5.2 Static immersion test

Prepare a sufficient number (at least three) of magnets, magnetic assemblies or keepers such that the total surface area is at least 2 cm^2. Prepare the magnets, magnetic assemblies or keepers in accordance with ISO 10271. Use these magnets, magnet assemblies or keepers for the static immersion test.

NOTE ISO 10271 requires the total surface area of the sample to be at least 10 cm^2 after preparation; however, this would require an impractical number of pieces for testing (e.g. 25 pieces to 50 pieces). Therefore, the required surface area has been reduced to at least 2 cm^2. This surface area results in a minimum volume of test solution of 2 ml when the ISO 10271 test procedure (which states "add the solution to each container sufficient to produce a ratio of 1 ml of solution per 1 cm^2 of sample surface area") is followed. These 2 ml provide an adequate volume of test solution for analysis by ICP.

