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Dentistry — Magnetic attachments

Médecine bucco-dentaire — Attaches magnétiques

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Foreword

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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 13017 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

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.

Dentistry — Magnetic attachments

1 Scope

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

This International Standard does not specify qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risk, which can be assessed using ISO 10993-1 and ISO 7405.

2 Normative references

The following referenced documents are indispensable for the application 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 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part1: General requirements*

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

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

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

3 Terms and definitions

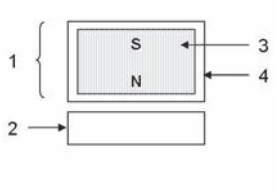
For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1
magnetic attachment
device to provide retention of a prosthesis utilizing magnetic attraction as shown in Figures 1 and 2

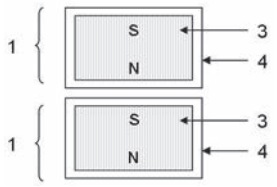
3.1.1
open magnetic circuit attachment
magnetic attachment which utilizes an open magnetic circuit between coupled components

NOTE 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, and utilizes the attractive force between either two magnets or between a magnet and a ferromagnetic alloy keeper as retentive coupling components.

See Figure 1.



a) Combination of a magnet and a keeper



b) Combination of two magnets

Key

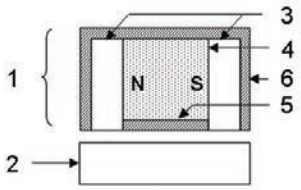
1 magnet
2 keeper
3 magnet core
4 cover

Figure 1 — Schematic diagrams of open magnetic circuit attachment

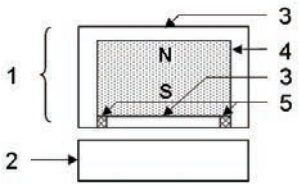
3.1.2
closed magnetic circuit attachment
magnetic attachment which utilizes a closed magnetic circuit between the coupled device components

NOTE The attachment consists of a combination of a magnetic assembly and a keeper. Examples are sandwich type and 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 non-magnetic spacers, completing closed magnetic circuits

NOTE 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 used to retain a prosthesis

NOTE The keeper is placed across the poles of a magnet or a magnetic assembly to complete the magnetic circuit and fixed to an abutment to retain a prosthesis.

3.4
yoke
ferromagnetic alloy component connected to a permanent magnet 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 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 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 International Standard, the elements nickel, cadmium and beryllium are designated hazardous elements.

4.2.2 Permitted limits for the hazardous elements cadmium and beryllium

Materials of dental magnetic attachments shall not contain more than 0,02 % (mass fraction) cadmium or beryllium.

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 7 f)] and on the package, label or insert [see 8.2 d)]. The mass fraction shall not exceed the value stated in 7 f) and 8.2 d).

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 5 mm from the surface of the magnetic attachment is over 40mT[3], when tested in accordance with 6.2, this value shall be stated in the literature accompanying the package [see 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 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 6.4.1.4) at (37 ± 1) °C in a time period of 7 d ± 1 h shall not exceed 200 $\mu g \cdot cm^{-2}$ in accordance with ISO 22674 when tested in accordance with 6.4.1.

4.6.2 Breakdown potential

Breakdown potentials of 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 6.3.2). Dry with oil- and water-free compressed air.

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 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.

5.3 Anodic polarization

Prepare the magnet or the magnetic assembly, the keeper and the working electrode in accordance with ISO 10271.

6 Test methods

6.1 Information, instructions and marking

Inspect visually to check that the requirements specified in Clauses 7 and 8 have been met.

6.2 Magnetic flux leakage

6.2.1 Apparatus

6.2.1.1 Gauss meter, in accordance with IEC 17025.

6.2.2 Test procedure

The maximum magnetic flux 5 mm from the surface of the dental magnetic attachment is measured with a Gauss meter (6.2.1) using a Hall element under conditions of use (e.g. a keeper being attached to a magnetic assembly). Report the average of five measurements.

6.3 Retentive force

6.3.1 Apparatus

6.3.1.1 Mechanical testing machine, with an appropriate accuracy greater than 1 % of the measured value and a cross-head speed of 5,0 mm min^{-1} or less, and with an adapter appropriate for the fixing and alignment of specimens.

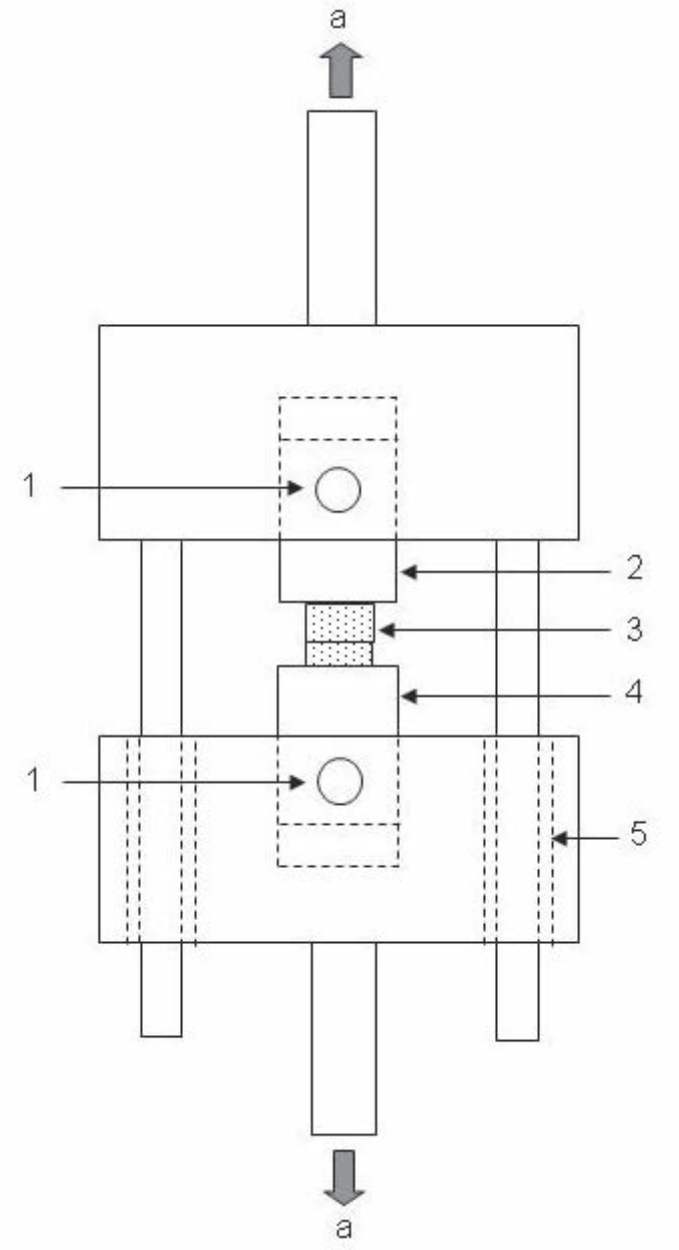
6.3.1.2 Device for fixing and pulling the specimens vertically, installed in the mechanical testing machine. An example of the device for measuring retentive force is shown in Figure 3.

6.3.2 Test procedure

Load the test specimen in tension in the mechanical testing machine (6.3.1.1) at a cross-head speed of 5,0 mm min^{-1} or less until the magnet or the magnetic assembly separates completely from the keeper. Install the device for fixing and pulling the specimens vertically (6.3.1.2) in the mechanical testing machine for accurate and reproducible measurement.

For each specimen, record the median value that is obtained from five measurements.

Calculate the retentive forces as the mean of the median values obtained from at least five specimens. Report the retentive force in newtons to the nearest 0,1 N.



Key

1 set screw
2 upper non-magnetic adapter
3 specimen
4 lower non-magnetic adapter
5 linear-motion bearing to minimize friction

[a] Connected to the universal testing machine.

Figure 3 — Example of a device for measuring retentive force

6.4 Corrosion resistance

6.4.1 Static immersion test

6.4.1.1 Reagents

Use reagents in accordance with ISO 10271.

6.4.1.2 Apparatus

6.4.1.2.1 pH meter, in accordance with ISO 10271.

6.4.1.2.2 Test tube, made of borosilicate glass complying with ISO 3585, or made of polyethylene (PE) or polypropylene (PP) for ICP or AA analysis.

6.4.1.3 Test solution

Prepare a fresh solution for each test in accordance with ISO 10271.

6.4.1.4 Test procedure

Determine the pH of the test solution (6.4.1.3) using a pH meter (6.4.1.2.1) and record it. Place each specimen in a separate glass, PE or PP test tube (6.4.1.2.2) so that the specimens do not touch the inner surface of the tube except in a minimum support line or point. Add sufficient solution to each container to produce a ratio of 1 ml of solution per 1 cm^2 of sample surface area. The specimens shall be covered completely by the solution. Record the volume of solution to an accuracy of 0,1 ml. Close the container to prevent evaporation of the solution. Maintain at (37 ± 1) °C for 7 d ± 1 h. Remove the specimens and record the pH of the residual solution.

Use an additional container to hold a reference solution that is to be maintained in parallel with the solutions containing the specimens. The reference solution shall be used to establish the impurity level for each element of interest in the solution. Add approximately the same volume of solution as used for the solutions containing the specimens and record the volume to an accuracy of 0,1 ml. Close the container to prevent evaporation of the solution and maintain at (37 ± 1) °C for the same time period as the solutions containing the specimens.

6.4.1.5 Analysis

Combine all the solutions from each test tube after the test specimens are removed from the test tubes. Use chemical analysis instrumentation of adequate sensitivity (e.g. AAS and ICP). Analyse the solution qualitatively and quantitatively. Emphasis shall be on those elements listed in 7 a), but if impurities are found in a concentration greater than 0,1 % in materials other than the magnet core, they shall also be reported. For each element of interest, subtract the value obtained for the element in the reference solution from the value obtained in the test solution. The elements boron, carbon or nitrogen shall be disregarded.

6.4.2 Anodic polarization

6.4.2.1 Reagents

Use reagents in accordance with ISO 10271.

6.4.2.2 Apparatus

Use apparatus in accordance with ISO 10271.

6.4.2.3 Test solution

Prepare a fresh solution for each test in accordance with ISO 10271.

6.4.2.4 Test procedure

Obtain anodic polarization curves of the magnetic assembly and the keeper in accordance with ISO 10271.

6.4.2.5 Analysis

Obtain each breakdown potential from the anodic polarization curves of the magnetic assembly and the keeper, and compare the potential with that of wrought stainless steel in accordance with ISO 5832-1.

7 Information and instructions for use

The following information shall be included in the literature that shall accompany the package:

a) the composition of the material used for magnetic attachment; the principal constituents in accordance with ISO/IEC 60404-8-1 for the magnet core, and all constituent element names that are present in excess of 1,0 % (mass fraction) for materials other than the magnet core;

b) the maximum magnetic leakage 5 mm from the surface of the dental magnetic attachment in the conditions of use when the average of five measurements is over 40 mT;

c) the maximum permissible heating temperature;

d) the retentive force;

e) instructions for fixing to an abutment or an implant to retain a prosthesis;

f) if the product contains nickel in excess of 0,1 % (mass fraction), adequately detailed information regarding its potential for adverse reactions and the text: “This product contains nickel.”;

g) cautions and warnings for the use of the dental magnetic attachment, including any interference with medical instruments or devices (e.g. MRI or cardiac pacemaker) that it may cause.

8 Marking and labelling

8.1 Marking

Magnetic attachments shall be clearly and accurately marked to identify the manufacturer or supplier, the product name or an appropriate abbreviation (code) and the product size.

For magnetic attachments which are too small to be directly marked, this requirement does not apply. Rather, the information shall be available on packaging that is in direct contact with the magnetic attachment product.

8.2 Labelling

The label or insert on the package shall be marked with at least the following information:

a) manufacturer’s or distributor’s name or trademark and address;

b) trade name of the dental magnetic attachment;

c) lot number;

d) if the materials of the dental magnetic attachment other than the magnet core contain more than 0,1 % (mass fraction) nickel, a warning symbol (a triangle within which there is an exclamation mark) in accordance with ISO 15223-1.

Bibliography

[1] ISO 3696, *Water for analytical laboratory use — Specification and test methods*

[2] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

[3] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

[4] ISO 14971, *Medical devices — Application of risk management to medical devices*

[5] WHO Environmental Health Criteria Monograph No.232, Static Fields, p.349-351

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