

TECHNICAL REPORT

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Dental implants — State of the art — Survey of materials

iTeh STANDARD PREVIEW
Implants dentaires — État de l'art — Répertoire des matériaux
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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 main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

- type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;
- type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;
- type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 10451, which is a Technical Report of type 2, was prepared by Technical Committee ISO/TC 106, *Dentistry*.

This document is being issued in the type 2 Technical Report series of publications (according to subclause G.6.2.2 of part 1 of the IEC/ISO Directives) as a "prospective standard for provisional application" in the field of dental implantology because there is an urgent need for guidance on how standards in this field should be used to meet an identified need.

This document is not to be regarded as an "International Standard". It is proposed for provisional application so that information and experience of its use in practice may be gathered. Comments on the content of this document should be sent to the ISO Central Secretariat.

A review of this type 2 Technical Report will be carried out not later than two years after its publication with the options of: extension for another two years; conversion into an International Standard; or withdrawal.

Annexes A, B and C of this Technical Report are for information only.

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Introduction

In ISO/TC 106, a recommendation was made to form SC 8 with the purpose of establishing an International Standard on dental implants at the plenary meeting held in Solna (1984).

The work of preparing a Technical Report, type 2, was carried out in Milan (1985), Hong Kong (1986), Buenos Aires (1987) and Chicago (1988).

In addition to knowledge of basic medical sciences, dental implants also require extensive knowledge of the structure and function of the oral cavity, including soft and hard tissues.

Dental implants are located in the unique environment of the oral cavity, soft and hard tissues, and accordingly are in contact with different media:

- saliva and other contents of the oral cavity,
- crevicular fluid and the mucosa interface,
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bone and blood, and soft tissues.

The dental implant is influenced further by the chemical, physical and mechanical properties of the material of which it is made.

Dental implants have been used successfully for many years. However, since implantology is a developing discipline, coupled with the circumstance that there are inadequate data to produce a Standard, it was recommended, following the meeting in Milan, that a type 2 Technical Report be produced describing the present state of the art of the materials.

In addition to the properties of the materials, it was deemed advisable to include design and implantation procedures in the scope of this Report.

In order to fulfil all the requirements for a Standard, it was decided in Hong Kong in 1986 to provide the biological component in collaboration with FDI/ISO/TC 106 joint working Group on biological evaluation.

It is the intention of ISO/TC 106 that this Technical Report will be reviewed regularly in the light of technological advances and the availability of more data, with the ultimate objective of using it as a basis for an International Standard.

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Dental implants — State of the art — Survey of materials

1 Scope

This Technical Report surveys the materials used in the discipline of dental implantology.

Characterization sheets are included as product information guidelines for a standardized sampling of data related to materials and implantation procedures.

2 Normative references

The following standards, contain provisions which, through reference in this text, constitute provisions of this Technical Report. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this Technical Report are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942-1:1989, *Dental vocabulary — Part 1: General and clinical terms*.

ISO 5832-1:1987, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel*.

ISO 5832-2:1978, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*.

ISO 5832-3:1990, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*.

ISO 5832-4:1978, *Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy*.

ISO 5832-5:1978, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy*.

ISO 5832-6:1980, *Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*.

ISO 5832-8:1987, *Implants for surgery — Metallic materials — Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy*.

ISO 6474:1981, *Implants for surgery — Ceramic materials based on alumina*.

ISO/TR 7405:1984, *Biological evaluation of dental materials*.

ISO/TR 9966:1989, *Implants for surgery — Biocompatibility — Selection of biological test methods for materials and devices*.

3 Definitions

For the purposes of this Technical Report, the definitions given in ISO 1942-1 and the following definitions apply.

3.1 dental implant: Device specially designed to be placed surgically within or on the mandibular or maxillary bone as a means of providing resistance to displacement of a dental prosthesis. (ISO 1942-1:1989, definition 1.080)

NOTE 1 It can be either transgingival (with part of the implant emerging from gingiva for direct abutment), or fully embedded under the gingiva (only aiming at the support of a removal prosthesis).

3.2 transendodontic implant; transradicular implant: Rod specially designed and/or prepared to be inserted either through the root canal or through the root in the bone.

3.3 endosseous implant: (Dental) implant placed partly or entirely within bone.

3.4 fully embedded dental implant: Dental implant which is fully covered by gingiva or mucosa.

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3.5 transgingival [transmucosal] implant: Dental implant that has extension(s) into the oral cavity through the mucosa for providing resistance to the displacement of a dental prosthesis.

3.6 subperiosteal implant: Dental implant placed between periosteum and the surface of the bone.

3.7 intramucosal implant: Dental implant placed into the soft tissue lining of the oral cavity.

4 Classification of materials

4.1 General classification

Implants may be of the following materials:

- 1) Metallic materials (see table 1);
- 2) Ceramic materials (see table 2);
- 3) Polymeric materials (see table 3);
- 4) Fibrous composite materials (see table 4);
- 5) Coating materials (see table 5);
- 6) Multiple combination of materials (see table 6).

4.2 Family

This classification has been assembled in the form of one table per family, each composed of six columns specifying

- Column 1: the number of the class, followed by the name of the basic chemical nature of the material.
- Column 2: the number of the sub-class in relation with the specific chemical composition grade of the material.
- Column 3: the International Standard reference, when applicable.
- Column 4: the designation of the materials, with an indication of their general chemical composition, their physical constitution and their basic manufacturing process.
- Column 5: the type of use of the implant concerned, with the material taken into account, subdivided as follows:

- A transgingival (or transmucosal) implants,
- B transendodontic (or diodontic) implants,
- C embedded implants,
- D subperiosteal implants,

with an indication of the corresponding level of advancement:

“E” = experimental,

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X = currently in use.

- Column 6: possible comments, for instance, some particularities of constitution.

Table 1 — Metallic materials

1	2	3	4	5				6
				Use				
Class	Sub-class	References	Form and composition	A	B	C	D	Observations
1.1 Stainless steel	1.1.1	---	Cast stainless steel	---	X	X	---	---
	1.1.2	ISO 5832-1 modified	Wrought stainless steel	E	X	E		---
1.2 Commercially pure titanium	1.2.1	ISO 5832-2	Wrought titanium	X	X	X	E	---
	1.2.2	---	Cast and machined titanium	X	---	X	E	---
1.3 Titanium alloys	1.3.1	ISO 5832-3 modified	Wrought titanium, 6 aluminium, 4 vanadium alloy	X	X	X	E	---
	1.3.2	Document ISO/TC 150/1 N 117 Rev.	Wrought titanium, 5-aluminium, 2,5-iron alloy	E	E	---	---	---
1.4 Cobalt chromium alloys	1.4.1	ISO 5832-4	Cast cobalt chromium – molybdenum alloy	E	E	X	X	---
	1.4.2	ISO 5832-4 modified	Wrought cobalt chromium – molybdenum alloy	E	E	X	X	---
	1.4.3	ISO 5832-5	Wrought cobalt chromium – tungsten – nickel alloy	---	X	X	X	---
	1.4.4	ISO 5832-6	Wrought cobalt – nickel – chromium – molybdenum alloy	---	X	X	X	---
	1.4.5	ISO 5832-8	Wrought cobalt – nickel – chromium – molybdenum – tungsten – iron alloy	---	X	---	---	---
1.5 Tantalum	1.5.1	---	Pure tantalum	X	X	E	---	---
1.6 Niobium	1.6.1	---	Pure niobium	E	E	E	---	---
	1.6.2	---	Niobium – zirconium alloy	E	E	E	---	---
1.7 Gold	1.7.1	---	Gold alloy	X	E	E	E	---
1.8 Platinum	1.8.1	---	Pure platinum	E	E	E	E	---
	1.8.2	---	Platinum alloy	E	E	E	E	---

Table 2 — Ceramic materials

1	2	3	4	5				6
				Use				
Class	Sub-class	References	Form and composition	A	B	C	D	Observations
2.1 Ceramic based on alumina	2.1.1	ISO 6474 modified	Dense sintered crystalline alumina (Al ₂ O ₃)	X	X	X	---	---
	2.1.2	---	99,9 % pure porous alumina	E	---	E	---	---
	2.1.3	---	97 % pure porous alumina	E	---	E	---	---
	2.1.4	---	Zirconia reinforced alumina	E	E	---	---	Partially stabilized
	2.1.5	---	Calcium phosphate alumina	---	---	E	---	---
	2.1.6	---	Single crystal of alumina	X	X	---	---	---
2.2 Ceramic based on glass	2.2.1	---	Porous vitroceramic	E	---	E	---	---
	2.2.2	---	Dense vitroceramic	E	---	E	---	---
2.3 Ceramic based on calcium phosphate	2.3.1	---	Dense sintered hydroxy apatite	X	---	X	---	Not biodegradable
	2.3.2	---	Porous sintered hydroxy apatite	X	---	---	---	Not biodegradable
	2.3.3	---	Dense sintered beta whitlockite	---	---	X	---	Biodegradable
	2.3.4	---	Porous sintered beta whitlockite	---	---	X	---	Biodegradable
	2.3.5	---	Other types	E	---	X	---	Biodegradable
2.4 Ceramic based on calcium carbonate	2.4.1	---	Porous sintered calcium carbonate	---	---	X	---	---
	2.4.2	---	Natural porous calcium carbonate	---	---	X	---	---
2.5 Ceramic based on zirconia	2.5.1	---	Alumina stabilized zirconia	E	---	---	---	---
	2.5.2	---	Yttria partially stabilized zirconia	E	---	---	---	---
	2.5.3	---	Ceria partially stabilized zirconia	E	---	---	---	---

Table 3 — Polymeric materials

1 Class	2 Sub-class	3 References	4 Form and composition	5 Use				6 Observations
				A	B	C	D	
3.1 Polysiloxane	3.1.1	---	Polysiloxane heat cured	---	---	X	---	---
3.2 Polysulfone	3.2.1	---	Porous polysulfone	---	---	X	---	---
	3.2.2	---	Non-porous polysulfone	---	---	X	---	---
3.3 Polymethacrylate	3.3.1	---	Methacrylate	---	---	E	---	---

Table 4 — Fibrous composite materials

1 Class	2 Sub-class	3 References	4 Form and composition	5 Use				6 Observations
				A	B	C	D	
4.1 Composite based on carbon/carbon	4.1.1	---	Porous pyrolytic carbon matrix reinforced with carbon fibres	E	E	E	---	With thin pyrolytic carbon coating
4.2 Composite based on carbon/ceramic	4.2.1	---	Porous silicon carbide matrix reinforced with carbon fibres	E	E	E	---	With thin silicon carbide coating