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Dentistry — Materials for dental instruments —

Part 1: Stainless steel

Médecine bucco-dentaire — Matériaux pour instruments dentaires —

Partie 1: Acier inoxydables

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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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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 21850 series can be found on the ISO website.

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

There is an increasing number of newly developed dental surgical techniques with an increasing number of procedures such as dental implant placements. The market for the dental instrument is also rapidly growing with demands for new and better instruments.

This document is intended to harmonize the approval procedures and to reduce the costs caused by repeated approval and test procedures in different countries with regard to the stainless steel materials used in dental instruments.

Dentistry — Materials for dental instruments —

Part 1: Stainless steel

1 Scope

This document specifies stainless steel commonly used in manufacturing dental instruments.

It is applicable to stainless steel materials used to manufacture either an entire instrument or a part of the instrument.

It is applicable to single-use and reusable dental instruments, whether it is or it is not connected to a power-driven system.

This document is not applicable to devices and instruments used long-term in the mouth of the patient (e.g. crown, bridges, implants) or to devices and instruments not made of stainless steel.

It contains a current selection of stainless steels suitable for use in the manufacture of dental instruments.

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 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

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

ISO 15510, *Stainless steels — Chemical composition*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 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 http://www.electropedia.org/

3.1
dental instrument
tool specially designed for use in dentistry

3.2
stainless steel
steel whose most characterizing element is chromium of at least 10,5 % (mass fraction) Cr and maximum 1,2 % (mass fraction) C, and the primary importance of which is its resistance to corrosion

3.2.1
austenitic stainless steel
stainless steel (3.2) typically composed of less than 0,2 % (mass fraction) C, at least 16 % (mass fraction) Cr, typically about 18 % (mass fraction) Cr and over 8 % (mass fraction) Ni, which cannot be hardened by heat treatment

3.2.2
martensitic stainless steel
stainless steel (3.2) with low to medium carbon, at least 0,08 % (mass fraction) C and between 11,5 % (mass fraction) and 19 % (mass fraction) Cr, which can be hardened by quenching and tempering

3.2.3
precipitation-hardening stainless steel
stainless steel (3.2) with a high strength resulting from the precipitation of intermetallic compounds (the formation of very fine intermetallic phases, carbides and laves phases in the structure) by a final heat treatment

3.2.4
ferritic stainless steel
stainless steel (3.2) with low carbon with less than 0,1 % (mass fraction) C and between 10,5 % (mass fraction) and 30 % (mass fraction) Cr, but which cannot be hardened by heat treatment

4 Materials

4.1 Material designation

The specification of the chemical composition and the material designation of the stainless steel shall be in accordance with ISO 15510, if applicable. There can be minor differences in the chemical compositions of stainless steel grades that are considered to equivalent to one another, where details can be found in Annex A.

4.2 Composition of stainless steels

In Tables 1, 2, 3, and 4, composition of various stainless steels that are used for the manufacture of instruments used in dentistry are listed.

Table 1 — Austenitic stainless steels (composition)

Number in this document	% (mass fraction), maximum values unless indicated otherwise									
	C	Si	Mn	P	S[a]	N	Cr	Mo	Ni	Others
A1	0,02	0,75	2,00	0,035	0,015	0,15	19,0 to 22,0	4,0 to 5,0	23,5 to 26,0	Cu: 1,00 to 2,00
A2	0,03	1,00	2,00	0,045	0,030	0,12 to 0,22	17,5 to 19,5	—	8,0 to 11,0	—
A3	0,03	1,00	2,00	0,045	0,030	0,10	17,0 to 19,0	2,5 to 3,0	12,5 to 15,0	—
A4	0,07	1,00	2,00	0,045	0,030	0,10	17,5 to 19,5	—	8,0 to 10,5	—
A5	0,08	1,00	2,00	0,045	0,030	0,10	16,0 to 18,0	2,0 to 3,0	10,0 to 13,0	—
A6	0,12	1,00	2,00	0,060	minimum 0,15	0,10	17,0 to 19,0	—	8,0 to 10,0	Cu:1,0

[a] Particular ranges of sulfur mass fraction may provide improvement in certain properties. For polishability, a controlled sulfur mass fraction of 0,015 % maximum is recommended.

[b] Stainless steel is not listed in ISO 15510, but listed in EN 10088-1.

Table 1 *(continued)*

Number in this document	% (mass fraction), maximum values unless indicated otherwise									
	C	Si	Mn	P	S[a]	N	Cr	Mo	Ni	Others
A7	0,05 to 0,15	2,00	2,00	0,045	0,030	0,10	16,0 to 19,0	0,8	6,0 to 9,5	—
A8[b]	0,06	1,00	2,00	0,045	0,015	0,11	17,0 to 19,0	—	11,0 to 13,0	—
A9[b]	0,03	1,00	2,00	0,045	0,1 to 0,2	—	16,5 to 18,5	2,0 to 2,5	10,0 to 13,0	Cu: 1,3 to 1,8
A10	0,03	1,00	2,00	0,045	0,030	0,10	17,5 to 19,5	—	8,0 to 10,5	—
A11	0,03	1,00	2,00	0,045	0,030	0,10	16,5 to 18,5	2,0 to 3,0	10,0 to 13,5	—
A12[b]	0,10	1,00	2,00	0,045	0,15 to 0,35	0,10	17,0 to 19,0	—	8,0 to 10,0	Cu: 1,0

[a] Particular ranges of sulfur mass fraction may provide improvement in certain properties. For polishability, a controlled sulfur mass fraction of 0,015 % maximum is recommended.

[b] Stainless steel is not listed in ISO 15510, but listed in EN 10088-1.

Table 2 — Martensitic stainless steels (composition)

Number in this document	% (mass fraction), maximum values unless indicated otherwise									
	C	Si	Mn	P	S[a]	N	Cr	Mo	Ni	Others
M1	0,12 to 0,17	1,00	1,00	0,040	0,015	—	12,0 to 14,0	—	—	—
M2	0,12 to 0,22	1,00	1,50	0,040	0,030	—	15,0 to 17,0	—	1,50 to 2,50	—
M3	0,16 to 0,25	1,00	1,50	0,040	0,030	—	12,0 to 14,0	—	—	—
M4[d]	0,21 to 0,24	1,00	1,00	0,040	0,200	—	12,5 to 14,0	1,00 to 1,20	0,75 to 1,10	—
M5[d]	0,25 to 0,35	1,00	1,00	0,040	0,025	—	14,0 to 16,0	0,85 to 1,10	0,3 to 0,5	—
M6	0,26 to 0,35	1,00	1,50	0,040	0,030	—	12,0 to 14,0	—	—	—
M7	0,33 to 0,45	1,00	1,50	0,040	0,015	—	15,5 to 17,5	0,80 to 1,30	1,00	—
M8	0,43 to 0,50	1,00	1,00	0,040	0,030	—	12,5 to 14,5	—	—	—
M9	0,45 to 0,55	1,00	1,00	0,040	0,015	—	14,0 to 15,0	0,50 to 0,80	—	V: 0,10 to 0,20
M10	0,43 to 0,50	1,00	2,00	0,040	0,15 to 0,35	—	12,5 to 14,0	—	—	—
M11	0,60 to 0,75	1,00	1,00	0,040	0,030	—	16,0 to 18,0	0,75	0,60	—

[a] Particular ranges of sulfur mass fraction may provide improvement in certain properties. For polishability, a controlled sulfur mass fraction of 0,015 % maximum is recommended.

[b] Stainless steel is not listed in ISO 15510, but listed in EN 10088-1.

[c] Stainless steel is not listed in ISO 15510, but listed in ASTM A959.

[d] Stainless steel is not listed in ISO 15510, not listed in EN 10088-1.

Table 2 *(continued)*

Number in this document	% (mass fraction), maximum values unless indicated otherwise									
	C	Si	Mn	P	S[a]	N	Cr	Mo	Ni	Others
M12[b]	0,85 to 0,95	1,00	1,00	0,040	0,030	—	17,0 to 19,0	0,90 to 1,30	—	V: 0,07 to 0,12
M13[b]	0,95 to 1,20	1,00	1,00	0,040	0,030	—	16,0 to 18,0	0,40 to 0,80	—	—
M14[d]	0,35 to 0,40	1,00	1,00	0,045	0,030	—	14,0 to 15,0	0,40 to 0,60	—	V: 0,10 to 0,15
M15	0,08 to 0,15	1,00	1,50	0,040	0,030	—	11,5 to 13,5	—	0,75	—
M16[b]	0,60 to 0,70	0,50	1,00	0,030	0,025	—	12,0 to 13,5	—	0,5	—
M17	0,35 to 0,50	1,00	1,00	0,040	0,015	0,1 to 0,3	14,0 to 16,0	1,0 to 2,5	0,5	V: 1,5
M18[b]	0,10 to 0,17	1,00	1,50	0,040	0,15 to 0,35	—	15,5 to 17,5	0,20 to 0,60	—	—
M19[c]	0,15 to 0,30	1,00	1,00	0,040	0,030	—	13,5 to 15,0	0,40 to 0,85	0,55 to 0,85	—
M20[c]	0,15	0,50	1,00	0,040	0,030	—	11,50 to 13,00	—	0,030	—
M21	0,08 to 0,15	1,00	1,50	0,040	minimum 0,15	—	12,0 to 14,0	0,60	—	—
M22	0,25 to 0,40	1,00	1,50	0,060	minimum 0,15	—	12,0 to 14,0	0,60	0,60	—

[a] Particular ranges of sulfur mass fraction may provide improvement in certain properties. For polishability, a controlled sulfur mass fraction of 0,015 % maximum is recommended.

[b] Stainless steel is not listed in ISO 15510, but listed in EN 10088-1.

[c] Stainless steel is not listed in ISO 15510, but listed in ASTM A959.

[d] Stainless steel is not listed in ISO 15510, not listed in EN 10088-1.

Table 3 — Precipitation-hardening stainless steels (composition)

Number in this document	% (mass fraction), maximum values unless indicated otherwise									
	C	Si	Mn	P	S[a]	N	Cr	Mo	Ni	Others
P1	0,07	1,00	1,50	0,040	0,030	—	15,0 to 17,0	0,60	3,0 to 5,0	Cu: 3,0 to 5,0 Nb: 0,15 to 0,45
P2	0,09	1,00	1,00	0,04	0,015	—	16,0 to 18,0	—	6,5 to 7,8	Al: 0,70 to 1,50

[a] Particular ranges of sulfur mass fraction may provide improvement in certain properties. For polishability, a controlled sulfur mass fraction of 0,015 % maximum is recommended.

Table 4 — Ferritic stainless steels (composition)

Number in this document	% (mass fraction), maximum values unless indicated otherwise									
	C	Si	Mn	P	S[a]	N	Cr	Mo	Ni	Others
F1	0,08	1,00	1,00	0,040	0,015	—	16,0 to 18,0	—	—	—
F2	0,03	1,00	0,50	0,040	0,15 to 0,35	—	17,5 to 19,0	2,00 to 2,50	—	Ti: 0,30 to 0,80 (C+N): max 0,040
F3	0,08	1,50	1,50	0,040	0,15 to 0,35	—	16,0 to 18,0	0,20 to 0,60	—	—

[a] Particular ranges of sulfur mass fraction may provide improvement in certain properties. For polishability, a controlled sulfur mass fraction of 0,015 % maximum is recommended.

5 Selection of materials

5.1 Selection of stainless steels for dental instruments

Materials for the manufacture of instruments used in dentistry shall be selected with regard to the properties required for the intended purpose, taking into account the effects of manufacture, handling, sterilization and storage (see Clause 6 and Annex B).

The suitability of a given material for a particular application shall be demonstrated by either:

a) design evaluation in accordance with Clause 6; or

b) selection from the materials specified in 4.2, which are found suitable by proven clinical use in similar applications.

In all cases, a biological evaluation for the final product or representative samples from the final product shall be made in accordance with ISO 7405 and ISO 10993-1.

5.2 Certificate of analysis

Manufacturer shall confirm the composition of the stainless steel. The methods of confirmation are at the discretion of the manufacturer.

NOTE One way this can be done is by asking the supplier of the stainless steel to deliver a certificate of analysis (CoA) showing the technical delivery conditions of the stainless steel, such as the chemical composition, mechanical properties and heat treatment. ISO 10474 specifies several types of inspection documents supplied to the purchaser.

5.3 Examples of stainless steels for dental instruments

For most types of instruments used in dentistry, materials that are listed in Table 5, 6, 7 and 8 are known from experience to be suitable for those instruments.

Table 5 — Austenitic stainless steels

Number in this document	Example(s) of dental instruments
A1	impression trays
A2	dental handpiece

Table 5 *(continued)*

Number in this document	Example(s) of dental instruments
A3	sterilization trays/cassette syringe parts
A4	impression trays syringe parts bone collectors bone syringes diamond burs metal strippers orthodontic pliers probes rubber dam frames implant instruments dental tweezer retractors dental mirrors dental suction tubes dental handpiece
A5	sterilization trays/cassette
A6	dental handpiece mallets torque wrenches dressing forceps
A7	dental explorers springs in dental instruments filling instruments dental handpiece
A8	dental tweezers
A9	dental handpiece
A10	syringe tubes dental handpiece
A11	syringe parts dental handpiece
A12	dental handpiece

Table 6 — Martensitic stainless steels

Number in this document	Example(s) of dental instruments
M1	extraction forceps laboratory and orthodontic pliers explorers root elevators filling instruments dental and anatomical tweezers needle holder
M2	dental handpiece rotary instruments
M3	extraction forceps orthodontic pliers explorers root elevators filling instruments dental tweezers periotome dental handpiece rotary burs and cutters shanks for rotary instruments implant drivers torque wrenches excavators bone rongeurs scissors currettes chisel periosteal elevator forceps
M4	hand scalers/scaler tip curettes orthodontic pliers explorers filling instruments dental handpiece rotary instruments
M5	rotary instruments

Table 6 *(continued)*

Number in this document	Example(s) of dental instruments
M6	hand scalers/scaler tip curettes extraction forceps chisels orthodontic pliers explorers root elevators filling instruments tweezers rotary instruments dental handpiece dental and anatomical tweezers needle holder rubber dam plier rubber dam punch bone rongeurs scissors wire-cutting pliers periosteal elevators dental excavators
M7	hand scalers/scaler tip dental explorers root elevators filling instruments dental handpiece rotary instruments

Table 6 *(continued)*

Number in this document	Example(s) of dental instruments
M8	hand scalers/scaler tip dental explorers root elevators filling instruments dental handpiece rotary instruments rotary burs and cutters basic body for grinders, shanks and mandrels bone rongeurs knives chisels and gouges bone curettes wire-cutting pliers curettes chisels drills taps countersink cutters
M9	hand scalers/scaler tip curettes dental extraction forceps chisels orthodontic pliers dental explorers root elevators filling instruments dental tweezers
M10	dental handpiece rotary instruments rotary burs and cutters basic body for grinders, shanks and mandrels elevator

Table 6 *(continued)*

Number in this document	Example(s) of dental instruments
M11	hand scalers/scaler tip curettes extraction forceps dental chisels orthodontic pliers explorers root elevators filling instruments tweezers drills taps countersinks
M12	dental handpiece rotary instruments ancillaries for implant surgery instruments for manual use (hand instruments)
M13	dental handpiece
M14	curettes chisels root elevators explorers filling instruments
M15	dental and anatomical tweezers
M16	shanks for rotary instruments
M17	dental handpiece rotary instruments
M18	shanks for rotary instruments components for instruments for manual use (hand instruments)

Table 6 *(continued)*

Number in this document	Example(s) of dental instruments
M19	hand scalers/scaler tip bone scraper explorer probe retractor chisel periotome elevator root pick curette bone file periodontal knife drills implant depth gauge osteotome bone carrier sinus membrane elevator tissue punch dental excavator margin trimmer amalgam carrier carver amalgam plugger amalgam burnisher composite instruments root canal plugger spreader gingival retraction cord packer crown remover orthodontic instruments trephine burs
M20	pliers
M21	dental handpiece
M22	dental handpiece

Table 7 — Precipitation-hardening stainless steels

Number in this document	Example(s) of dental instruments
P1	implant drivers dental handpiece
P2	probes

Table 8 — Ferritic stainless steels

Number in this document	Example(s) of dental instruments
F1	dental handpiece
F2	dental handpiece
F3	basic body for multi-part burs, cutters, grinders, shanks and mandrels

6 Performance evaluation — Pre-clinical evaluation

The composition of stainless steel covered by this document has been employed successfully to manufacture dental instruments and long-term clinical use has shown that an acceptable biological response can be expected, when used as instructed.

A biological evaluation for the final product or representative samples from the final product shall be made in accordance with ISO 10993-1.

Annex A
(informative)

Equivalent stainless steels

In Tables A.1, A.2, A.3 and A.4, stainless steels that are used for the manufacture of instruments in dentistry are listed along with different designations used in this document and others.

Compositions of Tables 1 to 4 is according to ISO 15510, and below are the equivalent materials. Equivalency here does not indicate perfect matching of stainless steel by individual international and national standards.

Table A.1 — Austenitic stainless steels (equivalency)

Number in this document	Material short-term according to ISO 15510	Material number according to EN 10088–1	AISI-Type according to ASTM	UNS material number according to ASTM A959	Material number according to JIS G 4303	Material number according to GB/T 20878/ ISC	Material number according to KS D 3706
A1	X1NiCr-MoCu25-20-5	1.4539	304L	N08904	SUS 890L	S39042	STS 890L
A2	X2CrNiN18-9	1.4311	304LN	S30453	SUS 304LN	S30453	STS 304LN
A3	X2CrNi-Mo18-14-3	1.4435	316L	F 138	SUS 316L	S31603	STS 316L
A4	X5CrNi18-10	1.4301	304	S30400	SUS 304	S30408	STS 304
A5	X5CrNi-Mo17-12-2	1.4401	316	S31600	SUS 316	S31608	STS 316
A6	X10CrNiS18-9	1.4305	303	S30300	SUS 303	S30317	STS 303
A7	X10CrNi18-8	1.4310	301	S30100		S30110	STS 301
A8	—	1.4303	—	—	SUS 305	—	—
A9	X2CrNiMoC-uS17-10-2	1.4598	—	—	—	—	—
A10	X2CrNi18-9	1.4307	—	S30403	SUS 304L	S30403	STS 304L
A11	X2CrNi-Mo17-12-2	1.4404	—	S31603	SUS 316L	S31603	STS 316L
A12	—	1.4305[a]	—	—	—	—	—

[a] Also known as X8CrNiS18-9 in accordance to EN 10088-1.

Table A.2 — Martensitic stainless steels (equivalency)

Number in this document	Material short-term according to ISO 15510	Material number according to EN 10088–1	AISI-Type according to ASTM	UNS material number according to ASTM A959	Material number according to JIS G 4303	Material number according to GB/T 20878/ ISC	Material number according to KS D 3706
M1	X15Cr13	1.4024	410	S41000	SUS 410	—	STS 410
M2	X17CrNi16-2	1.4057	431	S43100	SUS 431	S43120	STS 431
M3	X20Cr13	1.4021	420A	S42000	SUS 420J1	S42020	STS 420J1
M4	—	1.4197	420MOD	—	—	—	—
M5	—	—	—	—	—	—	—
M6	X30Cr13	1.4028	420	S42000	SUS 420J2	S42030	STS 420J2
M7	X39CrMo17-1	1.4122	—	S43409	—	—	—
M8	X46Cr13	1.4034	420C	S42000	—	S42040	—
M9	X50CrMoV15	1.4116	—	S42077	—	—	—