
**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

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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.

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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.

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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.

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2 Normative references (standards.iteh.ai)

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

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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. <https://standards.iteh.ai/catalog/standards/sist/c20f2df8-4a4d-43fc-aba7-b3c2d7854be1/iso-21850-1-2020>

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:

- design evaluation in accordance with [Clause 6](#); or
- 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