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Surgical instruments — Materials —

Part 1: Metals

Instruments chirurgicaux — Matériaux —

Partie 1: Métaux

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Contents

Page

Foreword ..... **iv**
1 Scope **1**
2 Normative references **1**
3 Fields of application of materials **1**
4 Materials **8**
Annex A (informative) **Examples of dental instruments** **11**
Bibliography **13**

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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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 170, *Surgical instruments*.

This third edition cancels and replaces the second edition (ISO 7153-1:1991), which has been extended from stainless steels to metals and has been technically revised.

It also incorporates the Amendment ISO 7153-1:1991/Amd 1:1999.

ISO 7153 consists of the following parts, under the general title *Surgical instruments — Materials*:

— *Part 1: Metals*

Surgical instruments — Materials —

Part 1: Metals

1 Scope

This part of ISO 7153 specifies metals commonly used to manufacture various types of standard surgical instruments, including but not limited to those used in general surgery, orthopaedics and dentistry.

While this part of ISO 7153 is not intended for surgical instruments used in special applications, such as implantology and minimally invasive surgery, parts of it might be applicable to those instruments.

NOTE When selecting the grade of steel and the shape, dimensions and delivery conditions of the raw material for manufacturing surgical instruments, it is necessary to take into account factors, such as the design of the instrument or the production facilities of the manufacturer, that are not covered by this part of ISO 7153. For this reason, it is not intended, nor is it possible, for the information given in this part of ISO 7153 to remove the decision-making responsibility from the instrument manufacturer for selecting an appropriate raw product with suitable properties; nor is it intended to preclude the use of other types of steel in the manufacture of instruments, such as the use of carbon steel for cutting instruments. International Standards for surgical instruments, when published, can be observed when making this decision as they may contain additional or new information to be taken into account when selecting appropriate steel grades.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 6508-1, *Metallic materials — Rockwell hardness test — Part 1: Test method*

EN 10088-1, *Stainless steels — Part 1: List of stainless steels*

ASTM B 265, *Standard Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate*

ASTM B 348, *Standard Specification for Titanium and Titanium Alloy Bars and Billets*

3 Fields of application of materials

Since there are different requirements to various surgical instruments, there also have to be different requirements to the materials from which the instruments are manufactured. For this reason, not all of the materials listed within Clause 4 are suited to use in every type of instrument. For most types of surgical instruments, materials are given in Tables 1 to 3 which are known from experience to be suitable for those instruments. Although it might be possible that other materials are also suited to the manufacture of some types of instruments, this is not covered by this part of ISO 7153.

Table 1 indicates which stainless steels are commonly used to manufacture various types of standard instruments and instrument components. In the first column, a reference letter is given pointing to the stainless steels specified within Table 4. In addition, the second column gives the respective reference letters used within the previous version of this part of ISO 7153. This additional information is only provided as a courtesy for users of this part of ISO 7153 who are familiar with the previous version.

Table 1 — Fields of application — Stainless steel

Reference letter for Table 4	Reference letter according to ISO 7153-1:1991 (withdrawn)	Surgical instruments																				Components			
		elevators/raspatories	forceps	forceps with wear protection (inserts or coating)	scissors	scissors with wear protection (inserts or coating)	forceps with bow handles	forceps with bow handles with wear protection (inserts or coating)	bone rongeurs	bone cutting forceps	laminectomy rongeurs	branch for ceps	conchotomes	scalpels/knives	retractors	probes	chisels and gouges / curettes / bone curettes	mallets	needle holders	needle holders with wear protection (inserts or coating)	self-retaining retractors / sternum spreaders	springs	solid handles	hollow handles	screws/rivets/guide pins
a	B	X	X	X[a]		X[a]	X	X[a]	X	X	X	X	X		X	X	X		X	X[a]	X	X			X
b	A		X	X[a]			X	X[a]				X			X	X			X	X[a]	X				X
c	D	X			X	X[a]			X	X	X		X	X			X								
d																									
e	L																	X					X		X
f	R																X								
g	I	X			X	X[a]			X	X	X		X	X			X								
h	H	X			X	X[a]			X	X	X		X	X			X								
i	M		X												X	X								X	X
j	N														X[b]	X[b]	X[b]	X					X		X
k	O																								
l	P														X	X									
m																									
o			X	X			X	X																	X
p	G+S		X	X			X	X																	X
q																	X								

[a] For instruments with wear protection hardness values are only applicable to the carrier material.

[b] For bendable shafts.

In Table 2, it is indicated which hard metals are commonly used to manufacture various types of standard instruments and instrument components. In the first column, a reference letter is given pointing to the hard metals specified within Table 6.

Table 2 — Fields of application — Hard metals

Reference letter for Table 6	Surgical instruments																				Components			
	elevators/ raspatories	forceps	forceps with wear protection (inserts or coating)	scissors	scissors with wear protection (inserts or coating)	forceps with bow handles	forceps with bow handles with wear protection (inserts or coating)	bone rongeurs	bone cutting forceps	laminectomy rongeurs	branch for ceps	conchotomes	scalpels/ knives	retractors	probes	chisels and gouges /curettes/ bone curettes	mallets	needle holders	needle holders with wear protection (inserts or coating)	self-retaining retractors/ sternum spreaders	springs	solid handles	hollow handles	screws / rivets / guide pins
aa					X																			
ab			X				X												X					
ac			X		X		X												X					

In Table 3, it is indicated which kind of titanium grades or alloys are commonly used to manufacture various types of standard instruments and instrument components. In the first column, a reference letter is given pointing to the titanium grades or alloys specified within Table 7.

Table 3 — Fields of application — Titanium

Reference letter for Table 7	Surgical instruments																				Components			
	elevators / raspatories	Forceps	forceps with wear protection (inserts or coating)	scissors	scissors with wear protection (inserts or coating)	forceps with bow handles	forceps with bow handles with wear protection (inserts or coating)	bone rongeurs	bone cutting forceps	laminectomy rongeurs	branch forceps	conchotomes	scalpels/ knives	retractors	probes	chisels and gouges/curettes/ bone curettes	mallets	needle holders	needle holders with wear protection (inserts or coating)	self-retaining retractors / sternum-spreaders	springs	solid handles	hollow handles	screws / rivets / guide pins
ba														X	X									
bb														X	X									
bc														X	X									
bd														X	X									
bf		X	X	X		X	X				X			X	X			X	X		X	X		X

4 Materials

In Table 4, grades of stainless steels commonly used to manufacture various types of surgical instruments are listed. Additionally, hardness values in Rockwell as well as in Vickers are given, where possible.

Table 4 — Stainless steel

Reference letter according to Table 1	Material number according to EN 10088–1:2014	Material short-term according to EN 10088–1:2014	Hardness in Rockwell (HRC) ISO 6508-1	Hardness in Vickers HV5/ HV10[a] ISO 6507-1	Steel grade
b	1.4006	X12Cr13	35	360	martensitic
e	1.4016	X6Cr17	N.A.	N.A.	ferritic
a	1.4021	X20Cr13	42 - 50	420 - 530	martensitic
b	1.4024	X15Cr13	40 - 48	400 - 500	martensitic
g	1.4028	X30Cr13	49 - 55	510 - 620	martensitic
c	1.4034	X46Cr13	50 - 58	530 - 675	martensitic
m	1.4037	X65Cr13	57 - 61	650 - 750	martensitic
d	1.4057	X20CrNi16–2	40 - 48	400 - 500	martensitic
e	1.4104	X14CrMoS17	30	310	martensitic
e	1.4105	X6CrMoS17	N.A.	N.A.	ferritic
q	(1.4108)[b]	X30CrMoN15–1	54 - 59	590 - 700	martensitic
p	1.4109	X70CrMo15	55 - 60	610 - 720	martensitic
f	1.4112	X90CrMoV18	52 - 60	545 - 720	martensitic
g	1.4116	X50CrMoV15	50 - 58	530 - 675	martensitic
h	1.4117[b]	X38CrMoV15	50 - 58	530 - 675	martensitic
f	(1.4121)[b]	X22CrMoNiS13–1	48 - 54	500 - 600	martensitic
c	1.4122	X39CrMo17–1	50 - 58	530 - 675	martensitic
f	1.4123	X40CrMoVN16–2	52 - 57	560 - 660	martensitic
—	1.4125	X105CrMo17	54 - 60	590 - 720	martensitic
f	1.4197[c]	X22CrMoNiS13–1	48 - 54	500 - 600	martensitic
i	1.4301	X5CrNi18–10	N.A.	N.A.	austenitic
j	1.4305	X8CrNiS18–9	N.A.	N.A.	austenitic
k	1.4310	X10CrNi18–8	N.A.	N.A.	austenitic
l	1.4401	X5CrNiMo17–12–2	N.A.	N.A.	austenitic
m	1.4441	X2CrNiMo18–15–3	N.A.	N.A.	austenitic
o	1.4542	X5CrNiCuNb16–4	selectable	selectable	precipitation hardening
p	1.4543	X3CrNiTiNb 12–9	selectable	selectable	precipitation hardening

[a] The conversion from Rockwell hardness to Vickers hardness is done according to ISO 18265:2003, Table A.1.

To the calculated HV5/HV10 value 1 HRC (value based on experience for stainless steels) was added.

[b] Not included in EN 10088–1. Where the material number is given in brackets, the material was only included in the steel-iron-list.

[c] Historic material number which is used in different fields of application than 1.4121, but is designated to the same material (as 1.4121). 1.4197 is used for rotating instruments.

Table 5 constitutes a correspondence between EN 10088-1 and the material classifications given by other steel-related standards. All the information in Table 5 is only given as a courtesy to users of this part of ISO 7153 and is not of normative character.

The second column relates the material number according to EN 10088-1 to the reference letter and the respective chemical compositions detailed in the withdrawn ISO 7153-1:1991. Since the material number according to EN 10088-1 does not in all cases correspond directly to the reference letters of ISO 7153-1:1991, the third column gives an indication when the chemical compositions are identical, very similar or differ substantially. "I" stands for the chemical compositions of the given steels being identical, "N" for very similar, but not identical and "W" means that they differ substantially.

In the fourth and fifth column, the same information is given with respect to ASTM F 899-12. In the sixth column, the also commonly used UNS material number is given simply as additional information.

Table 5 — Correspondence table between EN 10088–1 and other standards

Material number according to EN 10088–1:2014	Reference letter according to ISO 7153-1:1991 (withdrawn)	Degree of similarity[a] to ISO 7153-1:1991 (withdrawn)	AISI-Type according to ASTM F 899–12b	Degree of similarity[a] to ASTM F 899–12b	UNS material number according to ASTM
1.4006	A	I	410	I	S41000
1.4016	—	—	430	W	S43000
1.4021	B	I	420 A	I	S42000
1.4024	A	N	410	I	S41000
1.4028	C	I	420 B	N	S42000
1.4034	D	I	420 C	N	S42000
1.4037	F	I	—	—	—
1.4057	—	—	431	W	S43100
1.4104	L	N	—	—	—
1.4105	L	I	430 F	N	S43020
(1.4108)	—	—	—	—	S42027
1.4109	G+S	W	440 A	W	S44002
1.4112	R	I	440 B	W	S44003
1.4116	I	N	—	—	—
1.4117	H	I	420 Mod	W	S42000
(1.4121)	—	—	420 F Mod	N	—
1.4122	K	N	—	—	—
1.4123	—	—	420 Mod	W	S42000
1.4125	—	—	440C	I	S44004
1.4197	—	—	420 F Mod	N	—
1.4301	M	N	304/304H	N	S30400
1.4305	N	N	303	N	S30300
1.4310	O	I	~301/302	N	S30100 S30200
1.4401	P	N	316	N	S31600
1.4441	—	—	—	—	S31673
1.4542	—	—	630 (17–4 PH)	N	S17400
1.4543	—	—	XM-16	I	S45500

[a] I = identical; *N* = very similar, but not identical; W = bigger differences to EN 10088–1.

In Table 6, different types of hard metals are given which are commonly used to manufacture various types of surgical instruments. To specify these hard metals, their hardness in Vickers is given.

Table 6 — Hard metals

Reference letter according to Table 2	Designation	Alloy type	Hardness in Vickers ISO 6507-1
aa	filler rod or solder pad	Cobalt-Chrome-Tungsten	≥650 HV 10
ab	sinter plate	Tungsten carbide cobalt-binder	≥1 100 HV 10
ac	sinter plate	Tungsten carbide nickel-binder	≥1 100 HV 10

In Table 7, different grades of pure titanium and one titanium alloy are given. A reference to ISO 5832-2 and accordingly ISO 5832-3 is included to specify the quality required for surgical instruments. Additionally, similar references are given for ASTM standards.

Table 7 — Titanium

Reference letter according to Table 3	ISO implant quality	ASTM implant quality	ASTM B 265a, B 348 standard quality	Type
ba	5832–2 Grade 1	F67-Gr1	Grade 1	pure
bb	5832–2 Grade 2	F67-Gr2	Grade 2	pure
bc	5832–2 Grade 3	F67-Gr3	Grade 3	pure
bd	5832–2 Grade 4	F67-Gr4	Grade 4	pure
bf	5832–3	F136	Grade 5	alloy

Annex A
(informative)

Examples of dental instruments

In the previous edition of this part of ISO 7153, more detailed examples of instruments and the stainless steel types commonly used to manufacture them were provided. This information was especially helpful for dental instruments because, in some cases, these cannot be easily assigned to one of the types of instruments given in Table 1. It was, therefore, decided to update this information for dental instruments and provide it in the following Table A.1. References to commonly used materials for instrument components can be found in Table 1 and Table 3.

Table A.1 — Stainless steel grades commonly used for dental instruments

Reference letter for Table 4	Reference letter according to ISO 7153-1:1991 (withdrawn)	Dental instruments
a	**B**	dental extraction forceps laboratory and orthodontic pliers dental explorers root elevators filling instruments dental tweezers
b	**A**	dental tweezers
c	**D**	scalers dental explorers root elevators filling instruments
f	**R**	scalers dental curettes laboratory and orthodontic pliers dental explorers filling instruments
g	**C**	scalers dental curettes dental extraction forceps dental chisels laboratory and orthodontic pliers dental explorers root elevators filling instruments dental tweezers

Table A.1 *(continued)*

Reference letter for Table 4	Reference letter according to ISO 7153-1:1991 (withdrawn)	Dental instruments
i	**M**	impression trays
k	**O**	dental explorers
p	**S**	scalers dental curettes dental explorers filling instruments

Bibliography

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

[2] ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*

[3] ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

[4] ISO 18265:2003,[1)] *Metallic materials — Conversion of hardness values*

[5] EN 573-3, *Aluminium and aluminium alloys — Chemical composition and form of wrought products — Part 3: Chemical composition and form of products*

[6] ASTM F 899b, *Standard Specification for Wrought Stainless Steels for Surgical Instruments*

1) Withdrawn. Replaced by ISO 18265:2013.

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