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ISO/DIS 7153-1

ISO/TC 170

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Surgical instruments — Materials —

Part 1: Metals

Instruments chirurgicaux — Matériaux —

Partie 1: Métaux

ICS: 11.040.30; 77.140.20

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ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

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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.

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 7153-1 was prepared by Technical Committee ISO/TC 170, *Surgical instruments*, Subcommittee SC , and by Technical Committee CEN/TC 55, *Dentistry* in collaboration.

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

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

— *Part 1: Metallic Materials*

Surgical instruments — Materials — Part 1: Metals

1 Scope

This document specifies metallic materials 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 document 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 standard. For this reason, it is not intended, nor is it possible, that the information given in this standard should 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, should 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 753-3, *Aluminium and aluminium alloys - Chemical composition and form of wrought products - Part 3: Chemical composition and form of products*

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

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

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

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

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 of which the instruments are manufactured. For this reason not all of the materials listed within Clause 4 are suited to be used for 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 manufacture some types of instruments, this is not covered by this International Standard.

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In Table 1 it is indicated 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 standard. This additional information is only provided as a courtesy for users of this standard 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 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
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>i</i>	M		X												X	X										X	X
<i>j</i>	N														X ^b	X ^b	X ^b	X							X		X
<i>k</i>	O																										
<i>l</i>	P														X	X											
<i>m</i>																											
<i>o</i>			X	X			X	X																			X
<i>p</i>	G+S		X	X			X	X																			X
<i>q</i>																	X										
<p>^a For instruments with wear protection hardness values are only applicable to the carrier material.</p> <p>^b For bendable shafts.</p>																											

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						
aa	ab	ac		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
						X																					
										X																	