

**SLOVENSKI STANDARD
SIST EN ISO 7153-1:2001****01-november-2001**

Kirurški instrumenti - Kovinski materiali - 1. del: Nerjavno jeklo (ISO 7153-1:1991, vključno z dopolnilom 1:1999)

Surgical instruments - Metallic materials - Part 1: Stainless steel (ISO 7153-1:1991, including Amendment 1:1999)

Chirurgische Instrumente - Metallische Werkstoffe - Teil 1: Nichtrostender Stahl (ISO 7153-1:1991, einschließlich Änderung 1:1999)

Instruments chirurgicaux - Matériaux métalliques - Partie 1: Acier inoxydable (ISO 7153-1:1991, Amendement 1:1999 inclus)

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Ta slovenski standard je istoveten z: EN ISO 7153-1:2000**ICS:**

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials
77.140.20	Visokokakovostna jekla	Stainless steels

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 7153-1

October 2000

ICS 11.040.30; 77.140.20

English version

Surgical instruments - Metallic Materials - Part 1: Stainless steel
(ISO 7153-1:1991, including Amendment 1:1999)

Instruments chirurgicaux - Matériaux métalliques - Partie 1:
Acier inoxydable (ISO 7153-1:1991, Amendement 1:1999
inclus)

Chirurgische Instrumente - Metallische Werkstoffe - Teil 1:
Nichtrostender Stahl (ISO 7153-1:1991, einschließlich
Änderung 1:1999)

This European Standard was approved by CEN on 9 September 2000.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

The text of the International Standard from Technical Committee ISO/TC 170 "Surgical instruments" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC 55 "Dentistry", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 7153-1:1991, including Amendment 1:1999, has been approved by CEN as a European Standard without any modification.

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INTERNATIONAL STANDARD

ISO
7153-1

Second edition
1991-04-01

Surgical instruments — Metallic materials —

Part 1: Stainless steel

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Instruments chirurgicaux — Matériaux métalliques —

Partie 1: Acier inoxydable

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Reference number
ISO 7153-1:1991(E)

ISO 7153-1:1991(E)

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.

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.

International Standard ISO 7153-1 was prepared by Technical Committee ISO/TC 170, *Surgical instruments*.

This second edition cancels and replaces the first edition (ISO 7153-1:1983); it has been extended to include dental instruments.

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

- *Part 1: Stainless steel*

Future parts of ISO 7153 will cover other metallic materials.

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Surgical instruments — Metallic materials —

Part 1: Stainless steel

1 Scope

This part of ISO 7153 contains a survey and a selection of stainless steels available for use in the manufacture of surgical, dental and specific instruments for orthopaedic surgery.

NOTE 1 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, that the information given in this part of ISO 7153 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 infor-

mation to be taken into account when selecting appropriate steel grades.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7153. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7153 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 683-13:1986, *Heat-treatable steels, alloy steels and free-cutting steels — Part 13: Wrought stainless steels.*

ISO 4957:1980, *Tool steels.*

3 Survey

Table 1 — Steel grades

Reference letter of steel grade (see table 2)	cutting instruments	Preferably used for non-cutting instruments	fitting parts and other assemblies
	Examples	Examples	Examples
A		tissue forceps, dressing forceps, retractors, probes, dental tweezers	rivets, solid handles, guide pins, screws, nuts
B	bone rongeurs, bone-cutting forceps, conchotomes, chisels and gouges, bone curettes, scissors with carbide inserts	forceps, forceps with bow handles, branch forceps, retractors, probes, dental extraction forceps, laboratory and orthodontic pliers, dental explorers, root elevators, filling instruments, dental tweezers	springs, solid handles, screws, nuts, rivets
C	bone rongeurs, scissors, scalars, dental curettes, dental chisels	laboratory and orthodontic pliers, dental explorers, dental tweezers, dental extraction forceps, root elevators, filling instruments	
D	scissors, bone rongeurs, bone-cutting forceps, conchotomes, scalpels, knives, chisels and gouges, bone curettes, wire-cutting pliers, scalars, dental curettes, dental chisels, drills, taps, countersink cutters	root elevators, dental explorers, filling instruments	
E	scalpels		
F	scalpels		
G	scalpels, chisels and gouges, shears		

Reference letter of steel grade (see table 2)	cutting instruments	Preferably used for non-cutting instruments	fitting parts and other assemblies
	Examples	Examples	Examples
H	scissors, bone rongeurs, conchotomes, chisels and gouges, bone curettes, wire-cutting pliers, drills, taps, countersink cutters		
I	scissors, bone rongeurs, bone-cutting forceps, conchotomes, scalpels, knives, chisels and gouges, bone curettes, wire-cutting pliers drills, taps, countersink cutters		
K	chisels and gouges, bone curettes		
L			solid handles, guide pins, screws, nuts
M		retractors, impression trays	hollow handles, guide pins, rivets, screws
N	chisels and gouges, bone curettes	probes	solid handles, guide pins, screws, nuts, rivets
O		dental explorers	springs, screws, rivets
P			screws, rivets
R	scalars, chisels, dental curettes, drills, taps, countersink cutters	filling instruments, dental explorers, laboratory and orthodontic pliers	

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