Surgical instruments - Materials - Part 1: Metals (ISO 7153-1:2016)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 7153-1:2016 sisaldab Euroopa standardi EN ISO 7153-1:2016 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 7153-1:2016 consists of the English text of the European standard EN ISO 7153-1:2016.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 26.10.2016.	Date of Availability of the European standard is 26.10.2016.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.30, 77.140.20

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7153-1

October 2016

ICS 11.040.30; 77.140.20

Supersedes EN ISO 7153-1:2000

English Version

Surgical instruments - Materials - Part 1: Metals (ISO 7153-1:2016)

Instruments chirurgicaux - Matériaux - Partie 1: Métaux (ISO 7153-1:2016)

Chirurgische Instrumente - Werkstoffe - Teil 1: Metalle (ISO 7153-1:2016)

This European Standard was approved by CEN on 10 September 2016.

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 CEN-CENELEC 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 7153-1:2016 E

European foreword

This document (EN ISO 7153-1:2016) has been prepared by Technical Committee ISO/TC 170 “Surgical instruments” in collaboration with 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 2017, and conflicting national standards shall be withdrawn at the latest by April 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7153-1:2000.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 7153-1:2016 has been approved by CEN as EN ISO 7153-1:2016 without any modification.

Contents

Page

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).

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.

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.