INTERNATIONAL STANDARD

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Surgical instruments — Materials —

Part 1: Metals

Instruments chirurgicaux — Matériaux —

Partie 1: Métaux

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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.

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.