



FINAL DRAFT International Standard

ISO/FDIS 7151

Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods

Instruments chirurgicaux — Instruments articulés, non tranchants — Spécifications générales et méthodes d'essai

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Foreword

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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 of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 170, *Surgical instruments*.

This third edition cancels and replaces the second edition (ISO 7151:1988), which has been technically revised.

The main changes are as follows:

- normative references updated;
- test methods for the determination of resistance against autoclaving, corrosion and thermal exposure updated to reference ISO 13402.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods

1 Scope

This document specifies general requirements and corresponding test methods for a general range of non-cutting instruments in surgery.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

ISO 7153-1, *Surgical instruments — Materials — Part 1: Metals*

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

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

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

4 Material

The instrument, except for inserts, shall be made of the grade of stainless steel specified in ISO 7153-1 in accordance with [Table 1](#).

Table 1 — Steel grades

Instrument and component parts			Steel grade – Reference letter in accordance with ISO 7153-1
Non-cutting, articulated instruments, except retractors			a
Retractors	Blade		a, b and i
	Body	Small	a and b
		Large	a
Rivets and screws			a, b, e, i, j, k and l

5 Requirements

5.1 Heat, treatment and hardness for component parts, excluding rivets and screws and part manufactures of material grade i

5.1.1 Heat treatment

The component parts of the instruments shall be heat-treated under suitable conditions to ensure conformity to the requirements of [5.1.2](#) and [5.1.3](#) for the material used.

5.1.2 Hardness of instruments

The Rockwell hardness of the finished instruments shall be in the range of 40 HRC to 48 HRC (approximately equivalent to a Vickers hardness range of 390 HV to 485 HV) when tested in accordance with ISO 6508-1 and ISO 6507-1.

Mating surfaces on the same instrument, such as opposite jaws and shanks, shall not vary in hardness by more than 4 units on the Rockwell hardness scale.

5.1.3 Hardness of tungsten carbide inserts

The Vickers hardness of the tungsten carbide inserts shall be at least 1 000 HV 10 when tested in accordance with ISO 6507-1.

5.2 Corrosion resistance

5.2.1 General

The instruments shall conform to one or both of the requirements given in [5.2.2](#) and [5.2.3](#).

When placing an order, the purchaser may state which of the tests shall be carried out. In the absence of such a request, the choice of at least one test is left to the manufacturer.

5.2.2 Test for resistance to copper sulfate

The test for resistance to copper sulfate shall be performed as specified in ISO 13402.

5.2.3 Test for resistance to boiling water

The test for resistance to boiling water shall be performed as specified in ISO 13402.

5.3 Workmanship

Serrations shall mesh exactly in the fully closed position of the instrument.