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

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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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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, l, o and p

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.

Teeth and prongs shall be appropriately sharp and equally shaped on both parts of the instrument. They shall mesh exactly and there shall be no resistance when the instrument is reopened.

Unless otherwise specified, there shall be no sharp edges. Sharp edges around the sides of jaws shall be removed.

The instruments shall have joints which move smoothly and which shall be neither too loose nor too tight; it shall be possible to close and reopen the instrument easily with two fingers.

5.4 Surface condition

5.4.1 General

All surfaces shall be free from pores, crevices and grinding marks. The instruments shall be supplied free from residual scale, acid, grease, and grinding and polishing materials. Conformity to these requirements shall be checked by inspection using normal vision, corrected if necessary.

5.4.2 Surface finish

The surface finish shall be one of, or a combination of, the following:

a) mirror polished;

b) reflection-reducing, e.g. satin finish, matt black finish;

c) an applied surface coating, e.g. for insulation purposes.

The satin finish should be achieved using an appropriate procedure, e.g. grinding, brushing, electro-polishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth, and it should reduce glare.

Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks in order to achieve a mirror finish. This should be achieved using an appropriate procedure, e.g. polishing, brushing, electro-polishing and mirror buffing.

5.4.3 Passivation and final treatment

The instruments shall be finally cleaned and passivated using a suitable validated process and suitable cleaning and passivation agent (immersion or spraying process). The surfaces shall be biocompatible in accordance with ISO 10993-1. Joints and/or sliding surfaces shall be lubricated with a biocompatible, silicone free sterilizable oil.

5.5 Elasticity

The elasticity of the instruments shall be tested in accordance with 6.3.

After the test, no distortion, cracks or any other permanent modifications shall be visible.

5.6 Function of needle holders

The function of needle holders shall be tested in accordance with 6.4.

The fibre shall not slip out, irrespective of whether the direction of the load is longitudinal or transverse.

6 Test methods

6.1 Copper sulfate test

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

6.2 Boiling water test

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

6.3 Elasticity test for haemostatic forceps and needle holders

Place a test wire in accordance with Table 2 or Table 3 as appropriate between the tips of the instrument jaws. Fully close the instrument to the last ratchet position. Leave the instrument in this position for 3 h at room temperature. Examine the instrument for the presence of cracks and permanent deformation.

Table 2 — Test wire for haemostatic forceps

Dimensions in millimetres

Test wire	Diameter of test wire	Nominal length (overall length) of haemostatic forceps
Wire of stainless steel grade i, in accordance with ISO 7153-1 or other similar material	2	Up to 130
	3	130 – 150
	4	150 – 200
	5	Over 200

Table 3 — Test wire for needle holders

Dimensions in millimetres

Type	Diameter of test wire	Nominal length (overall length) of needle holder
Wire of stainless steel grade i, in accordance with ISO 7153-1 or other similar material	0,8	Up to 160
	1	Over 160

6.4 Function test of needle holders

Place a plastic fibre (e.g. a suture filament) of maximum diameter 0,2 mm between the jaws of the instrument at a point within the third of the length nearest the tip. Fully close the instrument and apply a tensile force of 20 N to the fibre. Record whether the fibre is pulled out from the jaws.

7 Marking

The instrument shall be marked with at least the trademark of the manufacturer or supplier.

Instruments having tungsten carbide inserts shall have gold-coloured handles.

The marking shall be done according to ISO 20417.