INTERNATIONAL STANDARD

ISO
7151

Second edition
1988-12-01

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

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

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

Reference number
ISO 7151 : 1988 (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 approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 7151 was prepared by Technical Committee ISO/TC 170, *Surgical instruments.*

This second edition cancels and replaces the first edition (ISO 7151 : 1983), of which it constitutes a minor revision.

Printed in Switzerland

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

1 Scope

This International Standard specifies general requirements and corresponding test methods for a general range of non-cutting, articulated instruments used in surgery.

2 References

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 683-13 : 1986, *Heat-treated steels, alloy steels and free cutting steels — Part 13: Wrought stainless steels.*

ISO 6507-1 : 1982, *Metallic materials — Hardness test — Vickers test — Part 1:* HV 5 *to* HV 100.

ISO 6508 : 1986, *Metallic materials — Hardness test — Rockwell test (scales A — B — C — D — E — F — G — H — K).*

ISO 7153-1 : 1983, *Instruments for surgery — Metallic materials — Part 1: Stainless steel.*

3 Material

The instruments, 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			B
Retractors	— blade		A, B and M
	— body	small	A and B
		large	B
Rivets and screws			A, B, L, M, N, O and P

4 Requirements

4.1 Heat treatment and hardness for component parts, excluding rivets and screws and parts manufactured of material grade M

4.1.1 Heat treatment

The component parts of the instruments shall be heat-treated under suitable conditions to ensure compliance with the requirements of 4.1.2 and 4.1.3 for the material used.

4.1.2 Hardness of instruments

The Rockwell hardness of the finished instruments shall be within the range 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 and ISO 6507-1 respectively.

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.

4.1.3 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. The inserts of opposite blades shall not vary in hardness by more than 50 units on the Vickers HV 10 hardness scale.

4.2 Corrosion resistance

4.2.1 General

The instrument shall comply with one or both of the requirements given in 4.2.2 and 4.2.3.

NOTE — Two test methods are specified for determining corrosion resistance. When placing an order, it is intended that the purchaser state whether both tests are to be carried out or, if not, which of the tests is to be carried out. If the purchaser does not so indicate, the choice is left to the discretion of the manufacturer.

4.2.2 Test for resistance to copper sulfate

Except as specified below, there shall be no plating of copper on the instruments, when tested as specified in 5.1. Copper plating at the edges of the drops of the copper sulfate solution, or at soldered or brazed junctions, or dulling of polished surfaces caused by the copper sulfate solution, shall be disregarded. A slight plating of copper in small areas of the joints, ratchets and serrations of the jaw shall be disregarded.

4.2.3 Test for resistance to boiling water

When tested as specified in 5.2, there shall be no visible signs of corrosion.

4.3 Workmanship

The instruments shall be manufactured in accordance with the recognized standards of 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 the 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.

4.4 Surface condition

4.4.1 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. Compliance with these requirements shall be checked by inspection using normal vision, corrected, if necessary.

4.4.2 Surface finish

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

a) mirror polished;

b) reflection-reducing, for example satin finish, matt black finish;

c) an applied surface coating, for example for insulation purposes.

NOTES

1 The satin finish should be achieved using an appropriate procedure, for example grinding, brushing, electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth, and it should reduce glare.

2 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, for example polishing, brushing, electropolishing and mirror buffing.

4.4.3 Passivation and final treatment

The instruments shall, unless the metallurgical characteristics of the instrument (for example the presence of brazed or soldered joints) renders it inappropriate, be treated by a passivation process in accordance with good practice for these types of stainless steel.

NOTES

1 Examples of methods of passivation are by electropolishing or by treating with 10 % (*V*/*V*) nitric acid solution for not less than 30 min at a temperature of not less than 10 °C and not exceeding 60 °C. The instruments should then be rinsed in water and dried in hot air.

2 If the joints are lubricated, the lubricant should be non-corrosive and suitable for medical application in accordance with the relevant national pharmacopoeia.

4.5 Elasticity

The elasticity of the instruments shall be tested in accordance with 5.3.

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

4.6 Function of needle holders

The function of needle holders shall be tested in accordance with 5.4.

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

5 Test methods

5.1 Copper sulfate test

5.1.1 Test solution

Copper(II) sulfate pentahydrate ($CuSO_4 \cdot 5H_2O$)	4 g
Sulfuric acid [$\varrho(H_2SO_4) = 1{,}84$ g/ml]	10 g
Distilled or de-ionized water	90 ml

5.1.2 Apparatus

Glass or ceramic beaker.

5.1.3 Preparation of sample

Scrub the instrument using soap and warm water, rinse thoroughly in distilled water, dip in 95 % (*V*/*V*) ethanol and dry.

5.1.4 Procedure

Immerse the instrument in the test solution contained in the beaker at room temperature for 6 min. Remove the instrument and wash it with distilled water or water of equivalent quality, or wipe it with wet cotton wool. Examine the instrument for evidence of copper deposits.

5.2 Boiling water test

5.2.1 Reagent

Distilled or de-ionized water.

5.2.2 Apparatus

Glass or ceramic beaker or suitable corrosion-resistant stainless steel vessel.

5.2.3 Preparation of sample

Scrub the instrument using soap and warm water, rinse thoroughly in water (5.2.1) and dry.

5.2.4 Procedure

Immerse the instrument in boiling water (5.2.1) in the beaker or vessel for at least 30 min. Subsequently, allow the instrument to cool for at least 1 h in the water used for the test.

Then remove the instrument from the water and leave it exposed to the air for 2 h. Rub the instrument vigorously with a dry cloth and examine it for the presence of blemishes.

5.3 Elasticity test for haemostatic forceps and needle holders

Place a test wire in accordance with table 2 or 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.

5.4 Function test of needle holders

Place a plastics 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.

6 Marking

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

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

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 11 in accordance with ISO 683-13 or other similar material	2	up to 130
	3	over 130 to 150
	4	over 150 to 200
	5	over 200

Table 3 — Test wire for needle holders

Dimensions in millimetres

Test wire	Diameter of test wire	Nominal length (overall length) of needle holders
Wire of stainless steel grade 11 in accordance with ISO 683-13 or other similar material	0,8	up to 160
	1	over 160

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UDC 615.472

Descriptors : medical equipment, surgical equipment, retractors (surgical instruments), tests, specifications.

Price based on 3 pages