
International Standard 7151

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Instruments for surgery — Haemostatic forceps — Requirements

Instruments chirurgicaux — Pincés hémostatiques — Exigences

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Foreword

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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.

International Standard ISO 7151 was developed by Technical Committee ISO/TC 170, *Surgical instruments*, and was circulated to the member bodies in December 1981.

It has been approved by the member bodies of the following countries:

China	Germany, F.R.	South Africa, Rep. of
Czechoslovakia	India	United Kingdom
Denmark	Mexico	USSR
Egypt, Arab Rep. of	Poland	
France	Romania	

No member body expressed disapproval of the document.

Instruments for surgery — Haemostatic forceps — Requirements

1 Scope and field of application

This International Standard specifies requirements and corresponding routine test methods for a general range of haemostatic forceps used in surgery.

NOTE — It is intended to extend the scope of this International Standard to cover other types of forceps.

2 References

ISO/R 80, *Rockwell hardness test (B and C scales) for steel*.

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

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

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

3 Material

3.1 Component parts

The component parts of the instruments, excluding the rivet or screw, shall be made of stainless steel complying with the requirements for grade 4 of ISO 683/13 and as given in ISO 7153/1.

3.2 Rivet and screw

The rivet or screw shall be made of stainless steel chosen, at the discretion of the manufacturer, from the grades specified in ISO 683/13.

4 Requirements

4.1 Heat treatment and hardness for component parts, excluding rivets and screws

4.1.1 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 The Rockwell hardness of the finished instruments shall be within the range 40 to 48 HRC (approximately equivalent to a Vickers hardness range of 390 to 485 HV) when tested in accordance with ISO/R 80 and ISO 6507/1, respectively.

4.1.3 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.

4.2 Corrosion resistance

Two methods of test are specified for determining corrosion resistance (see 4.2.1 and 4.2.2). The purchaser shall specify 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 specify, it is left to the discretion of the manufacturer as to which test to use.

4.2.1 Test for resistance to copper sulfate

Except as specified hereinafter, there shall be no plating of copper on the instruments, when tested as specified in 5.1. Copper plating at the periphery 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 parts of the joints, ratchets and serrations of the jaw shall be disregarded.

4.2.2 Test for resistance to boiling water

The instruments subjected to the test specified in 5.2 shall be wiped with a dry cloth and inspected for visible signs of corrosion. Any blemish not removed by vigorous hand rubbing with a cloth shall be considered as evidence of corrosion.

4.3 Workmanship

The instruments shall be manufactured according to 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 reopening the instrument.

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

The instruments shall have smooth moving joints which shall neither be too loose nor too tight, it being 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.

NOTE — The satin finish should be effected by an appropriate procedure, such as 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.

Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. The mirror finish should be effected by an appropriate procedure, such as 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 suitable passivation process, for example by electropolishing or by treatment with 10 % (V/V) nitric acid solution for not less than 30 min at a temperature not less than 10 °C and not exceeding 60 °C. The instruments shall then be rinsed in water and dried in hot air.

NOTE — If the joints are lubricated, the lubricant should be non-corrosive and suitable for medical application according to 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.

5 Methods of test

5.1 Copper sulfate test

5.1.1 Test solution

Copper(II) sulfate pentahydrate ($\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$)	4,0 g
Sulfuric acid (H_2SO_4) ($\rho = 1,84 \text{ g/ml}$)	10,0 g
Distilled water	90,0 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 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 deposition of copper.

5.2 Boiling water test

5.2.1 Reagent

Distilled 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 distilled water and dry.

5.2.4 Procedure

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

Remove the instrument from the distilled water and leave exposed to the air for 2 h. Examine the instrument for evidence of corrosion.

5.3 Elasticity test

Place a test wire in accordance with the table between the working portions at the tip of the instrument. Fully close the instrument (to the last ratchet position). Leave the instrument under this strain for 3 h at room temperature. Examine the instrument for the presence of cracks and permanent deformation.

Table — Test wire

Dimensions in millimetres

Test wire	Diameter of test wire	Nominal length (overall length) of instrument
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

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