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# International Standard



# 7741

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## Instruments for surgery — Scissors and shears — General requirements and test methods

*Instruments chirurgicaux — Ciseaux et cisailles — Spécifications générales et méthodes d'essai*

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**Descriptors** : medical equipment, surgical equipment, surgical scissors, specifications, tests, performance tests.

## 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.

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 7741 was prepared by Technical Committee ISO/TC 170, *Surgical instruments*.

Users should note that all International Standards undergo revision from time to time, and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

# Instruments for surgery — Scissors and shears — General requirements and test methods

## 1 Scope and field of application

This International Standard specifies general requirements and corresponding routine test methods for scissors and shears which are used in surgery.

## 2 References

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

ISO 4957, *Tool steels.*

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

ISO 6508, *Metallic materials — Hardness test — Rockwell test — Scales A, B, C, E, F, G, H.<sup>1)</sup>*

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 in accordance with table 1.

Table 1 — Material — Steel grades

Reference letter according to ISO 7153/1	Steel grade	
	Grade No. according to ISO 4957	ISO 683/13
B*	27*	4*
C**	28	5
D	—	—
H	—	—
I	—	—

\* Only for scissors and shears with tungsten carbide or stellite inserts.

\*\* Special attention should be given to meeting the requirements of 4.1.2.

### 3.2 Rivet or 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 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 for instruments without tungsten carbide or stellite inserts

The Rockwell hardness of the finished instruments shall be within the range from 50 HRC to 58 HRC (approximately equivalent to Vickers hardness range from 530 HV to 670 HV) when tested in accordance with ISO 6508 and ISO 6507/1, respectively. Opposite blades shall not vary in hardness by more than 4 units on the Rockwell C hardness scale.

#### 4.1.3 Hardness for instruments with tungsten carbide or stellite inserts

The Vickers hardness of the tungsten carbide or stellite inserts shall be at least 710 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.

The Rockwell hardness of the body of the instruments with tungsten carbide or stellite inserts shall be 40 HRC min.

### 4.2 Corrosion resistance

#### 4.2.1 Scissors and shears made of steel grade C

Two test methods are specified for determining corrosion resistance (see 4.2.3 and 4.2.4). Both of these tests shall be carried out.

1) At present at the stage of draft. (Revision of ISO/R 80-1968 and ISO 2713-1973.)

#### 4.2.2 Scissors and shears made of steel grades B, D, H and I

Two test methods are specified for determining corrosion resistance (see 4.2.3 and 4.2.4).

NOTE — When placing an order, the purchaser should 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 provide such a statement, the choice is left to the discretion of the manufacturer.

#### 4.2.3 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 shall be disregarded.

#### 4.2.4 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.

The instruments shall have joints which move smoothly and 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 instrument shall be supplied free from residual scale, acid, grease and grinding and polishing materials. Compliance with these requirements shall be checked by inspection under normal vision, corrected, if necessary.

##### 4.4.2 Surface finish

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

- mirror polished;
- reflection-reducing, for example satin finish, matt black finish;
- an applied surface coating, for example for electrical 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 with a 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.

3 Attention is drawn to the fact that some surface coatings applied to surgical instruments can be detrimentally affected if the instrument is cleaned in a solvent-cleaning machine. Such incompatibilities should be anticipated and avoided or minimized.

#### 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 junctions) renders it inappropriate, be treated by a suitable passivation process.

#### NOTES

1 Examples of methods of passivation are by electropolishing or by treatment 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 Cutting ability

The cutting ability of the instruments shall be tested in accordance with clause 5.3.

The testing material shall be cut cleanly without tearing.

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

### 5 Test methods

#### 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 [ $\rho$ ( $\text{H}_2\text{SO}_4$ ) = 1,84 g/ml]	10,0 g
Distilled water	90,0 ml

##### 5.1.2 Apparatus

Glass or ceramic beaker.

##### 5.1.3 Preparation

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-resisting, 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. Record the presence of blemishes.

## 5.3 Cutting ability

The instrument shall be cleaned, as specified in 5.2.3, before testing.

The testing material in accordance with table 2 shall be cut non-stop three times along two-thirds of the blade without lateral pressure.

## 6 Marking

6.1 The instrument shall be marked with at least the trade mark of the manufacturer or supplier.

6.2 Instruments not having tungsten carbide inserts shall not have gold-coloured handles.

**Table 2 — Testing materials**

Testing material	Number of layers	Category of instrument	Examples
Wetted tissue paper	1	Micro-spring	Barraquer scissors Iridectomy scissors De Wecker scissors
Gauze No. 18 <sup>1)</sup>	2	Lightweight Bow-handled	Iris scissors Strabismus scissors Stevens tendon scissors Kilner dissecting scissors Potts-de-Martell scissors Joseph scissors
	5	Medium weight Bow-handled	Mayo scissors Metzenbaum scissors Nail scissors Sims uterine scissors Dauphine dressing scissors Tonsil scissors
	8	Heavyweight	Lister bandage scissors Smith bandage scissors Bowel scissors Doyen flesh scissors

1) In accordance with the European pharmacopoeia.

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