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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*

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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.

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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 | |
| — blade | A, B and M | |
| Retractors | — body small | A and B |
| | — body 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.