

Surgical instruments —

Part 2: Specification for instruments with pivot joints (excluding cutting instruments)

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/43, upon which the following bodies were represented:

- British Steel Industry
- British Surgical Trades Association Incorporated
- Department of Health
- Institute of Sterile Services Management
- Medical Sterile Products Association
- National Association of Theatre Nurses
- Royal College of Nursing and National Council for the Nurses of the UK
- Royal College of Surgeons of Edinburgh
- Royal College of Surgeons of England
- Coopted experts

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Foreword

This Part of BS 5194 has been prepared under the direction of the Health Care Standards Policy Committee and supersedes BS 5194-2:1985, which is withdrawn. This new edition introduces technical changes to bring this Part of BS 5194 up-to-date but it does not reflect a full review of BS 5194-2, which will be undertaken in due course.

This Part of BS 5194 takes cognizance of ISO 7151:1988 “*Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods*”, prepared by Technical Committee 170, Surgical instruments, of the International Organization for Standardization (ISO). The main reason for ISO 7151 not being completely acceptable is the method of test for the elasticity of general purpose artery forceps and needle holders (which is reproduced in Appendix A for information and guidance). This method has not been used to assess the requirements of this Part of BS 5194 because its validity with respect to all types of forceps and needle holders has not been established. It should be noted, however, that forceps and needle holders which comply with this Part of BS 5194 and satisfy the appropriate criteria in Appendix A will also comply with ISO 7151.

The committee responsible for the preparation of this Part of BS 5194 considered it neither feasible, nor desirable (in view of the multiplicity of existing patterns of instrument and the wish not to inhibit future design development) to specify detailed requirements for joints, racks and jaws. Guidance on these features is given in Appendix D to Appendix G.

Attention is drawn to the foreword of BS 5194-1.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 10, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This Part of BS 5194 specifies requirements for surgical instruments made of stainless steel and having pivot joints, such as artery forceps, needle holders, mouth gags and other instruments of similar design, but excluding cutting instruments, such as scissors, shears and bone-nibbling forceps (bone rongeurs).

NOTE 1 A method of test for the elasticity of artery forceps and needle holders is given for guidance in Appendix A.

NOTE 2 The titles of the publications referred to in this Part of BS 5194 are listed on the inside back cover.

2 Materials

The component parts of the instrument, excluding any carbide or stellite inserts, shall be made of stainless steel specified in BS 5194-1 and as given in Table 1.

Table 1 — Materials of construction

Instrument and component parts	Steel grade: reference letter in accordance with BS 5194-1
Non-cutting, articulated instruments, except retractors	B
Retractors:	
blade	A, B or M
body:	
small	A or B
large	B
Rivets and screws	A, B, L, M, N, O or P

3 Hardness and heat treatment

3.1 General

The component parts of the instrument, excluding rivets, screws, parts made of steel grade M and inserts, shall be heat treated using hardening and tempering procedures so as to produce throughout the instrument the hardness specified in 3.2.

3.2 Hardness

The Rockwell hardness of the instrument, except for any carbide or stellite insert and parts made of steel grade M, shall be within the range 40 HRC to 48 HRC when tested as described in BS 891-1. Mating steel surfaces on the same instrument, e.g. opposing jaws and shanks, shall not differ in hardness by more than 4 units on the Rockwell HRC scale.

The Vickers hardness of any carbide or stellite insert shall be not less than 1 000 HV 10 when tested as described in BS 427-1. Opposing inserts on the same instrument shall not differ by more than 50 units on the Vickers HV 10 scale.

NOTE Approximate Vickers hardnesses, measured in accordance with BS 427-1, are as follows:

Rockwell HRC hardness	Vickers hardness
40	390HV 10
48	485HV 10
60.5	710HV 10

Attention is drawn to BS 860 regarding the equivalence of hardness scales.

4 Corrosion resistance

4.1 Resistance to copper sulphate

When tested as described in Appendix B, there shall be no plating of copper on the instrument.

4.2 Resistance to boiling water

When tested as described in Appendix C, the instrument shall show no visible evidence of corrosion.

5 Design and workmanship

NOTE This Part of BS 5194 does not specify requirements for racks. Guidance on racks is given in Appendix D.

5.1 General

There shall be no sharp edges other than those required by the pattern of the instrument.

5.2 Screw joints

Screws shall have an ISO metric screw thread in accordance with BS 3643-1 and BS 3643-2. They shall be so fixed that they are immovable without the use of a tool.

NOTE Guidance on screw joints is given in Appendix E.

5.3 Box joints

Rivets shall be rendered immovable.

NOTE Guidance on box joints is given in Appendix F.

5.4 Jaws

The serrations of the jaws shall have the crests truncated. The surface of the crests shall be flat across the inner face of the jaw.

NOTE Guidance on jaws is given in Appendix G.

5.5 Needle holders

When tested as described in Appendix H, the fibre shall not slip from the jaws irrespective of whether the direction of the force is longitudinal or transverse.