



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 2766-2022

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

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1 Scope

This document specifies the materials, requirements, test methods, and marking of non-cutting articulated instruments.

This document applies to non-cutting articulated instruments.

2 Normative references

The following documents contain the provisions which, through normative reference in this document, constitute the essential provisions of this document. For the dated referenced documents, only the versions with the indicated dates are applicable to this document; for the undated referenced documents, only the latest version (including all the amendments) is applicable to this document.

GB/T 230.1-2018 Metallic materials - Rockwell hardness test - Part 1: Test method (ISO 6508-1:2016, MOD)

NOTE: There is no technical difference between the referenced content of GB/T 230.1-2018 and the referenced content of ISO 6508:1986.

GB/T 4340.1-2009 Metallic materials - Vickers hardness test - Part 1: Test method (ISO 6507-1:2005, MOD)

NOTE: There is no technical difference between the referenced content of GB/T 4340.1-2009 and the referenced content of ISO 6507-1:1982.

YY/T 0149-2006 Medical instruments of stainless steel - Test methods of corrosion

resistance (ISO 13402:1995, MOD)

YY/T 0294.1-2016 Surgical instruments - Metallic materials - Part 1: Stainless steel (ISO 7153-1:1991, MOD)

NOTE: There is no technical difference between the referenced content of YY/T 0294.1-2016 and the referenced content of ISO 7153-1:1983.

The test shall be carried out according to the provisions of GB/T 230.1-2018 or GB/T 4340.1-2009. The Rockwell hardness of the finished product (except 05Cr17Ni4Cu4Nb) shall be within the range of 40HRC~48HRC or the Vickers hardness shall be within the range of 390HV~485HV. The Rockwell hardness of the finished product made of 05Cr17Ni4Cu4Nb material shall be within the range of 36HRC~44HRC or the Vickers hardness shall be within the range of 330HV~410HV. The difference between the two pieces shall not be greater than Rockwell hardness 4HRC or Vickers hardness 40HV.

NOTE: The test force is determined by the manufacturer according to the product characteristics.

5.1.3 Hardness of tungsten carbide inserts The test shall be carried out according to the provisions of GB/T 4340.1-2009; the Vickers hardness of tungsten carbide inserts shall not be less than 1000HV10. The difference in hardness between the inserts of the two opposite jaws shall not exceed 50HV10.

5.2 Corrosion resistance The test shall be carried out according to the method specified in 6.1 or 6.2, and it shall not be lower than the requirements of level-b in 5.4 of YY/T 0149-2006.

5.3 Manufacturing process Instruments shall be manufactured according to appropriate process requirements.

When the instruments are fully locked, the jaw teeth shall be completely matched.

The teeth of the two parts of the instrument shall be clear, full, without sharp edges, and of the same shape. The teeth shall fit together and there shall be no resistance when reopening the instrument.

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

The joints of the instrument shall be able to move smoothly, with proper tightness; the instrument shall be able to be easily opened and closed by operating the control handle with one hand.

5.4 Surface condition

5.4.1 General rules The surface is checked with normal vision or corrected vision; there shall be no abscesses, cracks, or wear marks on the surface of the instrument. Instruments

shall be free from residual scale, residual acid grease, and residues of grinding additive and polishing agent.

5.4.2 Surface finishing Surface finishing shall be one of the following situations or a combination of them:

- a) Mirror polishing;
- b) Processing to reduce reflection, such as satin polishing, matting, and blackening processing;
- c) Additional coating, e.g. a coated layer for insulation purposes.

NOTE 1: A satin finish is usually achieved by appropriate processes such as grinding, polishing, and electropolishing followed by satin polishing (glass bead rolling or satin brushing). The smooth surface is uniform, smooth, and weak glare.

NOTE 2: Instruments with a mirror finish are usually ground sufficiently to remove all surface imperfections and polished to remove grinding marks to achieve a mirror finish. A mirror finish is achieved by appropriate processes such as polishing, lapping, electropolishing, and mirror polishing.

5.4.3 Passivation and final treatment Unless the metallurgical properties of the instrument are unsuitable (for example, with brazed or soft-soldered welded seam), the instrument shall be passivated or other electrochemically treated in accordance with the properties of such stainless steel.

NOTE 1: Regarding the method of passivation treatment, such as electropolishing or treatment in 10% (volume fraction) nitric acid solution, the treatment time is not less than 30 min, and the temperature is within 10 °C~60 °C. The instruments are then rinsed with water and dried in hot air.

NOTE 2: If the joint is lubricated, a non-corrosive lubricant that meets the requirements of the Pharmacopoeia of the People's Republic of China shall be used.

5.5 Elasticity The test shall be carried out in accordance with the provisions of 6.3, and the instrument shall not have obvious deformation, cracks, or any other permanent deformation.

5.6 Clamping function The test shall be carried out in accordance with the provisions of 6.4; for needle holders, there shall be no slippage of the fiber material, whether the loading direction is longitudinal or transverse; for other instruments, the loading direction is determined according to the tooth profile.

6 Test methods

6.1 Corrosion resistance (boiling water test)

6.1.1 Reagents Distilled or deionized water.

6.1.2 Apparatus Glass or ceramic beakers or suitable corrosion-resistant stainless-steel containers.

6.1.3 Sample preparation Wash instruments with soap and warm water, rinse thoroughly in reagent (6.1.1), and dry.

6.1.4 Test procedures Put the instrument into the beaker or other container containing the reagent (6.1.1) and boil for at least 30 min. The instrument is then cooled in test water for at least 1 h.

Remove the instrument from the water and expose it to air for 2 h. Wipe the instrument vigorously with a dry cloth and check for signs of corrosion on the instrument.

6.2 Corrosion resistance (pressure steam test)

6.2.1 Equipment A non-vacuum autoclave operating at 134 °C~138 °C and 0.22 MN - m-2.

6.2.2 Sample preparation Sample preparation is the same as 6.1.3.

6.2.3 Test procedures

6.2.3.1 Place the instrument in a tray and place them in the autoclave.

6.2.3.2 The amount of third-grade water shall be determined according to the pressure steam test cycle of the instrument, and 3+0.5 0 min, 134 °C~138 °C and 0.22 MN - m-2 shall be used as a pressure steam test cycle of the instrument.

6.2.3.3 After the test, remove the tray and allow the instrument to cool to room temperature in the air. Check for signs of corrosion on instrument surfaces.

6.3 Elasticity