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BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

गर्भाशय बायोप्सी क्यूरेट, कोणीय – विशिष्टि

(IS 12256 का पहला पुनरीक्षण)

Draft Indian Standard

UTERINE BIOPSY CURETTE, ANGLED – SPECIFICATION

(*First Revision of IS 12256*)

ICS 11.040.30

Obstetric and Gynaecological Instruments and Appliances Sectional Committee, MHD 03

Last date for comments: 28 September, 2025

FOREWORD

(Formal clause will be added later)

This standard was first published in 1988. The first revision of this standard has been brought out to align the standard with the latest style and format of Indian Standards.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 'Rules for Rounding Off Numerical Values (*second revision*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

1 SCOPE

This standard specifies dimensional and other requirements for uterine biopsy curette (angled) used in obstetrics and gynaecology.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

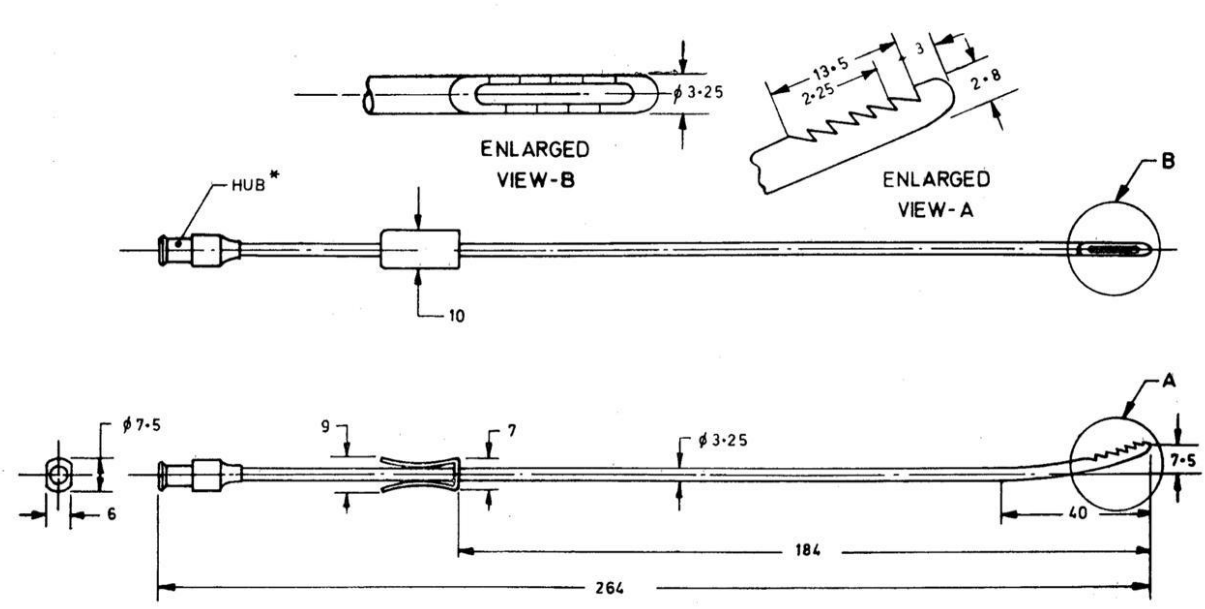
IS No.	*Title*
IS 6603: 2024	Stainless Steel semi-finished products, bars, wire rods and bright bars – Specification *(second revision)*
IS/ISO 80369-7: 2016	Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications
IS 7531:1990	Surgical instruments – Corrosion resistance of stainless steel surgical instruments - Methods of tests (*first revision*)

3 MATERIAL

The material shall be of stainless steel wire rod of Designation X04Cr18Ni10Ti or X04Cr19Ni9 of IS 6603.

4 SHAPE AND DIMENSIONS

The shape & dimensions shall be as shown in Fig. 1.



*See IS/ISO 80369-7

All dimensions in millimetres.

FIG. 1 GUIDE, SHIRODKAR'S PATTERN

4.1 Tolerances on linear dimensions shall be permitted as given below:

a) ± 0·1 mm on dimensions up to 10·0 mm,
b) ± 0·5 mm on dimensions above 10·0 mm and up to 25·0 mm,
c) ± 1·0 mm on dimensions above 25·0 mm and up to 50·0 mm,
d) ± 1·5 mm on dimensions above 50·0 mm and up to 100·0 mm, and
e) ± 2·0 mm on dimensions above 100·0 mm.

5 Requirements

5.1 The surface of the curette shall be free from scales, pits, burrs dents and other defects.

5.2 The tip of the curette shall be bulbous and smooth.

5.3 All edges shall be smoothly rounded off.

5.4 The instrument shall be treated by a suitable passivation process in 10 percent (v/v) nitric acid solution for not less than 30 minutes at a temperature of not less than 10°C and not exceeding 60°C. The instrument shall then be rinsed in water and dried in hot air.

5.5 The hub of the curette shall satisfy the requirements specified in IS/ISO 80369-7.

6. Tests

6.1 Corrosion Resistance Test

The curette shall be tested in accordance with IS 7531. The curette shall show no sign of corrosion after the test.

6.2 Leakage Test

Fit the curette to a tested syringe and connect the syringe to a water source on which pressure could be exerted. Run the water through the needle to eliminate air, seal the assembly outlet and bring the water pressure to 300 kPa. Maintain the pressure for 30 seconds. There shall be no leakage sufficient to form a falling drop. The conical fitting under test shall be horizontal.

7 MARKING

7.1 The product shall be legibly and indelibly marked with the following:

a) Manufacturer's name, initials or registered trade-mark;
b) Country of manufacture; and
c) The words 'Stainless Steel' or the letters 'SS'

7.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards*

Act, 2016 and the Rules and Regulations framed there under, and the product(s) may be marked with the Standard Mark.

8 PACKING

The curette shall be wrapped in moisture proof-paper or placed in polyethylene bags. The curette shall then be individually packed in cartons. The packing shall contain details of the manufacturer and year of manufacture.