

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
कैनुला, अंतर्गर्भाशयी, हिस्टेरोसलपिंगोग्राफी – विशिष्टि
(IS 10156: 1982 का पहला पुनरीक्षण)

Draft Indian Standard
**CANNULA, INTRA-UTERINE,
HYSTEOSALPINGOGRAPHY – SPECIFICATION**
(First Revision of IS 10156: 1982)

ICS 11.040.30

Obstetric and Gynaecological Instruments
and Appliances Sectional Committee, MHD 03

Last date for comments: 11 May 2024

FOREWORD

(Formal clause will be added later)

This standard was originally published in 1982. 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 provides general requirements for intra-uterine cannula used for hysterosalpingography.

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.

<i>IS No.</i>	<i>Title</i>
IS 6911 : 2017	Stainless steel plate, sheet and strip - Specification (<i>second revision</i>)
IS 6603 : 2001	Stainless steel bars and flats – Specification (<i>first revision</i>)
IS 7531 : 1990	Surgical instruments - Corrosion resistance of stainless steel surgical instruments - Methods of tests (<i>first revision</i>)

4 MATERIAL

3.1 Cannula

Cannula shall be of seamless drawn tube of stainless steel conforming to designation X04Cr18Ni10 or X07Cr18Ni9 of IS 6911.

3.2 Hub

Hub shall be of stainless steel conforming to designation X04Cr18Ni10 or X07Cr19Ni9 of IS 6603.

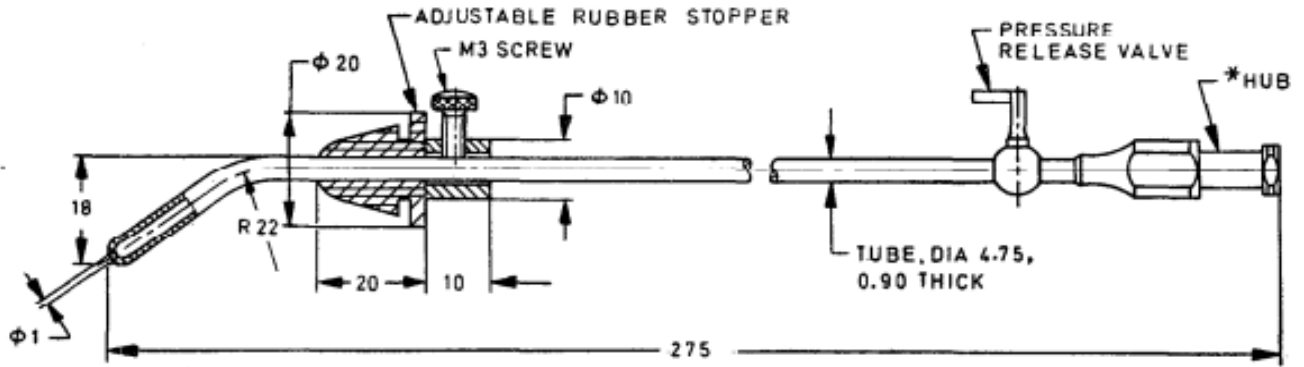
3.3 Stiletto

Stiletto shall be of hard-drawn brass wire or stainless steel wire.

4 SHAPE AND DIMENSIONS

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

4.2 A deviation of ± 2.5 percent shall be allowed on all dimensions.



*See IS/ISO 80369-7: 2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications

All dimensions in millimetres.

FIG. 1 CANNULA, INTRA - UTERINE, HYSTEROSALPINGOGRAPHY

5 WORKMANSHIP AND FINISH

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

5.2 Stiletto, supplied one for each cannula, shall be smooth, bright and free from kinks and shall slide smoothly into the cannula.

5.3 The fixing of the cannula with the hub shall be leak-proof.

5.4 Attachment for fixing vulsellum forceps may be provided on the cannula, if desired by the purchaser.

5.5 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.

6 TESTS

6.1 Corrosion Resistance Test

Test the cannula in accordance with IS 7531. The cannula shall show no sign of corrosion after the test.

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 cannula shall be wrapped in moisture-proof paper or packed in polyethylene bags. The cannula shall then be individually packed in cartons.