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भारतीय मानक मसौदा

कर्मन प्रकार का नम्य कैनुला – विशिष्टि

(IS 8313 का पहला पुनरीक्षण)

Draft Indian Standard

KARMAN TYPE FLEXIBLE CANNULA – SPECIFICATION

(*First Revision of IS 8313*)

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 1977. The first revision of this standard has been brought out to align the standard with the latest style and format of Indian Standards. In this revision, reference made to IS 3395 for material requirement has been replaced with IS 7328 since IS 3395: 1997 has been superseded by IS 7378: 2020.

This instrument is for use by trained surgeon only. It is expected that the performing surgeon is well versed with the procedure for medical termination of early pregnancy.

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 (s*econd 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 requirements for disposable Karman Type flexible cannula for menstrual regulation and medical termination of early pregnancy.

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.

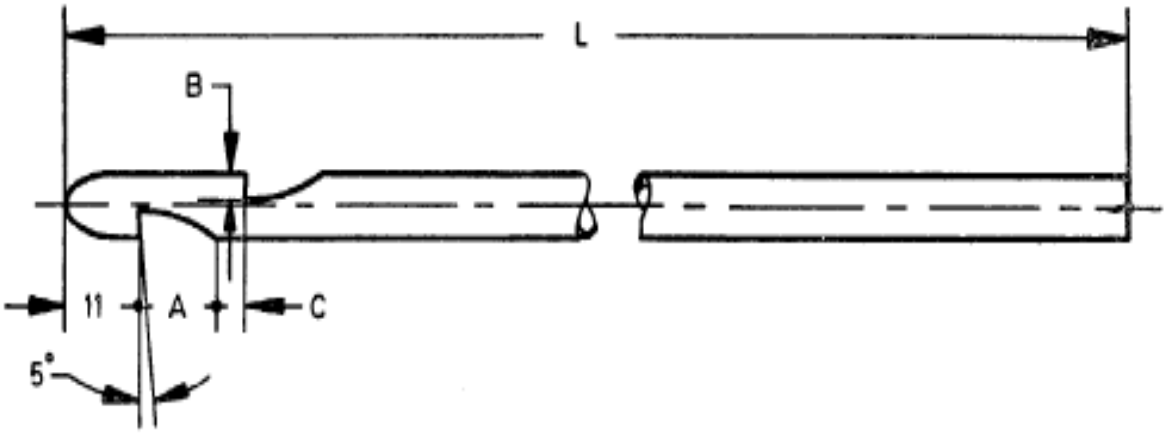
IS No.	Title
IS 7328: 2020	Specification for Polyethylene Material for Moulding and Extrusion *(third revision)*

3 MATERIAL

Nontoxic low density polyethylene of Grade G of IS 3395.

4 SHAPE AND DIMENSIONS

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



Size	*Outer Diameter*	*Inner Diameter*	*A*	*B*	*C*	*L*
1	4	3.0	6.0	1.80	2.0	200
2	5	3.5	7.5	2.25	2.5	200
3	6	4.5	9.0	2.70	3.0	200
4	8	6.5	12.0	3.60	4.0	230
5	10	8.0	15.0	4.50	5.0	230
6	12	10.0	18.0	5.40	6.0	230

All dimensions in millimetres.
FIG. 1 CANNULA, FLEXIBLE, KARMAN TYPE

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

5 WORKMANSHIP AND FINISH

5.1 All surfaces of cannula shall be free from pits, dents, burrs, scales and other defects.

5.2 V-shaped notches at the working end of the cannula shall be well formed.

5.3 The closed tip of the cannula shall be rounded and hemispherical.

5.4 The open end of the cannula shall be provided with suitable sleeves, where, necessary to give leakproof fitting with the corresponding component.

6 TESTS

6.1 The cannula in their ready for use state shall be compatible with human tissue without causing toxic, allergic or fibrous reaction.

6.2 Test for Toxicity

6.2.1 Fill a 150 mm length of cannula, by plugging open ends, with sterile pyrogen-free isotonic saline solution containing 9 g of sodium chloride per litre and immerse the filled set completely in water. Heat the water and maintain at not less than 85°C for 1 hour. Drain the contents of the cannula. Inject intravenously 0.5 ml of the solution so prepared into each of five healthy mice weighing 20 ± 3 g. At the end of 4, 24 and 48 hours examine the animals for discernible symptoms of toxicity. If any of the animals show gross signs of toxicity or die, repeat the test with five unused mice weighing 20 ± 3 g each. The test shall be deemed to be satisfied if all the animals survive for 48 hours.

6.2.2 Heavily inoculate a blood-agar plate over the entire surface with a young broth culture of streptococcus pyrogens. The blood-agar plate shall consist of nutrient agar containing 10 percent of horse blood in a petri dish. Select 5 mm length of representative sample of the cannula. Wash the' cannula sample in distilled water, then sterilize them by autoclaving in distilled water for 30 minutes at 120°C. Rinse twice in sterile distilled water and dry. Place the samples on the blood-agar surface applying slight pressure observing the usual asceptic precautions, with a minimum distance of 20 mm between each item. Incubate the whole thing at 37°C for 24 to 48 hours. In the absence of inhibitory substances, the growth of streptococcus pyrogens right to the edge of the sample, is evidenced by haemolysis of the red blood cells. In the presence of inhibitory substances, there is a ring of unhaemolysed block without bacterial growth around the sample.

6.3 The cannula, though flexible, shall have sufficient rigidity not to get flattened under a vacuum of 700 mmHg. When not in use, the cannula shall reasonably maintain their circular cross section.

7. INSTRUCTIONS

7.1 The cannula shall be supplied with instructions giving the following:

a) Disposable, supplied sterilized and ready for use; and

b) Instructions for use: To be connected to a suction device, capable of giving vacuum up to 86.4kN /m^2 (approximately 650 mmHg) for MR and 93.1 kN/m^2 (approximately 700 mmHg) for MTP up to an altitude of 200 m above sea level.

8 MARKING

8.1 Each Cannula shall be marked with the following:

a) Manufacturer's name, Initials or recognized trade-mark and

b) Size number in mm.

8.2 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.

9 PACKING

The cannula shall be packed as agreed to between the purchaser and the supplier. The packing shall be such as to avoid deformation of any cannula.