BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा लैप्रोस्कोपिक ट्रोकर और कैनुला – विशिष्टि

(IS 12271: 1988 का पहला पुनरीक्षण)

Draft Indian Standard LAPROSCOPIC TROCAR AND CANNULA – SPECIFICATION

(First Revision of IS 12271: 1988)

[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 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 provides material, dimensions and other requirements for laparoscopic trocar and cannula used in 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.

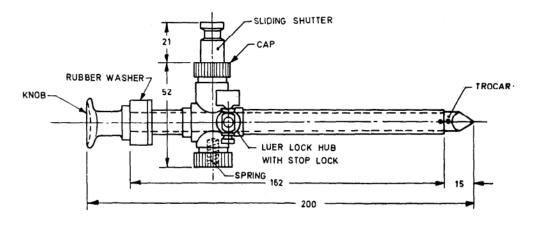
IS No.	Title
IS 6603 : 2001	Stainless steel bars and flats - Specification (first revision)
IS 1068: 1993	Electroplated coatings of nickel plus chromium and copper plus nickel plus chromium - Specification (<i>third revision</i>)
IS 7531: 1990	Surgical instruments - Corrosion resistance of stainless steel surgical
	instruments - Methods of tests (first revision)

3 MATERIAL

Trocar and cannula shall be made from stainless steel of Designation X30Cr13 of IS 6603. Other components shall also be made of stainless steel of the same grade except the knob, spring and sliding shutter which shall be of bakelite and brass, respectively.

4 SHAPE AND DIMENSIONS

4.1 The general shape and dimensions of laparoscopic trocar and cannula shall be as shown in Fig. 1, 2, 3 and 4.



All dimensions in millimetres.

FIG. 1 LAPROSCOPIC TROCAR AND CANNULA, TROCAR SIZE 11 mm

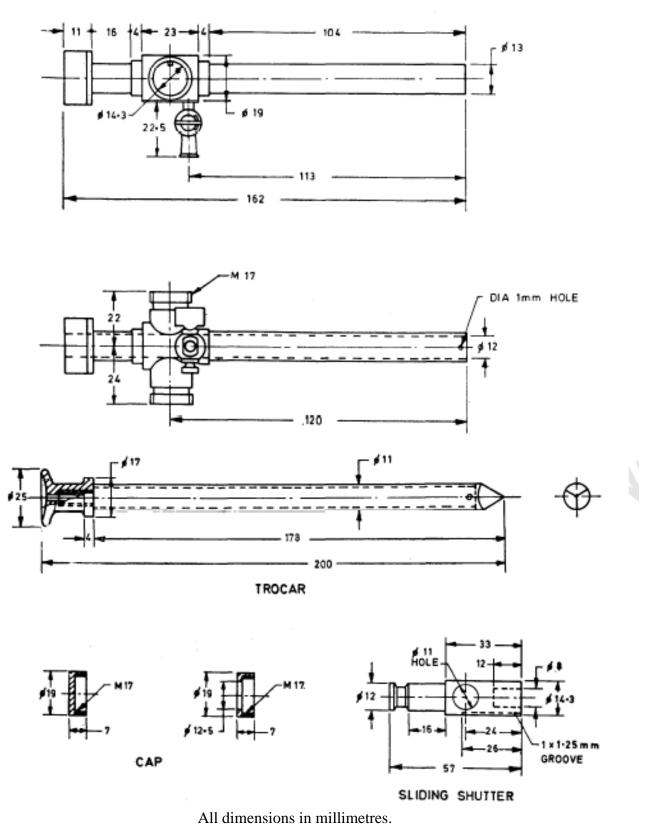
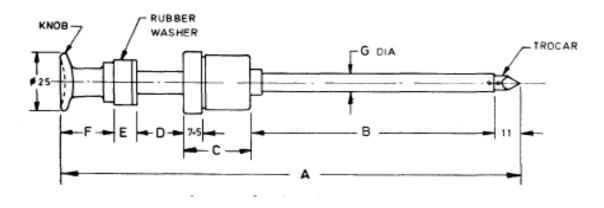


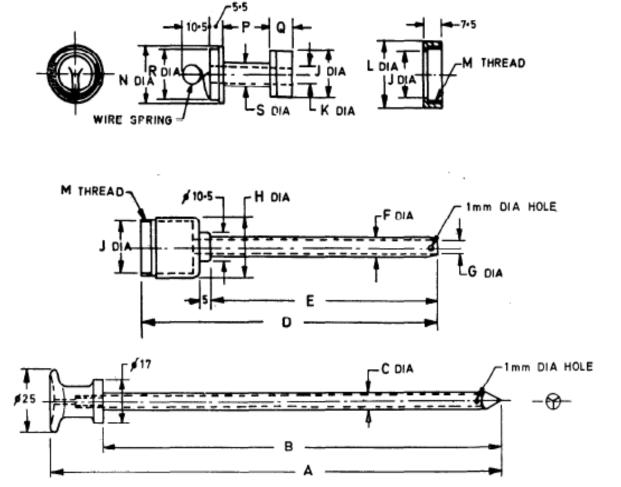
FIG. 2 DETAILED DIMENSIONS OF LAPROSCOPIC TROCAR AND CANNULA,
TROCAR SIZE 11 mm



\boldsymbol{A}	B	C	D	E	F	G, Dia
188	100	27	19	10	21	7.5
124	65	17	12	6	14	5.9

All dimensions in millimetres.

FIG. 3 LAPROSCOPIC TROCAR AND CANNULA, TROCAR SIZE 6.6 AND 5 mm



A	В	C Dia	D	Ε	F Dia	G Dia	H Dia	J Dia	K Dia	L Dia	M Thread	N Dia	P	Q	R Dia	S Dia
188	167	6.6	124	95	7.5	7	24	19	7	26.5	23	23	19	9.5	21	9
124	110	5	79	61	5.9	5.4	15.6	12.3	5.4	17.2	15	15	12.3	6	13.5	6

All dimensions in millimetres.

FIG. 4 DETAILED DIMENSIONS OF LAPROSCOPIC TROCAR AND CANNULA, TRQCAR SIZE 6.6 AND 5 mm

- **4.2** Tolerances on 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) \pm 1.0 mm on dimensions above 25.0 mm and up to 50.0 mm,
- d) \pm 1.5 mm on dimensions above 50.0 mm and up to 100.0 mm, and
- e) \pm 2.0 mm on dimensions above 100.0 mm.

5 REQUIREMENTS

- **5.1** The trocar and cannula shall be free from pits, burrs, cracks, scales and other surface defects.
- **5.2** All edges shall be smoothly rounded off except the tip of the trocar which shall be triangular and sharp.
- **5.3** The sliding shutter shall work smoothly and shall block the passage of the trocar tube after trocar rod is taken out and the stud is released.
- **5.4** The brass parts shall be plated chromium over nickel conforming to Service Grade No. 2 of IS 1068.
- **5.5** The hub shall be of luer lock type and the opening and closing mechanism shall work smoothly and effectively.
- **5.6** The working end of the trocar shall be hardened and tempered to give a hardness of 400 to 460 HV.

6 TESTS

6.1 Corrosion Resistance Test

The trocar and cannula after the removal of rubber, bakelite and brass components shall satisfy the boiling and autoclaving test as specified in IS 7531.

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

- **8.1** Each trocar and cannula shall be wrapped in moisture-proof paper or packed in polyethylene bags. The trocar and cannula shall then be packed in individual cartons and shall be provided with general instructions for maintenance and handling of the instrument.
- **8.2** The trocar and cannula may also be packed as agreed to between the purchaser and the supplier.