

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
प्लास्टिक सर्जरी उपकरण - क्रैनियोफेशियल - क्लेफ्ट पालते
रसपाटोर्य
(पहला पुनरीक्षण)

Indian Standard
**Plastic Surgery Instruments – Craniofacial - Cleft Palate
Raspatory**
(*First Revision*)

ICS 11.040.30

Surgical Instruments Sectional Committee,
MHD 01

Last date for comments: 25 June 2024

FOREWORD

(Formal clauses will be added later)

This Indian Standard was originally published in 1968 with the title ‘Specification for Raspatories, Cleft Palate, for Plastic Surgery’. This revision has been undertaken to align with the latest material requirements for plastic surgery instruments.

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*)’

1 SCOPE

This standard covers the product types/ varieties, dimensional, general, material, and performance requirements of Cleft Palate Raspatory, used in Craniofacial plastic surgery

2 REFERENCES

2.1 The following standard contains 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 the standards indicated below:

<i>Indian Standard</i>	<i>Title</i>
IS/ ISO 7153-1: 2016	Surgical Instruments – Materials Part 1 Metals
IS/ ISO 13402: 1995	Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure

3 TERMS AND DEFINITIONS

3.1 Raspatory

It is a surgical instrument for abrading or scraping the bone in surgery.

4 TYPES AND VARIETIES

4.1 The Cleft palate raspatory can be of the following types

4.1.1 McIndoe Double ended Raspatory

4.1.2 Curved Cleft Palate Raspatory (Left and Right, Curved Up and Curved Down)

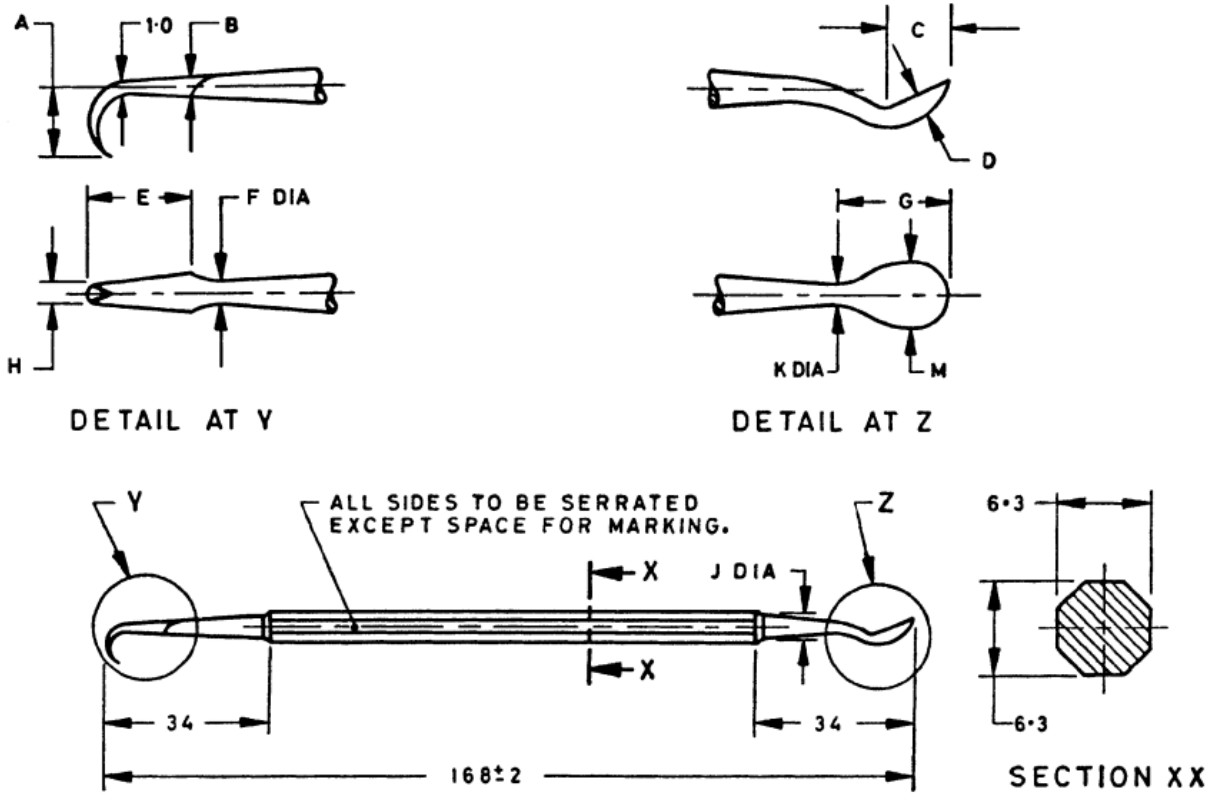
4.1.3 Straight Cleft Palate Raspatory (Left and Right)

5 MATERIAL REQUIREMENTS

5.1 The material used in the manufacture of Cleft palate raspatory shall be as specified in IS/ ISO 7153-1: 2016

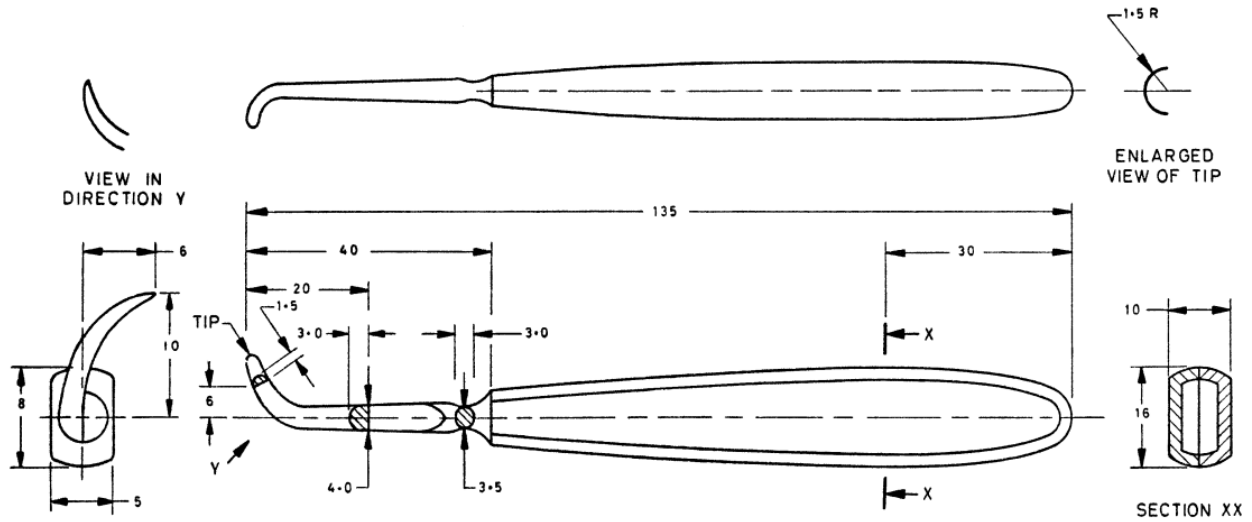
6 DIMENSIONAL REQUIREMENTS

6.1 The raspatory shall conform to the dimensions based on the type as given in Fig 1, Fig 2 and Fig 3.

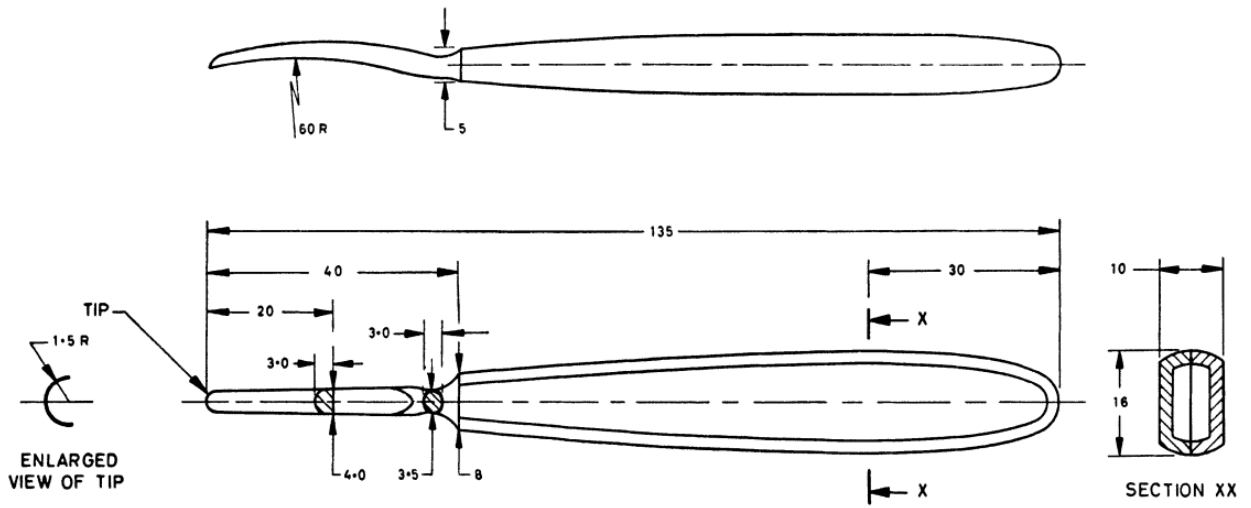


No.	A	B	C	D	E	F	G	H	J	K	M
1	6.25	2.0	9.0	2.10	10.0	2.5	12.0	2.50	4.9	2.50	6.7
2	5.75	1.8	7.0	1.80	11.0	2.1	10.5	2.00	4.7	2.25	5.5
3	5.25	1.6	5.0	1.40	11.5	1.8	9.0	1.50	4.5	2.00	4.2

All dimensions in millimeters
 FIG. 1 MCINDOE'S DOUBLE ENDED RASPATORY



All dimensions in millimeters.
 FIG. 2 CURVED CLEFT PALATE RASPATORY
 (RIGHT, LEFT, CURVED UP, CURVED DOWN)



All dimensions in millimeters.
 FIG. 3 STRAIGHT CLEFT PALATE RASPATORY

7 MECHANICAL REQUIREMENTS

7.1 The raspatories shall be hardened and tempered to give a uniform hardness of 430 to 490 *HV* at the scraping ends of the blade.

7.2 The raspatories shall undergo tests as specified in Clause 4 of IS/ ISO 13402: 1995. The raspatories shall not show any sign of corrosion without magnification.

7.3 The raspatories shall undergo tests as specified in Clause 5 of IS/ ISO 13402: 1995. The raspatories shall not show any sign of copper plating without magnification.

8 GENERAL REQUIREMENTS

8.1 The instruments shall be well-balanced.

8.2 The instruments shall be free from burrs, pits, seams and other surface flaws.

8.3 All sharp edges, except the scraping ends shall be rounded off.

8.4 The scraping ends shall be even and semi-sharp.

8.5 The raspatories shall be passivated and polished bright.

8.6 The working ends of all raspatories shall be examined under a magnification of 10X. The scraping edges and sharp points shall be well defined and free from defects under magnification.

8.7 The McIndoe's double-ended raspatories and the blades of the other raspatories shall be forged in one-piece with their ends well drawn and shaped.

8.8 The hook ends of the McIndoe's raspatories shall be sharp and pointed.

8.9 The McIndoe's double-ended raspatories shall be symmetrical on its central axis.

8.10 For raspatories other than McIndoe's, the blade shall be fitted to the handle by push fitting and brazing or silver soldering.

9 MARKING

9.1 The Raspatory shall be clearly and indelibly marked with the manufacturer's name or trade-mark and Batch/ Lot/ Serial Number.

9.2 When the marking is done on the blade portion, it shall be done by electro etching.

9.3 The Raspatory may also be marked with a Standard Mark.

9.4 The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

10 PERFORMANCE REQUIREMENTS

10.1 The scraping edges of the raspatory shall be applied to the surface of a piece of fresh bone and rubbed vigorously, to and fro, for one and a half minute. On completion of the test, the raspatory shall show no sign of damage.

10.2 The McIndoe's double-ended raspatories shall be held at the middle in a suitable vice so that each end protrudes outside the vice in the horizontal plane. A pull of 1 kgf shall be applied at the tip of the hook in a direction opposite to the curvature of the hook for two or three seconds. On completion of the test, the hook shall show no sign of damage.

10.3 The above test method shall also be applied to raspatories other than McIndoe's double-ended. In this case, the raspatories shall be held in vice jaws at the handles and the entire blade shall protrude beyond the jaws of the vice.

11 PACKING

11.1 Each raspatory shall be wrapped in moisture-proof polyethylene bag and packed in cartons in a manner that the instruments coming in contact with one another is avoided.