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# **BUREAU OF INDIAN STANDARDS**

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# भारतीय मानक मसौदा स्पेक्युलम नेज़ल थुडिचम के लिए विशिष्टि

(IS 5377 का पहला पुनरीक्षण)

# Draft Indian Standard Specification for Speculum Nasal Thudichum's

(First Revision of IS 5377)

# [ICS 11.040.30]

| Ear, Nose , Throat, Head & Neck Surgery | Last date for comments: 22 July, 2024 |
|-----------------------------------------|---------------------------------------|
| Instruments Sectional Committee, MHD 04 |                                       |

#### FOREWORD

(Formal clause will be added later)

This standard was originally published in 1969. The First revision of this standard has been brought out to align it with recent developments and to bring the standard in line 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.

#### *Indian Standard* SPECIFICATION FOR SPECULUM NASAL THUDICHUM'S

# **1 SCOPE**

Dimensional and other requirements of Thudichum's nasal speculum.

#### **2 REFERENCES**

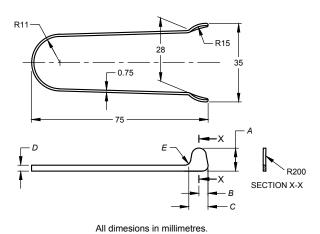
The standards given below contain provisions, which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate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

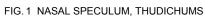
| IS No.                  | Title                                                                                                                   |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------|
| IS 1570 (Part 5) : 1985 | Schedules for wrought steels: Part 5 stainless and heat -                                                               |
|                         | Resisting steels (Second Revision)                                                                                      |
| IS 7531 : 1990          | Surgical instruments - Corrosion resistance of stainless steel surgical instruments - Methods of tests (First Revision) |

# **3 SHAPE AND DIMENSIONS**

As shown In Fig. 1.

| Size No. | Α  | B  | С   | D  | E Radius |
|----------|----|----|-----|----|----------|
| 1        | 10 | 40 | 80  | 25 | 30       |
| 2        | 12 | 45 | 85  | 25 | 30       |
| 3        | 14 | 50 | 95  | 25 | 30       |
| 4        | 18 | 55 | 110 | 40 | 10       |
| 5        | 20 | 60 | 115 | 40 | 10       |
| 6        | 22 | 65 | 120 | 40 | 10       |
| 7        | 24 | 70 | 145 | 40 | 10       |





#### **4 MATERIAL**

Stainless steel conforming to Designation 04Cr 19N19 or 07 Cr19N19 of IS. 1570(Part 5)

#### **5 WORKMANSHIP AND FINISH**

5.1 Specula shall be of one-piece construction free from pits and other surface flaws.

**5.2** All edges shall be even, rounded and not sharp.

**5.3** On closure, the blades shall come in contact with each other starting from the tips of the blades and progressing along the edges towards the bases of the blades While edges near the bases are in contact, the tips shall not gape. On release, the prongs shall return to their original positions.

**5.4** The speculum shall be finished dull.

#### 6 Test

**6.1 Load Closure Test** — Apply a force at the point where the blade ends to make the tips of the blades Just touch.

The force required shall be as follows:

| Size N. | Load N.                                               |
|---------|-------------------------------------------------------|
|         | $\pm 0.2 \text{ N} (\pm 20 \text{ gf approximately})$ |
| 1 to 3  | 1.5 (150 gf)                                          |
| 4 to 7  | 2.5 (250 gf)                                          |

**6.2 Corrosion Resistance** — The instrument shall satisfy the boiling and autoclaving test as specified in IS: 7531.

7 MARKING — Mark with the following:

- a) Manufacturer's name, initials, or recognized trademark.
- b) Words ' stainless steel ', and
- c) Size of the speculum.

#### 8 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 PAKING

Speculum shall be wrapped in moisture-proof paper and packed in cardboard cartons. On the package of the product batch Number, Lot Number, and Serial Number shall be mentioned.