Doc: MHD 04 (25934) WC

June 2024

#### **BUREAU OF INDIAN STANDARDS**

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### भारतीय मानक मसौदा

## नेज़ल कार्टिलेज चाकू के लिए विशिष्ट (बैलेंजर का पैटर्न)

(IS 6514 का पहला पुनरीक्षण)

Draft Indian Standard

# Specification for Nasal Cartilage Knife (Ballenger's Pattern)

(First Revision of IS 6514)

[ICS 11.040.30]

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

#### **FOREWORD**

(Formal clause will be added later)

This standard was originally published in 1972. 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.

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## Indian Standard SPECIFICATION FOR NASAL CARTILAGE KNIFE (BALLENGER'S PATTERN)

#### 1 SCOPE

Specifies the dimensional and other requirements of Ballenger's nasal cartilage knife straight and curved (two sizes) used in ENT surgery.

#### 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 1068: 1993	Electroplated coatings of nickel plus chromium and copper plus
	nickel plus chromium - Specification (Third Revision)
IS 7531: 1990	Surgical instruments - Corrosion resistance of stainless steel
	surgical instruments - Methods of tests (First Revision)
IS 1570 (Part 5): 1985	Schedules for wrought steels: Part 5 stainless and heat -
	Resisting steels (Second Revision)

#### **3 SHAPE AND DIMENSIONS**

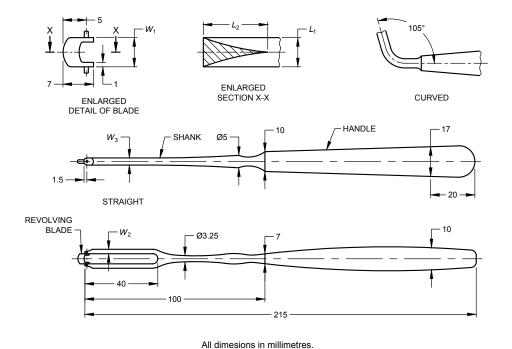
As shown in Fig. 1.

#### 4 MATERIALS

**4.1 Knife Shank and Revolving Blade** — Stainless steel conforming to designation 30Cr13 of IS: 1570(Part 5)

Materials	Percent
Carbon	0.35 to 0.45
Silicon	0.6 Max
Manganese	0.6 Max
Chromium	12 to 14
Nickel	0.6 Max
Sulphur	0.03 Max
Phosphorus	0.03 Max

**4.2 Handle** — Stainless steel conforming to Designation 30Cr13 or 04Cr19Ni9 or 07Cr19Ni9 of Schedule V of IS: 1570 (Part 1).



 ${\sf FIG.1.NASAL\ CARTILAGE\ KNIFE,\ BALLENGER'S\ PATTERN,\ STRAIGHT\ AND\ CURVED}$ 

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

- **5.1** The cutting edge on the revolving blade shall be hollow ground, well cut, clean, sharp and free from nicks, feathers and pits. The instrument shall be balanced and shall have a good feel.
- **5.2** The revolving blade shall be capable of freely revolving in any direction about its pivots in the Forked portion of the shank. It shall, however, be so pivoted that the spring action of the fork shall prevent the blade from revolving or changing its position due to its own weight.
- **5.3** All edges, except the cutting edge, shall be even, rounded and nowhere sharp. All surfaces shall be smooth and free from burrs, pits, cracks and other surface defects.
- **5.4** Handle shall be hollow and shall be fitted to the knife shank by screwing in and silver soldering. The silver soldering shall be sound and neat.
- **5.5** The knife shank, revolving blade and the handle, when made of stainless steel shall be passivated and polished bright. The handle, when made of brass, shall be plated chromium over nickel and the plating shall conform to Service Grade No. 2 of IS: 1068.

**6 Heat Treatment**— The revolving blade and forked shank shall be hardened and tempered to a hardness of 430 to 490 HV.

#### 7 TESTS

- **7.1 Performance Test**—Take a piece of cow curried leather 1 mm thick and 100 mm long. Make five slits with knife each 50 mm long. The blade shall make neat slits and shall not show any sign of damage or blunting after the test.
- **7.2 Corrosion Resistance** The instrument shall satisfy the boiling g and autoclaving test a s specified in IS: 7531.

#### 8 Marking

Mark with the following:

- a) Manufacturer's name, initials or recognized trademark;
- b) Words 'Stainless Steel' or letters 'SS' on the forked shank and the revolving blade; and
- c) Size of the blade.

#### **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 thereunder, and the product(s) may be marked with the Standard Mark.

#### 9 PACKAGING

As agreed, between the purchaser and the supplier. The revolving blade shall be suitably protected On the package of the product batch Number, Lot Number, and Serial Number shall be mentioned.