*भारतीय मानक*

**गाइड, सॉ, डी मार्टेल पैटर्न के लिए विशिष्टि**

*(पहला पुनरीक्षण)*

*Indian Standard*

**Specification for Guide, Saw, De Martel’s Pattern**

*(First Revision)*

ICS 11.040.30

Neurosurgery Instruments, Implants & Accessories Sectional Committee MHD 07.

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards after the draft finalized by the Neurosurgery Instruments, Implants & Accessories Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was originally published in 1978. This revision includes minor changes in references to incorporate the updated designation of steel and the currently used methods of test for hardness and corrosion resistance.

The composition of the Committee responsible for formulation of this standard is given in Annex A.

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**

These standard covers material, dimensions and other requirements for De Martel’s pattern saw guide in two sizes used in neurosurgery.

1. **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.

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| ***IS No.*** | ***Title*** |
| IS 6911: 2017 | Stainless Steel Plate, Sheet and Strip — Specification (Second Revision) |
| IS 7531: 1990 | Methods for testing of corrosion resistance of stainless-steel surgical instruments (First Revision) |

1. **MATERIAL**

The components shall be made of stainless-steel strip conforming to Designation X30Cr13 of IS 6911: 2017 Rivets and guide pin shall be made of the same material as used for the forceps.

1. **SHAPE AND DIMENSIONS —** Shall be as shown in Fig. 1.

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

1. **WORKMANSHIP AND FINISH**
	1. The guide shall be of one-piece construction and shall be free from burrs, pits, cracks and other surface defects. It shall have a gentle inside curve, concave towards the hook side as shown in Fig, 1. The front end or tip shall be suitably thickened by means of silver soldering as shown in Fig, 1.
	2. The hook for wire saw shall be punched out of strip and formed in the shape as shown in Fig,1. It shall be sufficiently strong and shall not be liable to yield or break up during use.
	3. All edges of the guide, including the hook for wire saw, shall be evenly rounded and shall be nowhere sharp. The silver soldering shall be clean and sound.
	4. The guide shall be polished bright and passivated.
2. **HEAT TREATMENT**

The guide shall be suitably hardened and tempered to give a uniform hardness of 400 to 450 HV.

1. **TESTS**
	1. **Flexibility Test** — bring two ends of the guide closer towards the concave side, to a distance of **50** mm from each other and release them, Repeat it five times. As a result of this test, the guide shall not acquire a permanent set.
	2. **Load Test** - Holding the guide vertically, hang a load of **20** N from the guide hook for a period of **5** minutes. The hook shall not yield or open up during the test.
	3. **Corrosion Resistance** - The guide shall conform to the requirements of IS 7531:1990.
2. **MARKING**

**8.1** Each guide shall be marked by etching or otherwise with the manufacturer’s name, initials or recognised trademark, along with its size, that is, ‘Adult’ or’ Child’ as the case may be. Manufacturer’s name, initials or registered trademark, Serial number, batch number in the provided space

1. **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.

1. **PACKAGING**

The guide shall be packed in a polyethylene cover. It may also be packed as agreed to between the purchaser and the supplier. On the package of the product batch Number, Lot Number, and Serial Number shall be mentioned.



**ANNEX A**

(*Foreword*)

 **COMMITTEE COMPOSITION**

Neurosurgery Instruments Implants and Accessories Sectional Committee, MHD 07

|  |  |
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| ***Organization*** | ***Representative(s)*** |
| G B Pant Hospital, New Delhi |  Dr. DALJIT SINGH (***Chairperson)*** |
| Abbott Healthcare India Private Limited, Mumbai | LIPI CHAKHAIYAR  |
|  SHWETA SHARMA (*Alternate Member)* |
| Association of Indian Medical Device Industry, New Delhi | NAVEEN KHANNA  |
|  PUHAZHENDI KALIYAPPAN (*Alternate Member I )* |
|  MR. ANKUR BHARGAVA (*Alternate Member II)* |
| Boston Scientific India Private Limited, Gurugram | DEV CHOPRA |
|  PRASHANTH PRABHAKAR (*Alternate Member)* |
| Central Drugs Standard Control Organization, New Delhi | MR. ASEEM SAHU |
|  MS. SHYAMNI SASIDHARAN (*Alternate Member)* |
| Defence Bio-Engineering and Electromedical Laboratory, Ministry of Defence, Bengaluru | JAYANT DANIEL |
|  G. SRIPATHY (*Alternate Member)* |
| Directorate General of Health Services, New Delhi | AJAY CHOUDHARY  |
|  K. B. SHANKER (*Alternate Member)* |
| Happy Reliable Surgeries Private Limited, Bangalore | HEMANT SAVALE |
|  SANJEEV GAUTAM (*Alternate Member)* |
| Indian Institute of Technology Hyderabad, Hyderabad | AVINASH ERANKI |
|  KOUSIK SARATHY S (*Alternate Member)* |
| Kalam Institute of Health Technology, Vishakhapatnam | SANTOSH KUMAR BALIVADA  |
|  DIVYA ANIL PATIL (*Alternate Member I)* |
|  PURVA SUHAS PHALKE(*Alternate Member II)* |
| Skull Base Surgery Society of India, Chennai | HARSH DEORA |
| In Personal Capacity | MR. ASOK KUMAR RAGHAVAN NAIR |
| BIS Directorate General | SHRI A. R. UNNIKRISHNAN, SCIENTIST ‘G’/ HEAD (MEDICAL EQUIPMENT AND HOSPITAL PLANNING) [REPRESENTING DIRECTOR GENERAL (Ex-officio)] |

*Member Secretary*

Ms. HARSHADA GANESH KADAM

SCIENTIST ‘B’/ASSISTANT DIRECTOR

(MEDICAL EQUIPMENT AND HOSPITAL PLANNING). BIS