*भारतीय मानक*

**न्यूरोसर्जिकल उपकरण - सुई धारक - आकार और आयाम**

**और लंबाई-चौड़ाई**

*(पहला पुनरीक्षण)*

*Indian Standard*

**Neurosurgical Instruments - Needle Holder - Shape and Dimensions**

*(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 1999. 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.

It has been revised to cover the requirements in respect of shape and dimensions only, as the specification part of these types of instruments is covered in IS 3642 (Part 1): 1990 ‘Surgical instruments - Specification: Part 1 Non-cutting, articulated instruments (second revision) ‘. This standard is, therefore, intended to be used only in respect of shape and dimensions, which are referred to in **4.1** of IS 3642 (Part 1): 1990.

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**

This standard prescribes shape and dimensions for needle holder 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 3642 (Part 1) : 1990 | Surgical instruments - Specification: Part 1 non - Cutting, articulated instruments (Second Revision) |

1. **SHAPE AND DIMENSIONS**
	1. The shape and dimensions holder shall be as shown in Fig. 1
	2. **Joint**

The joint shall be of box type in accordance with 13.2.2 of IS 3642 (Part 1).

* 1. **Ratchet**

Ratchet teeth shall conform to section **4** of IS 3642 **(Part 1)** with a combination of **3** in **3**.

**3.3.1** The ratchet teeth shall be designed such that the load at which the first ratchet just engages shall be between 2.0 to 2.5 kg.

* 1. **Finger Loop**

The finger loop shall conform to size No. 1 of Section 6 of IS 3642(Part 1)

* 1. **Bows**

The bows of needle holder shall be gold plated.

* 1. **Jaws**

 The needle holder shall have tungsten carbide insert jaws with matt finish.

* 1. **Serrations**

These shall be cross type serrations in accordance with Fig. 2C of IS 3642(Part 1)

1. **MARKING**

**4.1** Each Holder shall be marked with the following:

1. Manufacturer's name, initials or registered trade-mark in the space provided on
2. Country of manufacture; and
3. Serial number
4. Batch number
5. **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**

Each product shall be wrapped in a moisture-proof paper or polyethylene bag and packed in a suitable cardboard carton. The packing may also be done as agreed between the purchaser and the supplier. On the package of the product batch Number, Lot Number, and Serial Number shall be mentioned.

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**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