*भारतीय मानक*

**संदंश, ड्रेसिंग, संगीन आकार, गशिंग पैटर्न के लिए विशिष्टि**

*(पहला पुनरीक्षण)*

*Indian Standard*

**Specification for Forceps, Dressing, Bayonet Shape, Gushing’s Pattern**

*(First Revision)*

ICS 11.040.30

Neurosurgery Instruments, Implants & Accessories Sectional Committee MHD 07

FOREWORD

This Indian Standard (First 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. The first 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 Cushing’s pattern, bayonet

shape, dressing forceps of 150 mm and 187 mm size, used in neurosurgery.

1. **REFERENCES**

The standard 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 6603:2024 | Stainless Steel Semi-Finished Products, Bars, Wire Rods and Bright Bars Specification (Second Revision) |
| IS 3642 (Part 1): 1990 | Surgical Instruments – Specification Part 1 Non cutting Articulated Instruments (Second Revision) |
| IS 7531:1990 | Methods for testing of corrosion resistance of stainless-steel surgical instruments (First Revision |

1. **MATERIAL**
	1. The components of the forceps shall be made of stainless-steel conforming to Designation

X20Cr13 IS 6603:2024.

* 1. 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 forceps shall be symmetrical and well balanced. The opening and closing shall be in one

plane and smooth. The registration of the forceps shall correspond with the registration of the

guide-pin with the guide hole provided on the arms. The first closure shall be only at the tips and other serrations shall close progressively with the application of force.

* 1. The serrations at the tip’s shah be transverse and shall match crest to trough. They shall be clear and clean, of uniform depth throughout and shall be square with the tips. The profile and other requirements for serrations shall be in accordance with Section 2 of IS 3642 (Part 1):1990. Finer tips with or without serrations may also be provided, if required by the purchaser.
	2. Suitable transverse grooves shall be provided on the outside surface of the arms to facilitate holding (see Fig. 1). the grooves shall be neat, clean and free from burrs, sharp edges and other defects.
	3. The forceps shall be provided with block joint satisfying the requirements given under **Section**

**4** of IS 3642 (Part 1):1990.

1. **HEAT TREATMENT**

The forceps shall be evenly hardened and tempered to give a hardness of 380 to 430 HV.

1. **TESTS**
	1. **Tests for Engagement -** In accordance with **Clause 11.5** of IS 3642 (Part 1):1990.
	2. **Flexibility Test -** The flexibility of the arms of the forceps shall be tested in the following

manner:

1. The arms of the forceps after maximum closure by manual compression shall not take a permanent set and the jaws shall continue to engage and disengage accurately without sticking.
2. The riveted joint of the forceps shall be gripped firmly in a vice, By the application of force at the tip of the arm, one arm of the forceps shall be reflected in a plane at right angles to the plane of the arm by a distance of 50 mm measured at the tip of the forceps. On release of the force, no permanent set shall be observed. The test shall be repeated on the other arm.
	1. **Load Closure Test** – The tips of the forceps shall just close when a load between 1.57 N – 1.77 N is applied at the first finger groove from the tip.
	2. **Performance** – A latex sheet 0.05 mm thick shall be stretched over the tip of one of the fingers and then gripped lightly by the tips of the forceps. The forceps shall hold latex sheet firmly without any tendency to slip when pulled through a distance of 5 mm.
	3. **Corrosion Resistance Test** – The forceps shall conform to the requirements of IS 7531:1990.



1. **MARKING**
	1. The forceps to be marked by etching or otherwise with the manufacturer’s name, initials or registered trademark, Serial number , Batch number and Lot number
2. **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. **PACKING**

The forceps shall be wrapped with suitable cushioning material like folded tissue paper and packed in moisture-proof paper. Each forceps shall be put in a card board carton. Alternatively, the packing may be done as agreed to between the purchaser and the supplier.

**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