रोंग्यूर, क्रेनियल, डाहलग्रेन पैटर्न — विशिष्टि

IS 8334: 2024

(पहला पुनरीक्षण)

Rongeur, Cranial, Dahlgren's Pattern — Specification

(First Revision)

ICS 11.040.30

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Neurosurgery Instruments, Implants and 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 and Accessories Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1977. 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.

Indian Standard

RONGEUR, CRANIAL, DAHLGREN'S PATTERN — SPECIFICATION

(First Revision)

1 SCOPE

This standard covers dimensional and other requirement for Dahlgren's pattern cranial rongeur used in neurosurgery.

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 edition of these standards:

IS No.	Title
IS 6603 : 2024	Stainless steel semi-finished products, bars, wire rods and bright bars — Specification (second revision)
IS 7531 : 1990	Surgical instruments — Corrosion resistance of stainless steel surgical instruments — Methods of tests (first revision)

3 MATERIAL

Various components of the rongeur shall be made from stainless steel details of which are given below:

Sl No.	Components	s Material	Conforming to
(1)	(2)	(3)	(4)
i)	Arms and springs	Stainless steel	Designation X30Cr13 of IS 6603 : 2001
ii)	Blade	Stainless steel	Designation X40Cr13 of IS 6603 : 2001
iii)	Screws	Stainless steel	Designation X20Cr13 of IS 6603 : 2001

4 SHAPE AND DIMENSIONS

It shall be as shown in Fig. 1.

A deviation of \pm 2.5 percent shall be allowed on all dimensions except where specified.

5 MANUFACTURE, WORKMANSHIP AND FINISH

- **5.1** The rongeur shall be free from pits, burrs, scales, sharp edges, cracks and other surface defects on its external as well as internal surfaces.
- **5.2** The rongeur shall be provided with three blades (Fig. 2) having thickness of working edges as 3 mm, 2.7 mm and 2.4 mm respectively. The blade shall slide between the guides without any stiffness or undue play during use. The working edge of the blade shall be smooth and free from nicks and other defects.
- **5.3** The front face of the blade guide (*see* Fig. 1) shall be knurled to prevent slipping during operation.
- **5.4** The joints shall have no undue play, and shall work smoothly.
- **5.5** The screws shall be well formed and shall have regular threads.
- **5.6** The spring action shall be smooth. It shall be neither too hard nor too slack.
- **5.7** The rongeur shall be polished bright and passivated. The gripping portion of arms shall be matt finished.

6 HEAT TREATMENT

Various components of rongeur shall be suitably hardened and tempered to give hardness as indicated below:

a) 510 HV to 595 HV for blades;

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IS 8334: 2024

- b) 410 HV to 470 HV for arms and springs; and
- c) 290 HV to 320 HV for screws.

7 TESTS

7.1 Performance Test

Each rongeur shall be made to nibble the skull bone or teakwood of 3/4 cm thickness five times with each blade. On completion of the test, the blades as well as the rongeur shall show no sign of damage.

7.2 Rigidify Test

A compressive force of 110 N shall be applied to the rongeur arms at a distance of 75 mm from free ends in such a manner that it tends to press the arms together. The maximum force shall be attained gradually and shall act for two minutes. On completion of the test, the rongeur shall show no sign of damage.

7.3 Corrosion Resistance Test

The rongeur shall conform to the requirements of IS 7531

8 MARKING

Each Dahlgren's pattern cranial rongeur shall be marked with the following:

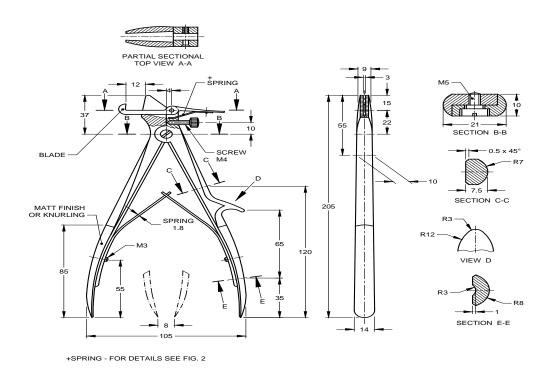
- Manufacturer's name, initials or registered trade-mark in the space provided on country of manufacture;
- b) Serial number;
- c) Batch number; and
- d) Lot number.

9 BIS CERTIFICATION MARKING

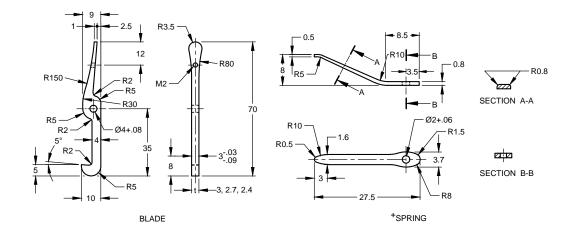
The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

10 PACKING

Each instrument shall be packed as agreed to between the purchaser and the manufacturer or in accordance with the current trade practices.



All dimensions in milimetres. Fig.1 Rongeur, Cranial, Dahlgren's Pattern



All dimensions in millimetres.

Fig. 2 Details of Blade and $\,^+$ Spring

ANNEX A

(<u>Foreword</u>)

COMMITTEE COMPOSITION

Neurosurgery Instruments Implants and Accessories Sectional Committee, MHD 07

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

Member Secretary
MS HARSHADA GANESH KADAM
SCIENTIST 'B'/ASSISTANT DIRECTOR
(MEDICAL EQUIPMENT AND HOSPITAL PLANNING), BIS

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Amendments Issued Since Publication

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