भारतीय मानक Indian Standard

वक्ष शल्य चिकित्सा उपकरण — संवहनी प्रतिबंधक — विशिष्टि

(पहला पुनरीक्षण)

Thoracic Surgery Instruments — Vascular Clamp — Specification

(First Revision)

ICS 11.040.30

© BIS 2024



भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS मानक भवन, 9 बहादुर शाह ज़फर मार्ग, नई दिल्ली - 110002 MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG NEW DELHI - 110002 www.bis.gov.in www.standardsbis.in

Price Group 4

June 2024

Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards after the draft finalized by the Medical and Surgical Cardiology Equipment Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in IS 9950 : 1981 "Specification for clamp vascular wister pattern". This revision aligns the cross references to the latest standards, incorporates the revised designation for stainless steel and includes certification clause.

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

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*)'.

Indian Standard

THORACIC SURGERY INSTRUMENTS — VASCULAR CLAMP — SPECIFICATION

(First Revision)

1 SCOPE

This standard specifies dimensional and other requirements for Wister pattern vascular clamp used in cardio-vascular surgery.

2 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:

IS No.	Title
IS 3642 (Part 1): 1990	Surgical instruments — Specification: Part 1 Non cutting, articulated instruments (second revision)
IS 6603 : 2001	Stainless steel bars and flats — Specification (<i>first revision</i>)
IS 7531 : 1990	Surgical instruments — Corrosion resistance of stainless steel surgical instruments — Methods for tests (<i>first revision</i>)

3 SHAPE AND DIMENSIONS

3.1 The clamp shall be made to shape and dimensions as shown in $\frac{\text{Fig. 1}}{1}$.

3.2 A deviation of ± 2.5 percent shall be allowed on all dimensions. However, the two halves of the instrument shall not differ at any specified dimension and shall be perfectly symmetrical.

3.3 Joint

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

3.4 Serrations

The clamp shall have non-cutting longitudinal jaw serrations with 60° profile and shall grasp the tissue delicately but firmly. In other respect the serrations shall be in accordance with Section 2 of IS 3642 (Part 1).

3.5 Ratchet

Teeth used in ratchets of the clamp shall conform to Section 4 of IS 3642 (Part 1) with a combination of 1 in 9. The load required to close the clamp on first step of the ratchet shall be 2.5 N, for second step be 5 N, for third step 7 N, and so on.

3.6 Finger Loops

The finger loops of the clamp shall be size No. 2 in accordance with Section 6 of IS 3642 (Part 1).

4 MATERIAL

The clamp shall be manufactured from stainless steel conforming to designation X20Cr13 or X30Cr13 of IS 6603.

5 WORKMANSHIP AND FINISH

5.1 The surfaces of the clamp shall be finished smooth and free from burrs, pits, cracks, scaleand other defects.

5.2 The jaws shall open and close with even and balanced movement. The opening and closing of the jaws shall be smooth and jerk free.

5.3 The clamp shall be passivated and shall be polished bright.

6 HEAT TREATMENT

The different components of the clamp shall be hardened and tempered to give a hardness of 400 HV to 460 HV.

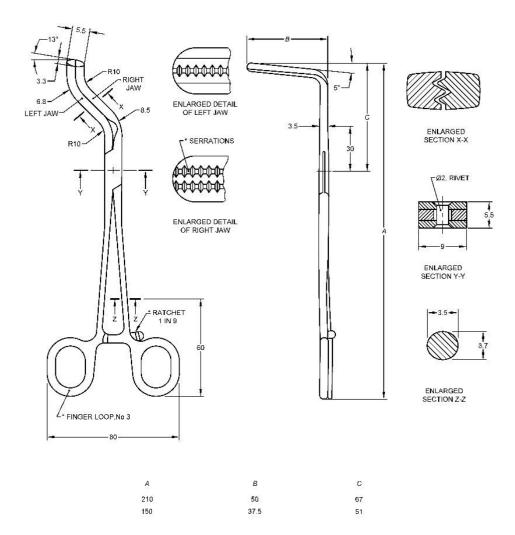
7 TESTS

7.1 Performance of Tips and Jaws

When first step of the ratchet is engaged, the teeth shall approximate to a gap of 2 mm and not interdigitate; the gap shall become 1 mm on engaging the second step; tips shall bite when the third step of ratchet engages. The jaws shall fully close when the last step engages. The teeth shall match perfectly and truly. In other respects, the jaws shall engage as stipulated in IS 3642 (Part 1).

To access Indian Standards click on the link below:

https://www.services.bis.gov.in/php/BIS 2.0/bisconnect/knowyourstandards/Indian standards/isdetails/



All dimensions in millimetres. FIG. 1 CLAMP, VASCULAR, WISTER PATTERN

7.2 Flexibility

Each arm of the clamp shall be fixed in a vice so that the entire arm projects above the vice. By gradual application of force on the finger loop, the arm shall be defected by 15 mm in the same plane as that of the finger loop. The arm shall not take a permanent set or break.

7.3 Corrosion Resistance

The clamp shall show no sign of corrosion when tested in accordance with IS 7531.

8 MARKING

8.1 The clamp shall be clearly' and indelibly marked, preferably by etching, with thefollowing:

a) Manufacturer's name, initials or registered

trade-mark; and

b) The words 'stainless steel' or letters 'SS'.

8.2 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.

9 PACKING

The clamp may be packed as agreed to between the purchaser and the supplier.

ANNEX A

(*Foreword*)

COMMITTEE COMPOSITION

Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06

Organization

In Personal Capacity (B-87, Alpha 1, Pilkhan Estate, 3rd Street, Greater Noida)

All India Institute of Medical Sciences, Delhi

Apollo Hospital, Chennai

B.L Lifesciences Private Limited, Delhi

Birla Institute of Technology and Science, Pilani

Boston Scientific India Private Limited, Gurugram

- CSIR-Central Scientific Instruments Organisation, Chandigarh
- Cardinal Health Medical Products India Private Limited, Mumbai
- Central Drugs Standard Control Organization, Delhi

Christian Medical College, Vellore

Directorate General Armed Forces Medical Service, Delhi

Dnyandeo Yashwantrao Patil Hospital, Navi Mumbai

Dr Ram Manohar Lohia Hospital, Delhi

Frontier Lifeline Private Limited, Chennai

Hindalco Industries Limited, Mumbai

Institute for Cardiac Treatment and Research, Delhi

India Medtronic Private Limited, Gurugram

Indian Association of Cardiovascular - Thoracic Surgeons, Bengaluru

Indian Heart Foundation, Hyderabad

Jawahar Lal Institute of Post Graduate Medical Education and Research, Puducherry

Representative(s)

DR DEEPAK KUMAR SATSANGI (Chairperson)

DR MILIND P. HOTE DR PRADEEP RAMAKRISHNA REDDY (Alternate)

DR C. S. VIJAYSHANKAR DR T. SUNDER (*Alternate*)

SHRI NONITA KAWATRA Shri Hemant Kumar Singh (*Alternate*)

DR PAWAN AJMERA DR SUJAN YENUGANTI (Alternate)

SHRI PRASHANTH PRABHAKAR SHRI DEV CHOPRA (*Alternate*)

SHRI NEELESH KUMAR DR SANJEEV SONI (Alternate)

SHRI SAUROBH PODDAR

DR RAVI KANT SHARMA

- SHRI RAVI SHANKAR DR SHALOM SYLVESTER ANDUGALA (Alternate)
- COL SAMEER KUMAR COL PAUL M. VARGHESE (Alternate)

DR JAMES THOMAS

DR VIJAY KUMAR GUPTA DR VIJAY GROVER (*Alternate*)

DR SANJAY CHERIAN DR KULASEKARAN (Alternate)

SHRI K. VENKATESH

DR R. JAGANATHAN DR N. R. RAVI SHANKAR (*Alternate*)

MS LATIKA VATS Shri Sanjeev Minhas (Alternate)

DR C. S. HIREMATH DR SHAMSHER SINGH LOHCHAB (Alternate)

DR SISHIR RAO DR SEVITH RAO (Alternate)

SHRI DURGA PRASAD RATH SHRI RAMSANKAR P. (Alternate)

Organization

Johnson and Johnson Private Limited, Mumbai

Kalam Institute of Health Technology, Vishakhapatnam

Meril Life Sciences Private Limited, Vapi

Ministry of Electronics and Information Technology, Delhi

Nizam's Institute of Medical Sciences, Hyderabad

North-Eastern Hill University, Shillong

Office of Development Commissioner (MSME), Delhi

Post Graduate Institute of Medical Education and Research, Chandigarh

South India Surgical Company Limited (SISCO), Chennai

Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram

Stryker India Private Limited, Gurugram

TTK Healthcare Limited (Heart Valve), Chennai

BIS Directorate General

Representative(s)

SHRI YATEEN SHAH SHRI AADITYA VATS (*Alternate*)

DR JITENDAR SHARMA SHRI DILIP KUMAR CHEKURI (Alternate)

SHRI NARENDRA PATEL MS GAYATHRI NAIR (Alternate)

SHRIMATI SUNITA VERMA SHRI RASHID SHABAN (Alternate)

PROF R. V. KUMAR DR M. AMARESH RAO (*Alternate*)

DR SUDIP PAUL SHRI SHYAMAL MANDAL (Alternate)

SHRI SUNIL KUMAR SHRI SUSANTA KUMAR SOM (*Alternate*)

PROF HARKANT SINGH DR ANAND K. MISHRA (*Alternate*)

SHRI ASHOK BAJAJ SHRI BHARAT BHUSHAN (*Alternate*)

PROF VIVEK V. PILLAI PROF BINEESH K. R. (*Alternate*)

SHRI SHIVKUMAR HURDALE

SHRI RAJIV K. NAIR MS INDU V. NAIR (*Alternate*)

SHRI A. R. UNNIKRISHNAN SCIENTIST 'G'/AND HEAD MEDICAL EQUIPMENT GENERAL AND HOSPITAL PLANING [REPRESENTING DIRECTOR GENERAL (*Ex-officio*)]

Member Secretary Shri Pawan Kumar Scientist 'B'/Assistant Director Medical Equipment and Hospital Planning, BIS this Page has been intertionally left blank

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

Headquarters:

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Head (Publication & Sales), BIS.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the website-www.bis.gov.in or www.standardsbis.in.

This Indian Standard has been developed from Doc No.: MHD 06 (20932).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

-			
	havan, 9 Bahadur Shah Zafar Marg, New Delhi 110002 es: 2323 0131, 2323 3375, 2323 9402	Website: www.bis.gov.in	
Regional	Offices:		Telephones
Central	: 601/A, Konnectus Tower -1, 6 th Floor, DMRC Building, Bhavbhuti Marg, New Delhi 110002		2323 7617
Eastern	: 8 th Floor, Plot No 7/7 & 7/8, CP Block, Sector V, Salt Lake, Kolkata, West Bengal 700091		<pre>{ 2367 0012 2320 9474 { 265 9930</pre>
Northern	: Plot No. 4-A, Sector 27-B, Madhya Marg, Chandigarh 160019		265 9930
Southern	: C.I.T. Campus, IV Cross Road, Taramani, Chennai 600113	3	{ 2254 1442 2254 1216
Western	: Manakalya, 4 th Floor, NTH Complex (W Sector), F-10, MI (East), Mumbai 400093	IDC, Andheri	{ 283 25838

Branches : AHMEDABAD, BENGALURU, BHOPAL, BHUBANESHWAR, CHANDIGARH, CHENNAI, COIMBATORE, DEHRADUN, DELHI, FARIDABAD, GHAZIABAD, GUWAHATI, HARYNA, HUBLI, HYDERABAD, JAIPUR, JAMMU & KASHMIR, JAMSHEDPUR, KOCHI, KOLKATA, LUCKNOW, MADURAI, MUMBAI, NAGPUR, NOIDA, PARWANOO, PATNA, PUNE, RAIPUR, RAJKOT, SURAT, VIJAYAWADA.