

स्किन ग्राफ्टिंग ब्लेड

(दूसरा पुनरीक्षण)

Skin Grafting Blade

(Second Revision)

ICS 11.040.30

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June 2024

Price Group 4

FOREWORD

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

This standard was first published in 1987 as IS 3759 : 1987 'Specification for blades, skin grafting'. This revision has been taken up in order to align the cross-references to the latest standards.

The composition of the Committee responsible for formulation of the standard is given in [Annex B](#).

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
SKIN GRAFTING BLADE
(Second Revision)

1 SCOPE

This standard specifies the requirements of skin grafting blades used in skin grafting knives and dermatomes.

2 REFERENCES

The standards given below contain provisions which through reference in this text, constitute provision 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:

<i>IS No.</i>	<i>Title</i>
IS 3642 (Part 1) : 1990	Surgical instruments — Specification: Part 1 non-cutting, articulated instruments (<i>second revision</i>)
IS/ISO 7153-1 : 2016	Surgical instruments — Materials: Part 1 Metals
IS 7531 : 1990	Surgical instruments — Corrosion resistance of stainless-steel surgical instruments — Methods of tests (<i>first revision</i>)

3 MATERIAL

The materials used in the manufacture of blades shall be as specified in IS/ ISO 7153-1.

4 SHAPE AND DIMENSIONS

Skin grafting blades shall conform to the shape and dimensions as shown in [Fig. 1](#).

5 MANUFACTURE, WORKMANSHIP AND FINISH

5.1 The blades shall be sharpened along the entire

length of the cutting edge and shall include an angle of $16^{\circ} \pm 1^{\circ}$.

5.2 The blade shall be perfectly straight and the centres of the holes shall be at equal distance from the cutting edge.

5.3 The cutting edge shall be perfectly straight, uniform throughout, surgically sharp and free from feathers, nicks, high spots and waviness.

5.4 The blades shall be highly polished and free from any blemishes. All edges, except the cutting edge, shall be rounded.

6 REQUIREMENTS

6.1 The cutting edge of the blade shall be examined under a magnification of at least 60 X in two directions along and perpendicular to the plane of the cutting edge, and it shall not reveal any feather edge, nicks, high spots, waviness or undulation.

6.2 The blade shall be tested by shaving a piece of chamois leather with moderate pressure at least five times. They shall cut easily and cleanly along the entire length of the cutting edge. On completion of the test, the blade shall show no sign of damage, when examined in accordance with

6.3 The blades shall be hardened and tempered to 700 HV to 800 HV.

6.4 The instrument shall show no sign of corrosion when put to boiling and autoclaving test in accordance with IS 7531.

7 PACKING AND MARKING**7.1 Packing**

The blades shall be coated with a thin film of a solution containing corrosion inhibitors, shall be wrapped with sterilization wraps and sealed with a tape which is a biological indicator or as agreed to between the purchaser and the supplier.

7.2 Marking

Each blade shall be clearly and indelibly marked with the following:

- a) Manufacturer's name, initials or recognized trade-mark; and
- b) Batch number.

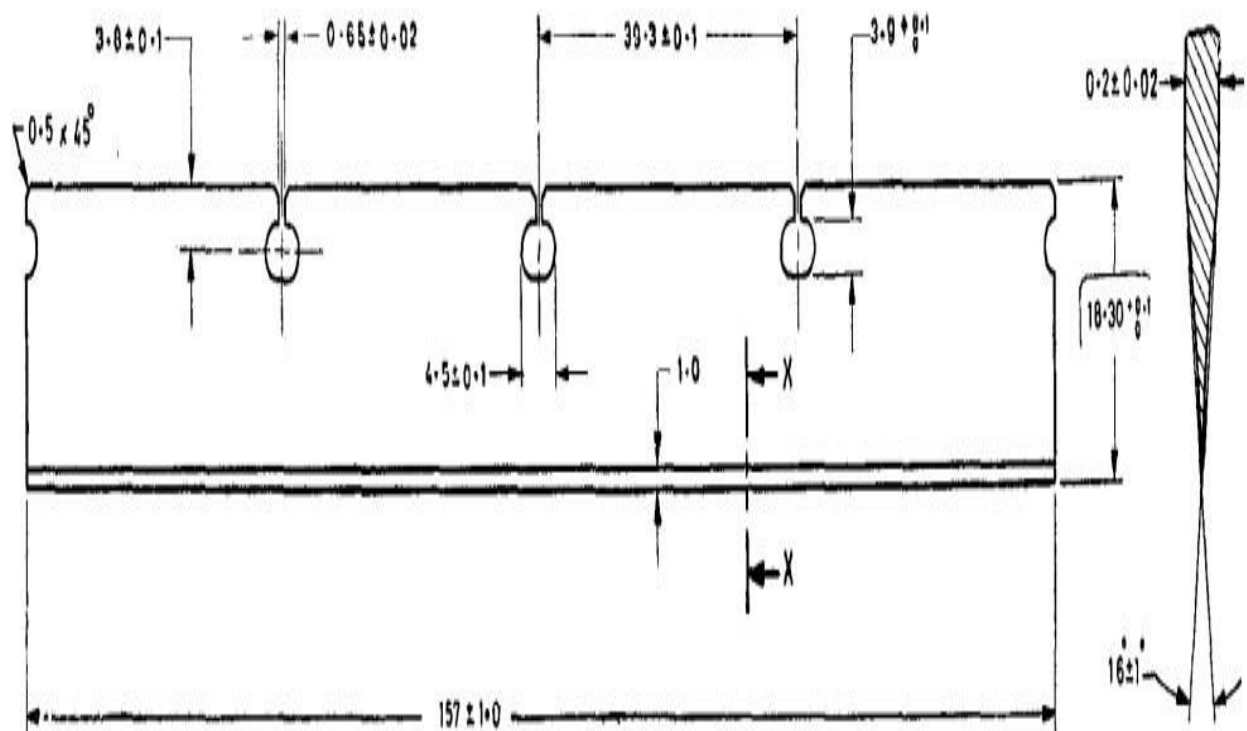
7.3 BIS Certification Marking

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 products may be marked with the Standard Mark.

8 SAMPLING

Sampling procedure and acceptance criteria for conformity may be as agreed to between the purchaser and the supplier. A recommended scheme for the same is given in [Annex A](#).



ENLARGED SECTION XX

All dimensions in millimetres.
FIG. 1 SKIN GRAFTING BLADE

ANNEX A

(Clause 8)

SAMPLING PLAN AND CRITERIA FOR CONFORMITY

A-1 LOT

In a consignment, all the blades of the same pattern and dimensions shall be grouped together to constitute a lot, not exceeding 50. Each lot shall be tested for the requirements of this specification.

A-2 SCALE OF SAMPLING AND CRITERIA FOR CONFORMITY

A-2.1 Eight blades from the lot shall be selected at random by using random number tables (*see* IS 4905) and tested for the requirements of shape and dimensions [4](#), material [3](#), workmanship

and finish [5](#), marking [7](#) and packing [7.1](#). Any blade failing to meet one or more of the above requirements shall be termed defective. No defectives shall be permitted in the sample if the lot is to be accepted under this clause.

A-2.2 The lot which has been found satisfactory as in [A-2.1](#) shall be tested for other requirements. For this purpose, three blades shall be sampled and tested for feathers, nicks, etc [5.3](#) and [6.1](#) and performance requirements [6.2](#). One blade shall be tested for hardness [6.3](#) and corrosion resistance [6.4](#). All samples shall pass the respective requirements if the lot is to be accepted under this clause.

ANNEX B

(Foreword)

COMMITTEE COMPOSITION

Surgical Instruments Sectional Committee, MHD 01

<i>Organization</i>	<i>Representative(s)</i>
Maulana Azad Medical College, New Delhi	DR PAWANINDRA LAL (<i>Chairperson</i>)
3M India Limited, Bengaluru	SHRI KULVEEN SINGH BALI DR PRABHA HEGDE (<i>Alternate</i>)
All India Institute of Medical Sciences, New Delhi	DR PEUSH SAHANI DR PRAMOD GARG (<i>Alternate</i>)
Association of Indian Medical Device Industry, New Delhi	DR ATUL SARDANA
B. Braun Medical India Private Limited, New Delhi	SHRI ANMOL KUMAR RAY MS GAYATRI GARG (<i>Alternate</i>)
Baxter R&D, Bengaluru	SHRI RAHUL GUPTA
Becton Dickinson India Private Limited, Gurugram	SHRI SUDHAKAR MAIRPADY
Carl Zeiss India (Bangalore) India Private Limited, Bangalore	SHRI SUNIL PUNSHI
Central Drugs Standard Control Organization, New Delhi	SHRI ARVIND R. HIWALE DR RAVI KANT SHARMA (<i>Alternate</i>)
HCL, Noida	SHRI MAKESH RAMALINGAM
Indian Institute of Technology Kanpur, Kanpur	DR K. S. VENKATESH
Intuitive Surgical India Private Limited, Bengaluru	SHRIMATI INDIRA B. NARAYAN MURTHY
Johnson and Johnson Private Limited, Mumbai	SHRI AADITYA VATS SHRI YATEEN SHAH (<i>Alternate</i>)
Kalam Institute of Health Technology, Vishakhapatnam	SHRI AMIT SHARMA SHRI DILIP KUMAR CHEKURI (<i>Alternate I</i>) MS SUSHMITA ROY CHOWDHURY (<i>Alternate II</i>)
Karl Storz Endoscopy India Private Limited, New Delhi	SHRI KAPIL RANA
Kehr Surgical Private Limited, Kanpur	SHRI RAJIV KEHR SHRI VISHAL KEHR (<i>Alternate</i>)
Lady Hardinge Medical College, New Delhi	DR YOGESH KUMAR SARIN DR SUBHASIS ROY CHOUDHURY (<i>Alternate I</i>) DR VIKRAM KHANNA (<i>Alternate II</i>)
Maulana Azad Medical College, New Delhi	DR RAJDEEP SINGH DR CHANDRA BHUSHAN SINGH (<i>Alternate I</i>) DR ANUBHAV VINDAL (<i>Alternate II</i>)
Medical Technology Association of India, Gurugram	SHRI NADEEM ANAM SHRI MOHAMMAD AFRAZ ALAM (<i>Alternate</i>)
Medtronic India Private Limited, Gurugram	SHRI PRIYANSHU GARG

<i>Organization</i>	<i>Representative(s)</i>
Ministry of Consumer Affairs, Food and Public Distribution, New Delhi	SHRI B. N. DIXIT SHRI RAJ KUMAR TYAGI (<i>Alternate</i>)
Ministry of Environment Forest and Climate Change, New Delhi	DR SATYENDRA KUMAR SHRI N. SUBRAHMANYAM (<i>Alternate</i>)
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Olympus Medical Systems India Private Limited, Gurgaon	MS NEHA GUPTA SHRI LALIT (<i>Alternate I</i>) SHRI LOVEDEEP NAGAR (<i>Alternate II</i>)
Rajindra Surgical Industries, Jalandhar	SHRI HARVINDER SINGH
South India Surgical Company Limited (SISCO), Chennai	SHRI DILIP BAJAJ SHRI ASHOK BAJAJ (<i>Alternate</i>)
Stryker India Private Limited, Gurugram	SHRI SHIVKUMAR HURDALE SHRI GAJENDER SHARMA (<i>Alternate I</i>) SHRI ARIJIT BHOWMICK (<i>Alternate II</i>) SHRI DEEPAK SHARMA (<i>Alternate III</i>)
The Surgical Manufacturers and Traders Association, New Delhi	SHRI RAKESH SAWHNEY SHRI NARESH GROVER (<i>Alternate</i>)
The Urological Society of India, Mumbai	DR ASHISH VISHWAS RAWANDALE PATIL DR RAJIV T. P. (<i>Alternate</i>)
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MS NAGAVARSHINI M.
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Bureau of Indian Standards

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This Indian Standard has been developed from Doc No.: MHD 01 (21041).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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