*भारतीय मानक*

***स्किन ग्राफ्टिंग ब्लेड***

*(दूसरा* ***पुनरीक्षण****)*

*Indian Standard*

# Skin Grafting Blade

*(Second Revision)*

**ICS 11.040.30**

Surgical Instruments Sectional Committee MHD 01

FOREWORD

This Indian Standard 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 originally 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*)’.

*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:

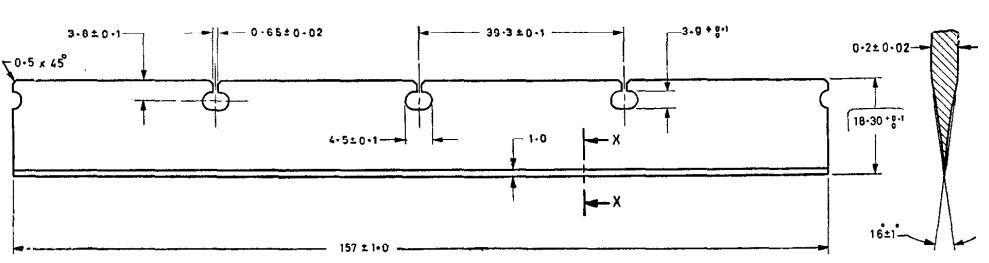
|  |  |
| --- | --- |
| *IS No.* | *Title* |
| IS 3642 (Part 1) : 1990 | Surgical instruments — Specification: Part 1 non-cutting, articulated instruments (*second revision*) |
| IS/ ISO 7153-1 : 2016 | Surgical instruments — Materials: Part 1 Metals |
| IS 7531 : 1990 | Surgical instruments — Corrosion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

**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 bladesshall conform to the shape and dimensions as shown in Fig. 1.



ENLARGED

SECTION XX

All dimensions in millimetres.

Fig. 1 Skin Grafting Blade

## 5 MANUFACTURE, WORKMANSHIP AND FINISH

**5.1** The bladesshall be sharpened along the entire length of the cutting edge and shall include an angle of 16 º ± 1º.

**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** Theblades shall be highly polished and free from any blemishes. All edges, except the cutting edge, shall be rounded.

## 6 REQUIREMENTS

**6.1** Thecutting 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 apiece 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:

1. Manufacturer’s name, initials or recognized trade-mark; and
2. 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 criteriafor conformity may be as agreed to between the purchaser and the supplier. A recommended scheme for the same is given in Annex A.

**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 testedfor 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

| *Organization* | | | *Representative(s)* | |
| --- | --- | --- | --- | --- |
| Maulana Azad Medical College, New Delhi | | | Dr Pawanindra Lal **(*Chairperson*)** | |
| 3M India Limited, Bengaluru | | | Shri Kulveen Singh Bali  Dr Prabha Hegde (*Alternate*) | |
|  | | |
| All India Institute of Medical Sciences, New Delhi | | | Dr Peush Sahani  Dr Pramod Garg (*Alternate*) | |
|  | | |
| 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 (*Alternate*) | |
|  | | |
| 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 (*Alternate*) | |
|  | | |
| 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 | |
| Kalam Institute of Health Technology, Vishakhapatnam | | | Shri Dilip Kumar Chekuri (*Alternate*) | |
|  | | | Shri Amit Sharma | |
|  | | | Ms Sushmita Roy Chowdhury | |
| Karl Storz Endoscopy India Private Limited, New Delhi | | | Shri Kapil Rana | |
| Kehr Surgical Private Limited, Kanpur | | | Shri Rajiv Kehr | |
|  | | | Shri Vishal Kehr (*Alternate*) | |
| Lady Hardinge Medical College, New Delhi | | | Dr Yogesh Kumar Sarin | |
|  | | | Dr Subhasis Roy Choudhury (*Alternate*) | |
|  | | | Dr Vikram Khanna (*Alternate*) | |
| Maulana Azad Medical College, New Delhi | | | Dr Chandra Bhushan Singh (*Alternate*) | |
|  | | | Dr Rajdeep Singh | |
|  | | | Dr Anubhav Vindal (*Alternate*) | |
| Medical Technology Association of India, Gurugram | | | Shri Nadeem Anam | |
|  | | | Shri Mohammad Afraz Alam (*Alternate*) | |
| Medtronic India Private Limited, Gurugram | | | Shri Priyanshu Garg | |
| Ministry of Consumer Affairs, Food and Public Distribution, New Delhi | | | Shri Raj Kumar Tyagi (*Alternate*) | |
|  | | | Shri B. N. Dixit | |
| Ministry of Environment Forest and Climate Change, New Delhi | | | Dr Satyendra Kumar  Shri N. Subrahmanyam (*Alternate*) | |
|  | | |
| Ministry of Railways, Lucknow | | | Dr Pankaj Kumar Arora | |
|  | | | Dr B. N. Tiwari (*Alternate*) | |
| Olympus Medical Systems India Private Limited, Gurgaon | | | Ms Neha Gupta  Shri Lalit (*Alternate* I)  Shri Lovedeep Nagar (*Alternate* II) | |
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| Rajindra Surgical Industries, Jalandhar | | | Shri Harvinder Singh | |
| South India Surgical Company Limited (SISCO), Chennai | | | Shri Ashok Bajaj (*Alternate*) | |
|  | | | Shri Dilip Bajaj | |
| Stryker India Private Limited, Gurugram | | | Shri Shivkumar Hurdale  Shri Gajender Sharma (*Alternate* I)  Shri Arijit Bhowmick (*Alternate* II)  Shri Deepak Sharma (*Alternate* III) | |
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| The Surgical Manufacturers and Traders Association, New Delhi | | | Shri Rakesh Sawhney  Shri Naresh Grover (*Alternate*) | |
|  | | |
| The Urological Society of India, Mumbai | | | Dr Ashish Vishwas Rawandale Patil  Dr Rajiv T. P. (*Alternate*) | |
|  | | |
| BIS Directorate General | | | Shri A. R. Unnikrishnan Scientist, ‘F’/Senior Director and Head (Medical Equipment and Hospital Planning) [Representing Director General (***Ex*-*officio*)]** | |
| *Member Secretary*  Ms Nagavarshini M.  Scientist ‘B’/Assistant Director  (Medical Equipment And Hospital Planning), BIS | | | | |