MHD 01 (21040) WC
May 2024
[Supersedes IS 3318, IS 3319, IS 3320]

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक

सर्जिकल उपकरण - स्केलपेल

Indian Standard
Surgical Instruments - Scalpel

[ICS 11.040.30]

Surgical Instruments Sectional Committee, MHD 01

Last date for comments:
24 June 2024

FOREWORD

(Formal clause will be added later)

This Standard supersedes the IS 3318: 1965 'General Requirements of Surgical Scalpels and Knives', IS 3319: 1995 'Blades, surgical, detachable (Bard Parker Type) and handles - Specification (Fourth Revision)' and IS 3320: 1973 'Specification for surgical scalpels (First Revision)'.

This Indian standard specifies the general requirement for Surgical Scalpel and blades used in general surgery for cutting or puncturing a tissue.

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 the same as that of the specified value in this standard.

1 SCOPE

1.1 This standard covers the general requirements of Surgical Scalpel, consisting of handle and blade, used in general surgery for cutting or puncturing a tissue.

1.2 This standard is applicable for single use, reusable, detachable blade, single piece scalpel and retractable scalpel.

2 REFERENCES

2.1 The following standard contains provision 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 the standards indicated below:

2.2 The Indian Standards given below are necessary adjuncts to this standard.

Indian Standard	***Title***
IS 4905: 2015/ ISO 24153: 2009	Random sampling and randomization procedures (*First Revision*)
IS/ ISO 7153-1: 2016	Surgical Instruments – Materials Part 1 Metals
IS/ ISO 13402: 1995	Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure

3 TERMINOLOGY

3.1 Scalpel – It is a sharp cutting instrument used in the surgical procedures for puncturing tissue.

3.2 Scalpel Handle - Scalpel Handle holds the scalpel blade

3.3 Scalpel Blade – Anterior functioning part of the scalpel

4 CLASSIFICATION

4.1 Single Use or disposable – The Scalpel is used only one and the same is disposed.

4.2 Reusable – The Scalpel is sterilized and used again.

4.3 Detachable Blade – The Blade is for single use whereas the handle can be sterilized and can be reused.

4.4 Single Piece Scalpel – The Handle and the Blade cannot be detached.

5 MATERIAL REQUIREMENTS

5.1 The material used in the manufacture of scalpels shall be as specified in IS/ ISO 7153-1: 2016

5.2 The instruments shall be treated by a suitable passivation process, for example, by electropolishing or by treatment with 10 percent nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

6 DIMENSIONAL REQUIREMENTS

6.1 The dimensions of blade and handle shall be as given in Table 1 read with Fig. 2 and 3, for small size and Table 2 read with Fig. 2 and 3 for large size. Figure 1 is given for illustration.

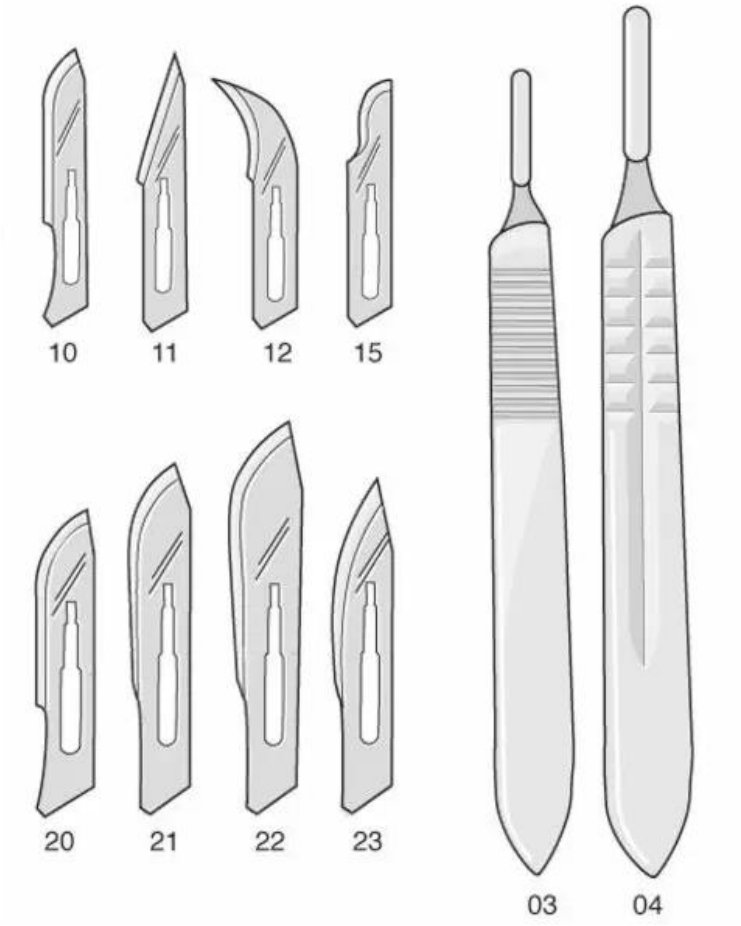


FIG. 1 SCALPEL BLADE AND HANDLE

Table 1 Dimensions for small size scalpel blade and handle

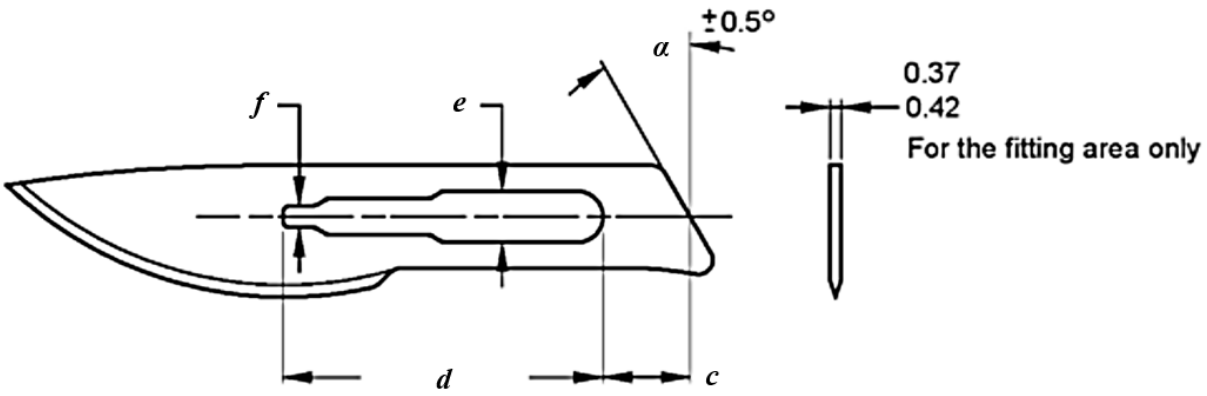
(Clause 6.1)

	α	***c***	***d***	***e***	***f***	***l***
		Min - Max (in mm)	***Min - Max (in mm)***	***Min - Max (in mm)***	***Min - Max (in mm)***	***Min (in mm)***
Blade	30°	4.50 – 4.65	17.83 – 17.90	2.43 – 2.48	1.18 – 1.23	-
Handle	40°	4.40 – 4.50	17.73 – 17.81	2.31 – 2.41	1.12 – 1.17	9

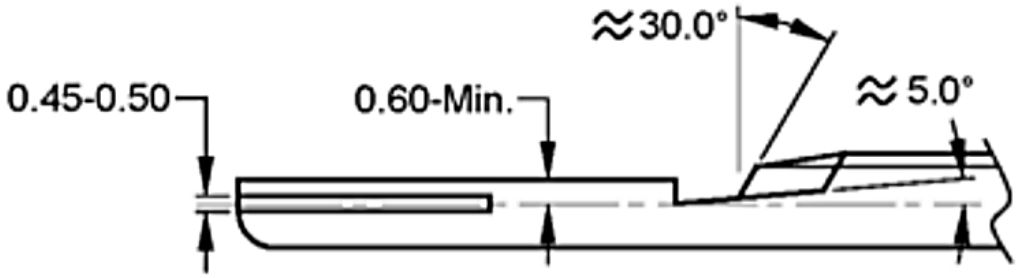
Table 2 Dimensions for large size scalpel blade and handle

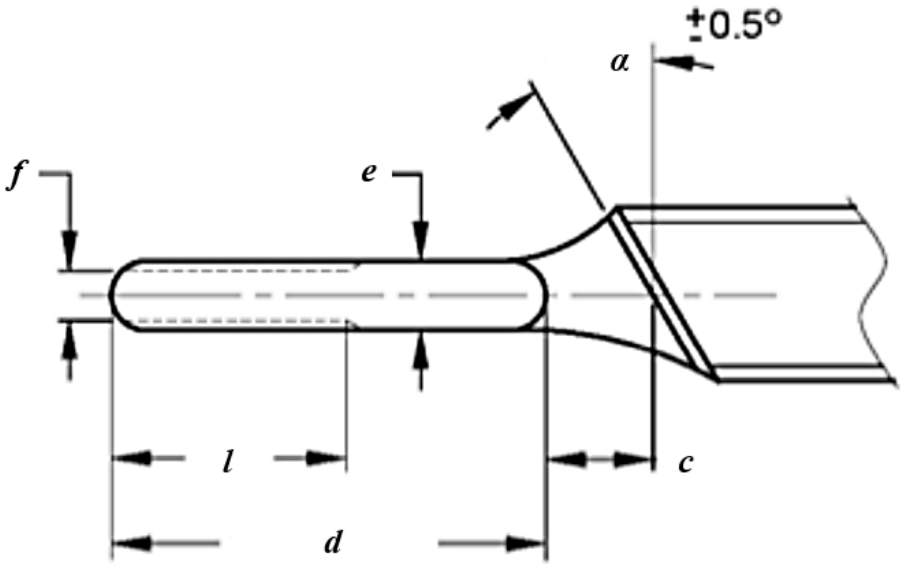
(Clause 6.1)

	α	***c***	***d***	***e***	***f***	***l***
		Min - Max (in mm)	***Min - Max (in mm)***	***Min - Max (in mm)***	***Min - Max (in mm)***	***Min (in mm)***
Blade	35°	7.50 – 7.60	24.20 – 24.27	3.72 – 3.77	1.95 - 2.00	-
Handle	35°	7.40 – 7.50	24.10 – 24.18	3.60 – 3.70	1.88 – 1.93	13



All dimensions in millimetres
FIG. 2 SCALPEL BLADE





All dimensions in millimetres
FIG 3. SCALPEL HANDLE

7 MECHANICAL REQUIREMENTS

7.1 The blades of surgical scalpels handle shall be hardened and tempered to 800 to 850 HV.

7.2 The Surgical Scalpel shall undergo test as specified in Clause 4 of IS/ ISO 13402: 1995. The Surgical Scalpel shall not show any sign of corrosion without magnification.

7.3 The Surgical Scalpel shall undergo test as specified in Clause 5 of IS/ ISO 13402: 1995. The Surgical Scalpel shall not show any sign of copper plating without magnification.

8 GENERAL REQUIREMENTS

8.1 The cutting edge 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, nick, high spot, waviness or undulation.

8.2 The cutting edge of the blade shall be central with respect to the thickness of the blade and it shall be in one plane, when examined with normal or corrected vision.

8.3 The handle shall be finished smooth with a matt surface. It shall be free from burrs, sharp or rough edges, pits and other surface defects. The edge shall be chamfered.

9 PERFORMANCE REQUIREMENTS

The scalpels and knives shall be tested by cutting a piece of Chamois leather with moderate pressure at least five times. They shall cut easily and clearly along the entire length of the cutting edge. On completion of the test, the scalpel or knife shall show no sign of damage, when examined in accordance with 8.1.

10 MARKING

10.1 The scalpels shall be clearly and indelibly marked with the manufacturer's name or trade-mark and Batch/ Lot/ Serial Number.

10.2 When the marking is done on the blade portion, it shall be done by electro etching.

10.3 The Surgical Scalpel may also be marked with a Standard Mark.

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

11 SAMPLING

The scale of sampling and criteria for conformity of the instrument to requirements of the specification shall be as per the sampling plan given in Annex A.

12 PACKING

The Surgical Scalpel shall be wrapped with sterilization wraps and sealed with a tape which is a biological indicator.

ANNEX A
(Clause 11)

A-1 LOT

A-1.1 In any consignment, all the instruments of the same type and pattern produced from the same material under similar conditions and having the same surface finish shall constitute a lot.

A-2 NUMBER OF INSTRUMENTS

A-2.1 The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with the below table.

Table 2 Scale of Sampling

Lot Size (1)	Sample Size (2)
up to 15	2
16 to 50	3
51 to 150	5
151 and above	8

A-2.2 These instruments shall be selected from the lot at random and in order to ensure randomness of selection, procedures given in IS 4905 may be followed.

A-3. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 For ascertaining the conformity of the material to the requirements of the specification, samples shall be tested from each lot separately.

A-3.2 All the instruments, selected according to column 1 and 2 of Table 2 shall be examined for shape and dimensions, general, mechanical, material and performance requirements. An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as having satisfied these requirements, if there is no defective in the sample.