

**SPECIFICATION SHEET****Doc. No.:** PSL/TDS/02PNSS**Revision** 00**Effective** 11-10-2025**Safety Scalpel
(Stainless Steel)**

Page 1 of 4

1.0 Product: Safety Scalpel in stainless steel**1.1** Model/Variant

Trade/ Brand Name	Product Name	Model	Reference No	EMDN Code
Paramount	Safety Scalpel	New Safety Scalpel MSC	PNSSMSC	V010101
		New Safety Scalpel 9	PNSS9	V010101
		New Safety Scalpel 10	PNSS10	V010101
		New Safety Scalpel 10A	PNSS10A	V010101
		New Safety Scalpel 11	PNSS11	V010101
		New Safety Scalpel 11K	PNSS11K	V010101
		New Safety Scalpel 11K	PNSS11P	V010101
		New Safety Scalpel 13	PNSS13	V010101
		New Safety Scalpel 15	PNSS15	V010101
		New Safety Scalpel 15B	PNSS15B	V010101
		New Safety Scalpel 15C	PNSS15C	V010101
		New Safety Scalpel 15D	PNSS15D	V010101
		New Safety Scalpel 15S	PNSS15S	V010101
		New Safety Scalpel 17	PNSS17	V010101
		New Safety Scalpel 18	PNSS18	V010101
		New Safety Scalpel 19	PNSS19	V010101
		New Safety Scalpel 20	PNSS20	V010101
		New Safety Scalpel 21	PNSS21	V010101
		New Safety Scalpel 22	PNSS22	V010101
		New Safety Scalpel 23	PNSS23	V010101
		New Safety Scalpel 24	PNSS24	V010101
		New Safety Scalpel 24D	PNSS24D	V010101
		New Safety Scalpel 25	PNSS25	V010101
		New Safety Scalpel 34	PNSS34	V010101
New Safety Scalpel 36	PNSS36	V010101		
New Safety Scalpel 36D	PNSS36D	V010101		

1.2 International Product Standards:**1.1** International Standard: ISO 7740: 1985 (EN 27740:1992): Instruments for Surgery - Scalpels with detachable blades - Fitting dimension.**1.2** International Standard: EN ISO 7153-1:2016 Surgical instruments —Metallic materials —Part 1: Stainless steel**2.0 Raw Material:**

Safety Scalpel are manufactured from Stainless Steel blade mounted on ABS handle with Polycarbonate slide. Steel used to produce the blades conform to the following standards

2.1 Stainless Steel composition is as defined in ISO 7153-1:2016 (Grade F)

Constituent	Percent
Carbon	0.6 to 0.7
Manganese	1.0 max.
Chromium	12.0 to 13.5
Silicon	0.5 max.
Phosphorus	0.03 max.
Sulphur	0.025 max.
Nickel	0.5 max.

3.0 Outline Shape, Fitment and Nomenclature:

Prepared By: Meghana (QA/RA Manager)

Approved By: Rajesh Sabikhi (Sr. GM)

**SPECIFICATION SHEET****Doc. No.:**

PSL/TDS/02PNSS

Revision

00

Effective

11-10-2025

**Safety Scalpel
(Stainless Steel)**

Page 2 of 4

3.1 Outline Shape:

As per Controlled drawings

3.2 Fitment with handle (slot size):

As per ISO 7740: 1985.

3.3 Nomenclature

As per Controlled drawings

4.0 Hardness, Workmanship & Finish**4.1 Hardness**

Stainless Steel Safety Scalpel blades have a minimum hardness of 700 HV on the Vickers Scale.

4.2 Blade Breaking Strength

There is no international specification/standard for breaking strength of the blade. Blades are tested for breaking strength as per company specification which is derived from the comparative data. The strength is different for every blade design.

4.3 Finish

When inspected by normal or corrected vision, blades shall have a smooth finish and shall be free from burrs and corrosion.

Blades are 100 percent visually inspected for -

- Any bends, (Lack of flatness)
- Stropping defect. (Burr in cutting edges, bends edges)
- Polishing deficiency, (Dull finish, un-polished surface)
- cleaning deficiency, (oil stain, water stain, residuals)
- Damaged, (handle cut, cutting edge damages, broken)
- Press marks, (burrs, dents)
- Surface Defects (Pitting, rust, spot, scratch mark)
- flash, black spot, short molding

4.4 Grinding defects-

Blades are 100% checked after grinding process for grinding defects like cut uneven, pointing round, profile defect, burning, no burr, waviness, feather.

4.5 Cutting Edge

The central plane of the cutting edge shall be central with respect to the blade and, when inspected by normal or corrected vision, shall be free from nicks, burs and feathered edges. Cutting angle of the blade should be 16° to 28°.

4.6 Sharpness test

Sharpness of blades is checked for each batch by cutting chamois leather.

4.7 Seal test/ Dye penetration Test

Five Safety Scalpel blades are taken from each batch at random from the finished lot and tested for soundness of seal. These safety pouches are Inject approx. 2 to 5 ml dye penetrant into the package approximately 5mm above from sealed area for 5 to 20 seconds. No leakage should appear.

4.8 Freedom from extraneous matters

Safety Scalpel Blades shall be clean and free from extraneous matter when inspected by normal or corrected vision.

4.9 Seal Strength Test

Two pouches from each batch at random tested for the seal strength as per EN 868 on the calibrated seal strength machine. The seal strength of 15mm specimen pouch should not be less than 1.5N

5.0 Packaging**5.1 Primary Packaging**

Sterile Stainless-Steel Safety Scalpel blades are individually packed in medical grade paper and soft blister film

5.1.1 Material Specification

- GSM of Medical grade paper is (65-75)
- GSM of Soft blister film is (70-80)

5.1.2 Dimension – Nominal

Size Stainless-Steel Safety Scalpel packet is given below for fitment 3 & 4.

Fitment- 3: 190 x 33 mm

Fitment- 4: 205 x 33 mm

Prepared By: Meghana (QA/RA Manager)

Approved By: Rajesh Sabikhi (Sr. GM)

**SPECIFICATION SHEET****Doc. No.:**

PSL/TDS/02PNSS

**Safety Scalpel
(Stainless Steel)****Revision**

00

Effective

11-10-2025

Page 3 of 4

5.2 Inner Safety Scalpel Dispenser Box

Ten (10) individually packed Stainless-Steel Safety Scalpel are contained in one inner box.

5.2.1 Material SpecificationInner boxes are made from ≥ 330 GSM printed paper, 2 sides flapped with tear-out dispensing aperture to the bottom right hand corner.**5.2.2 Dimension – Nominal**

Safety Scalpel Inner box dimension: 210 (L) x 70 (W) x 30 (H).

5.3 Export Carton

Fifty (50) printed paper inner boxes are placed in a 5ply Export Carton.

5.3.1 Material SpecificationExport cartons are made of 5 ply Top layer duplex/virgin and rest semi craft with ≥ 730 GSM.**5.3.2 Dimension – Nominal**

Safety Scalpel Export Cartons dimension: 440 (L) x 370 (W) x 330 (H)

6.0 Labeling and Marking

Labeling and marking of blades is fully compliant with the requirements of EN ISO 15223-1:2021, EN 1041.

6.1 Safety Scalpel Blades

Stainless Steel Safety Scalpel blades are stamped with the words "SS along with size ".

6.2 Primary Pouch (Sterile barrier System)**6.2.1 Top Web**

- Product Description
- CE 2460
- Don't use broken package symbol & Text
- Single use only symbol
- Keep away from heat symbol
- Keep in dry place symbol
- Do not re-sterile symbol
- Storage temperature Symbol
- Method of sterilization symbol
- Dispose in Sharps container symbol
- Packet peel direction
- Punch No if needed
- Manufacture Name & License number
- Medical Device Symbol

6.2.2 Bottom Web


The bottom web is transparent poly film and has no symbols.






- 6.3** • **Secondary Pack (Inner carton):** inner carton identifies the following information either preprinted or labeled on it:

I. Sl. No.	Descriptions	Symbol	Sl. No.	Descriptions	Symbol
1	Caution/ Warning (Read IFU before use)		11	Temperature limitation	
2	Product reference/Catalogue No.		12	Do not use if package is damaged	
3	Do Not Reuse		13	Consult for instruction	
4	Lot Number/Batch Number		14	CE Marking	
5	Date of Manufacturing with country of origin		15	Keep away from sunlight	
6	Use By / Expiry Date		16	European Authorized Representative	
7	Sterilized by Gamma Irradiation in conjunction with single barrier sterile system read size		17	Do not re-sterilize	

Prepared By: Meghana (QA/RA Manager)

Approved By: Rajesh Sabikhi (Sr. GM)

	SPECIFICATION SHEET	Doc. No.:	PSL/TDS/02PNSS
	Safety Scalpel (Stainless Steel)	Revision	00
		Effective	11-10-2025
Page 4 of 4			

8	Manufactured by & Mfg. License no.		18	Non-Pyrogenic	
9	Keep dry		19	Medical Device	
10	Moisture limitation				

6.4 Tertiary Pack (Export Cartons) Each Export Carton contains the information:

- | | | |
|--|--|---|
| <ul style="list-style-type: none"> • Description of contents • Consignee details • Sterile LOT number • Quantity • PO No. • Mfg. License No. | <ul style="list-style-type: none"> • Total No. Of cases • Shipping Marks • Packing List No. • Material • Invoice No. • Manufacturer Name | <ul style="list-style-type: none"> • Case No. of total No of Cases • Do not use hook Symbol • Fragile Symbol • This side up symbol • Keep away from water Symbol • Keep away from direct sunlight |
|--|--|---|

7.0 Sterilization of Safety Scalpel:

Sterilization by gamma radiation to a minimum dosage of 25 kGy (2.5 Mrads). Sterilization protocol in compliance with ISO 11137 and EN 552.

8.0 Shelf life of product

5 years from date of sterilization.

9.0 References

Prepared By: Meghana (QA/RA Manager)	Approved By: Rajesh Sabikhi (Sr. GM)
