

Spinal Needle

DISPOSAFE BRAND NAME	BRAND NAME
Disposafe Spinal Needle	**Spine safe**

1. PRODUCT DESCRIPTION

Spinal Needles are medical devices used for specific therapeutic or diagnostic medical procedures, such as delivering anaesthetic or analgesic agents intrathecally (in the space under the arachnoid membrane of the brain and spinal cord) for spinal anesthesia (total or partial loss of feeling or sensation), analgesia (absence of pain), and lumbar punctures for collecting cerebral spinal fluid (CSF).

2. DEVICE CLASSIFICATION AND RULE

Spinal Needle falls under Class-III (Rule 6) device as per EU MDR 2017/745 Annexure VIII.

3. PRODUCT CHARACTERISTICS & INTENDED USE

INTENDED USE:

Gain entry into or puncture the spinal cavity permitting injection (including anesthesia) / withdrawal of fluids for purposes of diagnostic lumbar puncture and myelography procedures.

- Suitable for Spinal anaesthesia. High flow rate enables faster cerebro spinal fluid flash back.
- Quincke point for smoother penetration.
- Colour coded hub for easy identification.
- Sterilization by ethylene Oxide.

4. PRODUCT VARIANTS

Following variants are available for the products

Sr. No.	Product	GMDN	Gauge/Size
1.	Spinal Needle	35212	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G

5. MATERIAL OF CONSTRUCTION

S.No.	Components	Material Used
1.	Stylet Hub	MABS (Methacrylate-Acrylonitrile-Butadiene-Styrene)
2.	SS Tube	Stainless Steel
3.	Needle Hub Type-M3	MABS (Methacrylate-Acrylonitrile-Butadiene-Styrene)
4.	Stylet	Stainless Steel
5.	Needle	Stainless Steel
6.	Needle Holder	MABS (Methacrylate-Acrylonitrile-Butadiene-Styrene)
7.	P.P. Tube	Poly Propylene

6. TECHNICALSPECIFICATION

Sr. No.	Parameter	Tolerance	Sizes									
4.1	**Gauge**	-	**18G**	**19G**	**20G**	**21G**	**22G**	**23G**	**24G**	**25G**	**26G**	**27G**
4.2	Needle OD (mm)	± 0.01	1.26	1.06	0.90	0.81	0.70	0.66	0.58	0.55	0.46	0.41
4.3	Stilette OD (mm)	± 0.01	0.90	0.70	0.55	0.45	0.35	0.35	0.25	0.25	0.25	0.20
4.4	Bonding strength of Needle (N)	≥	65	65	55	55	35	35	35	35	25	25
4.5	Bonding strength of Stilette (N)	≥	65	65	55	55	35	35	35	35	25	25
4.6	Needle Material	-	Stainless steel-304									
4.7	Stilette Material	-	Stainless steel-304									
4.8	Needle Type	-	**Quincke needle**									
4.9	Conical Fitting	-	6% female Taper with luer lock facility shall be leak free									
4.10	Colour of Stilette Hub	-	**18G**	**19G**	**20G**	**21G**	**22G**	**23G**	**24G**	**25G**	**26G**	**27 G**

Prepared by:	Reviewed by:	Approved by:	Issued by:	
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			Pink	Cream	yellow	Green	Black	Blue	Purple	orange	Brown	Grey
4.11	Effective length of needle in mm	± 1 mm	90	90	90	90	90	90	90	90	90	90
4.12	Freedom from Foreign matter	The Product shall be free from foreign matter, metal particles or chips ,Burr and other defects.										
4.13	Point of Needle	The Needle point shall be sharp, free from burr when examined under 15X magnification.										
4.14	Leakage Test	There is No Leakage from Joints at 3 Bar pressure in 10 second										

7. REFERENCE COMPLIANCE STANDARD

S. No.	Name Of Standard	Standards
1.	Needles, Spinal [MHD 1: Surgical Instruments]	IS 7350-1974
1.	Stainless steel needle tubes for the manufacture of medical needles. Requirements and test methods.	EN ISO 9626-2016
2.	Small bore connectors for liquids and gases in healthcare - Part 7: Particular requirements for connectors for intravascular or subcutaneous use.	EN ISO 80369-7:2021
3.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
4.	Medical Devices - Application for Risk Management to Medical Devices	EN ISO 14971:2019
5.	Biological evaluation of medical devices. Part 1: Evaluation and testing as part of the risk management process	EN ISO 10993-1:2020
6.	Biological evaluation of medical devices. Part 3: Genotoxicity, carcinogenicity and reproductive toxicity tests	ISO 10993-3:2014
7.	Biological Evaluation of Medical Devices - Part 4: Selection of Tests Relevant to Blood Interactions	EN ISO 10993-4:2017
8.	Evaluation of the biological effects of medical devices - Part 5: In vitro cytotoxicity tests.	ISO 10993-5:2009
9.	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residues.	EN ISO 10993-7:2008
10.	Evaluation of the biological effects of medical devices - Part 11: Systemic toxicity tests	EN ISO 10993-11:2018
11.	Biological evaluation of medical devices - Part 12: Sample preparation and control samples	EN ISO 10993-12:2021

12.	Symbols used on medical device labels in labeling and information provided.	EN ISO 15223-1:2023
13.	Sterilization of medical devices - Microbiological methods - Part 1: Determination of the microbial population on products	EN ISO 11737-1:2021
14.	European Union Medical Devices Regulation	MDR 2017/745
15	Medical devices - Part - 1: Application of usability engineering to medical products.	IEC 62366-1:2015/Amd 1:2020
16.	Clinical Investigations of Medical Devices in Humans - Good Clinical Practice	ISO 14155:2020
17.	Medical Devices - Aftermarket Surveillance for Manufacturers	ISO 20416:2020
18.	Sterilization of medical devices - Chemical indicator - Part 1 General requirements	EN ISO 11140-1:2015
19.	Medical devices-Post market Surveillance for manufacturer	ISO/TR 20416:2020
20	Sterilization of health care products-Biological indicator-Part 1 General requirement	EN ISO 11138-1:2017
21.	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	ASTM-F1980
22.	Catheter systems for neuraxial application — Sterile and single-use catheters and accessories	ISO 20698:2018

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	TYPE OF MATERIAL	PACKAGING
Primary Packaging	Hard Blister	01
Secondary Packaging (Inner Carton)	400 GSM	25
Tertiary Packaging (Master Carton)	5 Ply	1000

9. OTHER DETAILS

a. **Intended Use:** refer the instruction for use before the application.
b. **Storage:** store in a cool and dry place and keep away from direct sunlight and extreme heat.
c. **Method of Sterilization:** sterilized using ethylene oxide.
d. **Shelf life:** 05 years from the month / date of sterilization.
e. **Testing and Analysis:** Testing for sterility, pyrogen content and physical characteristics (Visual Checking, Moulding defect, Packaging Condition, Colour Coding, Corrosion, Sharpness, sealing etc) is performed on each batch before release.

f. **Biocompatibility:** the product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.

g. **Disposal:** Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

10. COMPLIANCE INFORMATION

Manufacturing Site Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2,Sec- 59, Phase-II, Ballabhgarh, Faridabad-121004, Haryana (INDIA)

Drug Manufacturing License No.: MFG/MD/2019/000106

QMS Certification: EN ISO 13485:2016

CE Marking: TUV-SUD Product Services GmbH 0123

GMDN: 35212