I.V CANNULA WITHOUT WINGS AND WITHOUT INJECTION PORT WITH SAFETY FEATURE	DISPOWAY-X-SAFE ALPHA



Fig.: I.V. Cannula without wings and without injection port with safety feature (Dispoway X-Safe Alpha)

1. PRODUCT DESCRIPTION

Safety I.V. Cannula / Catheter is a device for access to the human circulatory system for introduction of fluids or medicament and/or withdrawal of blood samples. It comprises of a short flexible plastic tube (the Catheter) etc., which is inserted into a vein over a hollow introducer needle, after which the needle is withdrawn and discarded.

Duration of Use: Short Term.

Material of Construction: PVC, PP, PTFE/FEP/PUR, HDPE/LDPE,SS.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 7, medical device (classification as per ANNEX–VIII of (EU) MDR 017/745) and Class II as per 21 CFR 880.5200 (USFDA Classification).

3. INTENDED USE

Safety I.V. Cannula is a device used for introduction of fluids or medicament and/or withdrawal of blood samples through peripheral vein. It is inserted into a vein over a hollow introducer needle after which the needle is withdrawn and discarded. Safety I.V. Cannula eliminates the chances of needle stick injuries and blood borne infections to the healthcare providers during needle withdrawal and disposal. It is used by following aseptic technique. The use of the product is restricted to a qualified doctor or a paramedic.

4. PRODUCT FEATURES

- Easy identification of the gauge size through color, as per ISO 10555-5.
- The Physical, Functional and Safety characteristics are conform to the International Standard EN ISO 10555- 1 & 5.
- Sterile, Pyrogen-free until the package is intact.
- **Needle:** The device comprises a siliconized and ground Stainless Steel with ultra-thin, ultra-sharp needle with triple facet bevel to ensure smooth and painless venipuncture during cannulation thus reducing pain and discomfort experienced during the insertion.
- **Catheter:** The catheter is an integral part of the device and is made of best-in-class kink resistant and biocompatible, with extremely smooth inner and outer surfaces to ensure easy

venipuncture with minimum trauma; gently tapered catheter tip aligns with the needle bevel to provide smooth transition from needle to catheter.

- **Flashback Chamber:** detachable Flashback chamber with hydrophobic filter to facilitate quick visualization of blood flashback and confirmation to successful catheter placement in vein and prevent any spillage.
- **Universal female 6% taper:** for ease of connection with other standard devices/ components having male 6% taper. The connection conforms to ISO 80369-7.
- **Needle Cover:** Transparent needle cover to prevent damage to the catheter.
- **X Type Clip:** Prevent from needle stick injury. It has a hole which prevents the used needle from coming out of the cage and prevents the re-use of the product.
- **Flow Control Hub:** The flow control hub has hydrophobic filter for allowing air to pass and don't allow blood to ooze out.

5. PRODUCT VARIANTS

Following options are available with the product Safety Intravenous Cannula:

- Hub cover or Hub cover with filter
- Catheter material options are available, with FEP / PUR / PTFE
- Color coded part cap options is available in Normal or Flip Design
- With PP tube or Molded needle cover
- Unit packaging with MKP or TYVEK
- Bulk-pack of the products are also available

6. MATERIAL OF CONSTRUCTION

S. No	Component Description	Material used
1.	Threaded Stopper	High-density polyethylene (HDPE) + Master Batch White
2.	Hub Cover	P.P. (Polypropylene)
3.	Needle Hub (X-Safe)	P.P. (Polypropylene)
4.	X-Clip	SS 304 Stainless Steel
5.	Teflon Holder	POM (Polyacetal)
6.	Body X-Safe	P.P. (Polypropylene)
7.	Catheter	F.E.P (Fluorinated ethylene propylene) PUR (Polyurethane) PTFE (Polytetrafluoroethylene)
8.	Needle	SS 304 Stainless Steel
9.	Needle Cover	P.P. (Polypropylene)

7. PRODUCT SPECIFICATION

S.no.	Gauge (G)	Length (mm)	Tolerance (mm)	Outer dia (±0.04mm)	Colour (Port cap)	Flow rate(ml/ min)	Tolerance of Flow rate
1.	18	64	± 1.0	1.3	Green	90	-10%-+15%
2.	20	32	± 1.0	1.1	Pink	60	-10%-+15%
3.	22	25	± 1.0	0.9	Blue	36	-20%-+25%
4.	24	32	± 1.0	0.7	Yellow	23	-20%-+25%
5.	26	19	± 1.0	0.7	Violet	15	-20%-+25%

8. PACKAGING DETAILS AND SPECIFICATIONS

Packaging Type	Packed Quantity			Packing Material / Specification
	Unit	Inner Carton (units)	Master Carton (units)	
Hard Blister (Unit Pack)	01	100	1000	**Hard Blister** **Inner Carton (Duplex Board)** **Master Carton (3 Ply CorrugatedBox)**

9. REFERENCE COMPLIANCE STANDARD

Sr. NO.	Title	Standard Ref. No.
1.	Intravascular Catheters- Sterile and single use catheters-Part 1- General requirements	ISO 10555-1:2023
2.	Intravascular Catheters- Sterile and single use catheters-Part 2- Over -needle peripheral catheters	EN ISO 10555-5:2013
3.	Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
4.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
5.	Sampling Procedure For Inspection By attributes	ISO 2859-1:2026
6.	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	EN ISO 15223-1:2021
7.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 11135:2014/A1:2019
8.	Sterilization of health care products - Biological Indicators - Part 1: General requirements	EN ISO 11138-1:2017
9.	Sterilization of health care products - Biological indicators for ethylene oxide sterilization processes	EN ISO 11138-2:2017
10.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
11.	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015
12.	Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018/ A1:2021

13.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2020/ A1:2023
14.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2020/ A11:2022
15.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2025
16.	Biological evaluation of medical devices - Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
17.	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)	EN ISO 10993-4:2017
18.	Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity	EN ISO 10993-5:2009/ A11:2025
19.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2023
20.	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018
21.	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	EN ISO 10933-12:2021
22.	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents	EN ISO 10993-17:2023
23.	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process	EN ISO 10993-18:2020
24.	Medical devices - Part -1: Applications of Usability engineering to the medical devices.	IEC 62366-1:2015/Amd 1:2020
25.	Medical Devices- Post market Surveillance for manufacturers	ISO 20416:2020
26.	Clinical Evaluation Assessment Report Template	MDCG 2020-13
27.	Medical Devices Regulations Clinical Evidence Requirements	MEDDEV 2.7.1 Rev 4,
28.	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM-F1980
29.	Medical devices - Information to be supplied by themanufacturer	ISO 20417:2021

10. OTHER DETAILS

10.1. **Intended Use:** Safety I.V. Cannula is a device used for introduction of fluids or medicament and/or withdrawal of blood samples through peripheral vein. It is inserted into a vein over a hollow introducer needle after which the needle is withdrawn and discarded. Safety I.V. Cannula eliminates the chances of needle stick injuries and blood borne infections to the healthcare providers during needle withdrawal and disposal. It is used by following aseptic technique. The use of the product is restricted to a qualified doctor or a paramedic.

Indications:

- The device is intended to be used for sample blood or administer fluids intravenously.
- The device may be used on any patient population with consideration

given to adequacy of vascular anatomy and appropriateness of procedure.

- Intermittent intravenous drug administration.
- Prophylactic creation of a secure venous access in patients who may require urgent intravenous drug administration, in particular prior to diagnostic or therapeutic procedures

10.2. **Storage:** Store in a cool and dry place and keep away from direct sunlight and extreme heat.

10.3. **Method of Sterilization:** sterilized using ethylene oxide.

10.4. **Shelf life:** 05 years from the month / date of sterilization.

10.5. **Testing and Analysis:** Testing for sterility, pyrogen content and physical characteristics (leakage testing, flow rate of lumen, penetration force, packaging integrity, etc.) is performed on each batch before release.

10.6. **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.

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

11. COMPLIANCE INFORMATION

Manufacturer 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**,** TUV SUD Product Service GmbH
CEMarking: TUV SUD Product Service GmbH, EC Notified body No. 0123
Basic UDI-DI: ++G401IVCS3
GMDN Code: 64574

12. ABBREVIATIONS

QMS – Quality Management System

GMDN – Global Medical Device Nomenclature