PRODUCT NAME	BRAND NAME
ACTIVE BC SAFETY IV CATHETER	DISPOSEAL PLUS



Fig.: ACTIVE BC SAFETY IV CATHETER WITHOUT WINGS AND WITHOUT INJECTION PORT (DISPOSEAL + (PLUS))

1. PRODUCT DESCRIPTION

This 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tube (the Catheter) etc., which is inserted into a vein over a hollow introducer needle, after which the needle is withdrawn and discarded.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, Silicon.

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. Catheter 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 It is inserted into a vein over a hollow introducer needle after which the needle is withdrawn and discarded.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. Catheter 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.

Prepared By:	Approved By:	
Name: Hardik Bhan Desig.: Sr. Executive, QA	Name: Krishanu Bose Desig.: General Manager	DISPOSAFE HEALTH AND LIFE CARE LTD.

4. PRODUCT FEATURES

- Easy identification of the gauge size through color, as per ISO 10555-5.
- The Physical, Functional and Safety characteristics are conforming 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:** Ultra soft radio-opaque catheter is thin-walled for increased flow rate with high chemical resistance to reduce chances of thrombogenicity.
- **Flashback Chamber:** Flash Back chamber allows easy visualization of blood, confirming correct placement of catheter.
- **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:** Prevention of contamination.
- **Safety mechanism:** Needlestick Push button safety protection.
- **Blood Control Feature:** Blood control septum closes to stop blood flowing out of the catheter hub in the absence of a secure luer connection.
- **Automatic Retraction and push button for needle retraction ensuring safety protection.**

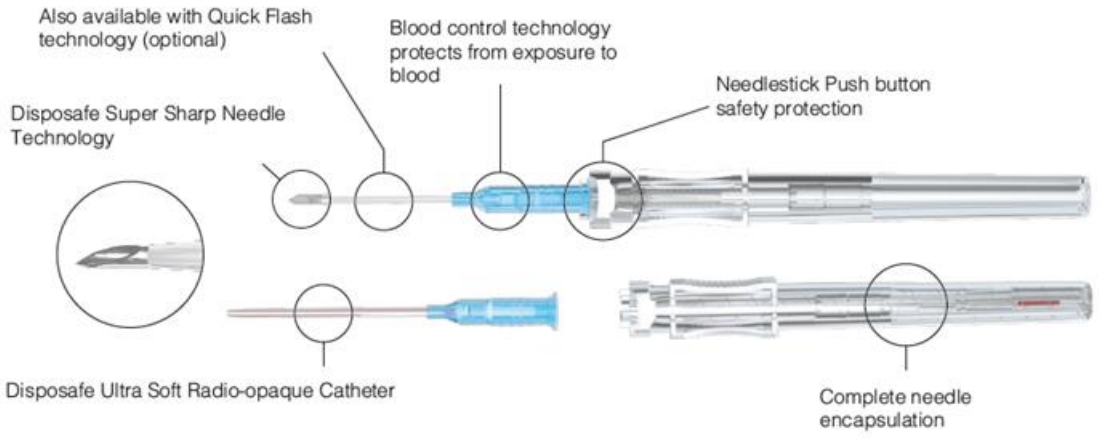


Fig.: Features of Disposeal + (Plus)

Prepared By:	Approved By:	
Name: Hardik Bhan Desig.: Sr. Executive, QA	Name: Krishanu Bose Desig.: General Manager	DISPOSAFE HEALTH AND LIFE CARE LTD.

5. MATERIAL OF CONSTRUCTION

S. No.	Components	Material Used
1.	Body (Plain) Body (with wings) Body (with thumb control)	P.P. (Polypropylene)
2.	Catheter Holder	Polyacetal
3.	Catheter	F.E.P (Fluorinated ethylene propylene) PUR (Polyurethane) PTFE (Polytetrafluoroethylene)
4.	Silicon Tube	Silicon
5.	Port Cap	High density polyethylene (HDPE) (50%) + Low density polyethylene (LDPE) (50%)
6.	Needle	SS 304 Stainless Steel
7.	Needle Hub	P.P. (Polypropylene)
8.	Hub Cover	P.P. (Polypropylene)
9.	Threaded Stopper	High-density polyethylene (HDPE)
10.	Needle Cover	P.P. (Polypropylene)

6. PRODUCT SPECIFICATION

Technical Specification (I.V. Cannula)							
S.no.	**Gauge (G)**	**Length (mm)**	**Tolerance (mm)**	**Outer dia (±0.04mm)**	**Colour (Port cap)**	**Flow rate (ml/min)**	**Tolerance of Flow rate**
1.	14	45	± 1.0	2.1	Orange	270	-10%-+15%
2.	16	45	± 1.0	1.8	Grey	200	-10%-+15%
3.	17	45	± 1.0	1.5	White	125	-10%-+15%
4.	18	45	± 1.0	1.3	Green	90	-10%-+15%
5.	20	32	± 1.0	1.1	Pink	60	-10%-+15%
6.	22	25	± 1.0	0.9	Blue	36	-20%-+25%
7.	24	19	± 1.0	0.7	Yellow	23	-20%-+25%
8.	26	19	± 1.0	0.6	Violet	15	-20%-+25%

Prepared By:	Approved By:	
Name: Hardik Bhan Desig.: Sr. Executive, QA	Name: Krishanu Bose Desig.: General Manager	DISPOSAFE HEALTH AND LIFE CARE LTD.

7. 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.	6% Luer- Small-bore connectors for liquids and gases in health care applications	ISO 80369-7:2021
4.	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
5.	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
6.	Sterilization of health care products - Biological indicators - Part 1: General requirements	EN ISO 11138-1:2017
7.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
8.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
9.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2019
10.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1: 2018
11.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008/Amd 1:2019(en)
12.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
13.	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM-F1980
14.	Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
15.	Medical devices - Information to be supplied by the manufacturer	ISO 20417:2021

Prepared By:	Approved By:	
Name: Hardik Bhan Desig.: Sr. Executive, QA	Name: Krishanu Bose Desig.: General Manager	DISPOSAFE HEALTH AND LIFE CARE LTD.

8. OTHER DETAILS

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.

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

Method of Sterilization: Sterilized using ethylene oxide.

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

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.

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.

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

9. Packaging Information

Primary Unit Packaging: Medical Kraft paper is sealed with soft PE film, using blister packing technology, maintains a sterile environment for the device inside.

Secondary Packaging: 400 GSM White Duplex.

Tertiary Packaging: Brown Master Carton, 3 Ply Corrugation Box.

Prepared By:	Approved By:	
Name: Hardik Bhan Desig.: Sr. Executive, QA	Name: Krishanu Bose Desig.: General Manager	DISPOSAFE HEALTH AND LIFE CARE LTD.

10. COMPLIANCE INFORMATION

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

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

QMS Certification: EN ISO 13485:2016**,** TUV SUD Product Service GmbH

CE Marking: TUV SUD Product Service GmbH, EC Notified Body No. 0123

GMDN: 64574

Prepared By:	Approved By:	
Name: Hardik Bhan Desig.: Sr. Executive, QA	Name: Krishanu Bose Desig.: General Manager	DISPOSAFE HEALTH AND LIFE CARE LTD.