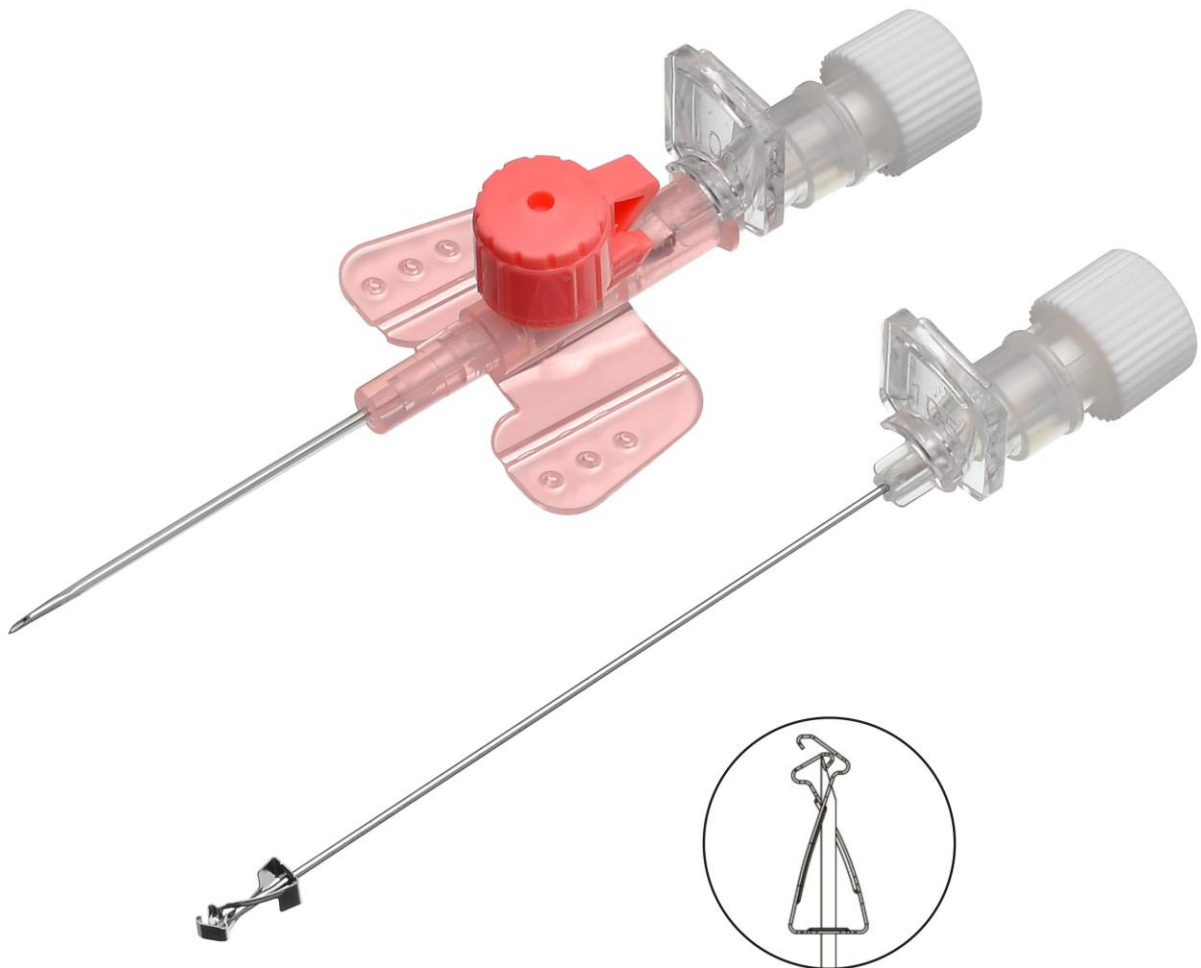




TECHNICAL DATA SHEET

Safety IV Cannula with wings and port

DESCRIPTION: **Safety IV Cannula** is a Class IIa (as per MDD/93/42/EEC) medical device that is used for peripheral intravenous access, while the anti needle stick prevention feature eliminates the risk of accidental needle-stick injury to patient and/or healthcare professionals during use of this device.





PRODUCT VARIANTS:

Following variants are available for the product **Safety IV Cannula:**

- Universal Color coded to indicate catheter gauge at a glance as per EN ISO-10555
- Available in 14/16/18/20/22 & 24 gauges which specification meets international standards.
- Unit packing option available in PP/PE Film with Tyvek Paper.
- Thin walled Catheters with PTFE Radio-opaque & PUR Radio-opaque are also available.

SPECIFICATION:

Gauge	Color of Catheter Body	Flow Rate ml/min	Catheter		Packing Inner/Outer
			Ext. Dia mm	Effective Length mm	
14	Orange	270	2.1	32/45	50/500
16	Grey	200	1.8	32/45	
18	Green	85	1.3	32/45	
20	Pink	55	1.1	25/32	
22	Blue	33	0.9	19/25	
24	Yellow	18	0.7	19	



PRODUCT CHARACTERISTICS:

- Safety I.V. Cannula pioneered the movement to innovative safety design that protect the healthcare worker from the risks associated with accidental needle-stick injuries, tapered hub for insertion ease and patient comfort.
- Safety IV cannula enables a needle safety feature that protects the users, i.e. Needle shield fully encapsulates the needle tip once activated to minimize needle-stick injury during cannulation.
- The unique, large volume chamber allows clear visual conformation through flashback and easy handling.
- Safety IV cannula device designed to help protect healthcare workers as well as hospital waste handlers from exposure to blood borne pathogens via needle-stick and mucocutaneous injuries.
- Safety IV cannula comprises a siliconized Stainless Steel Needle; Sharp needle technology provides both ease of penetration and improved patient comfort during cannulation.
- Safety IV cannula is made of best-in-class medical grade kink resistant and biocompatible PUR Catheters, 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.
- Thumb grip of the device is ergonomically designed to allow for a variety of user techniques to aid insertion.
- Safety IV cannulas do not contain elasticized PVC or natural rubber latex and can be used for Taxol administration.
- Safety IV cannula does not compromise the clinical condition or the safety of patients and reduces mechanical stress and intimal injury to blood vessel.
- Safety IV cannula is to be used in ambient conditions and should be used ONLY by a qualified doctor or a paramedic.



SPECIAL CHARACTERISTICS:

- Customized automated tipping technology for lower penetration forces.
- Minimum clearance between catheter and needle to avoid peel-back.
- Catheter Materials as per USP standard Class VI.

RECOMMENDED MAXIMUM TIME OF USE: 96hrs as per CDC guidelines

MATERIAL COMPOSITION:

COMPONENT	MATERIAL
Catheter	PUR/PTFE
Catheter holder	POM
Hub cover with filter	PP
Body (Catheter Hub)	PP
Silicon Tube (Valve)	Silicon Rubber
Needle	Stainless Steel
Needle Cover	PP
Flip type port cap	PP
Filter	ACRYLIC
Metallic Clip	Stainless Steel
Luer Lock Cap	HDPE
Needle Hub	K-Resin/SBC

PACKAGING MATERIAL:

ITEM	MATERIAL
Individual Sterile Packing (Blister)	PP+PE film with Tyvek/Paper
Inner Carton	Duplex Board
Master Carton	Kraft-Pulp Paper



Labels conform to requirements of EC Medical Device Directive (MDD) 2007/47/EC and international labeling standards.

EXPIRATION/VALIDITY: 5 years from date of manufacturing.

METHOD OF STERILIZATION: Terminal Ethylene Oxide (EtO gas) Sterilization; residual EtO gas within normative limits as per EN ISO 10993-7.

TESTING & ANALYSIS: Testing for sterility, pyrogen content and physical characteristics (leakage testing, flow rate of lumen, penetration force, packaging integrity, etc.) are performed on each batch before release.

BIOCOMPATIBILITY: The product Safety I.V Cannula is biologically safe as the device meets the requirement of ISO-10993.

STORAGE: Store in a cool and dry place at room temperature away from moisture, direct sunlight and heat sources.

METHOD OF DISPOSAL: Medical devices and sharps contaminated with blood or other body fluids must be discarded in special containers and disposed off by incineration. Disposal must be in conformity with relevant national/international standards. Please refer to hospital protocols for disposal.

INTENDED USE: The Product **Safety IV cannula** is intended for infusion/transfusion therapy through peripheral venous access.

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