Instructions for Use

PurSafe

SAFETY IV CANNULA WITH CATHETER & WITH INJECTION VALVE & WITH SMALL WINGS

MATERIAL USED :
PP, POM, MABS, ACRYLIC, Stainless Steel
Catheter: PTFE/FEP/PUR/ETFE (see the product ref. code)

COATING MATERIAL:
•Silicone Dispersion

DESCRIPTION
The device PurSafe Safety IV Catheter consists of major components as in Fig. (1), Fig. (2), & Fig. (3), (A) Stainless Steel Needle, (B) Metallic Clip, (C) Needle Hub, (D) Catheter Tube, (E) Needle Cover, (F) Flow Control Hub with Filter, (G) Catheter Hub, (H) Catheter tip, (I) Needle Bevel, (J) Injection Port, (K) Stabilization Wings
Catheter gauge size and length are identified on the product packaging. The color of the catheter body also indicates the gauge size of catheter.

GAUGE:	14G	16G	18G	20G	22G	24G
COLOR:	Orange	Grey	Green	Pink	Blue	Yellow

The materials used to manufacture this device do not contain natural rubber latex or PVC derivatives.

Fig. (1)
BEFORE USE

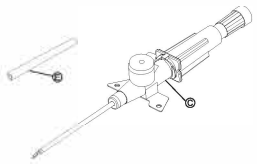
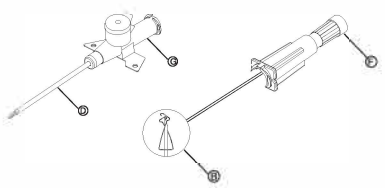


Fig. (2)
AFTER USE



INTENDED PURPOSE:
The PurSafe Safety IV Catheter is a safety medical device, whereby fluids can be introduced into human circulatory system during infusion therapy.

INDICATIONS :
•Infusion of IV Solutions (To maintain hydration and/or correct dehydration if patient is unable to take sufficient volume of oral fluid).
•Intermittent intravenous drugs administration.

CONTRAINDICATIONS:
•Product should not be used in patients with known hypersensitivity to any of the material used including coating materials.
•Product should not be used for administration of high viscocity fluids.
•Product should not be used for large volume blood transfusion.
•There is no known reactions between the catheter & Magnetic Resosnance Imaging (MRI).

PATIENT PREPARATION:
•Explain cannula insertion procedure to patient.
•Open cannula insertion kit, remove contents onto a clean, preferably sterile, surface.
•Locate an accessible and suitable peripheral vein visually and confirm by palpation.
•Wash hands with antiseptic soap solution and wear gloves.
•Disinfect site of insertion, rubbing for 30 seconds moving from center to periphery of site in circular motion.
•Allow insertion site to dry for approximately 1 minute.
•Apply tourniquet, if needed, proximally to insertion site.

CATHETER INSERTION:
•Carefully select and aseptically prepare the site.
•Select suitable size of IV Cannula and inspect visually to ascertain that package is intact.
•Remove safety IV catheter from individual packing.
•Remove and discard needle cover without touching catheter.
•DO NOT ROTATE CATHETER before insertion.
•Inspect catheter ensuring needle projects beyond tip and bevel points upwards.
•If needed, push/pull skin taut with non-dominant hand.
•Puncture the vein with the needle (bevel up).
•Confirm successful venipuncture by visualizing blood in Flow Control Hub.

RISK:
•This IV catheter is designed to reduce the risk of accidental needlesticks; however, care must be taken to aviod needlesticks. Universal precautions must be adhered to in accordance with Centers for Disease Control and Prevention/Occupational Safety and Health Administration (CDC/OSHA).

CATHETERADVANCEMENT (THREADING)
•Decrease angle of insertion further such that catheter is nearly parallel to skin surface.
•Advance entire device prior to threading catheter tip should enter vein.
•Thread catheter into vein using either one-handed or two-handed technique maintaining pressure on skin surface to straighten vein.

NEEDLE RETRACTION:
•Advance the catheter further into the vein, while slightly withdrawing the steel needle.
•Using adhesive tape, fix catheter to the skin. The steel needle still in site minimizes spillage of blood.
•Before removing the steel needle compress the vein at the tip of catheter with the middle finger, to prevent spillage of blood. At the same time stabilize the catheter hub with the index finger to prevent catheter dislodgement during needle removal. Remove needle by pulling needle straight back. Metal safety clip will automatically attach to needle tip as needle tip exits catheter hub. Dispose of needle immediately into sharps container.
•NEVER TRY TO REINSERT THE PARTIALLY OR COMPLETELY WITHDRAWN NEEDLE.

APPLICATIONS:
•The device is manufactured & tested in accordance with the international standard "Over needle Peripheral Catheters EN ISO 10555-1 & 5"
•The connecting port of this device is in compliance to ISO 80369-7
•Withdraw the needle completely while pressing the vein just after the tip of catheter into the vein and discard the needle in an appropriate container.
•Connect to the IV infusion set line.
•Cover the puncture site with sterile dressing.
•Perform routine monitoring and venipuncture site maintenance according to medical norms

Based on Clinical Evaluation Report (Ref HHPL-QA-CER-IVC), the following recommendations are made for use of the device:
•Upper limb placements are preferable to lower limbs.
•For blood sampling, it is recommended that larger gauge catheters be used for infusion.
•Use of specialized infusion teams for insertion and monitoring of IV catheters has been shown to lead to better patient outcomes.
•In case of any adverse events occurred during the usage of device it must be reported to manufacturer and the national competent authority.

Intended Patient Population:
The device can be used in all age group patients.
14G to 20G for adults, 22G & 24G for child.

Note:
•Consult doctor before use of this device in pregnant & breastfeeding women.
•Consult doctor for appropriate size/type of the device or depending upon the patient's condition.

TERM OF USE :
•Recommended Maximum Duration of Use: 96 hours.

UNDESIRABLE SIDE EFFECTS MAY BE CAUSED BY USE OF THE DEVICE :
•Allergy
•Inflammation
•Swelling
•Infection

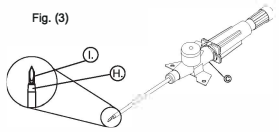
WARNINGS:
•Use is restricted to trained healthcare professionals only.
•The product should not be reprocessed as reprocessing may compromise the integrity of the device and/or lead to device failure.
•The product should be used according to the instructions for use.
•If there is any change in expected performance of the device or in case of any malfunction the device should be immediately removed & sent back to supplier for analysis.
•For known/reported adverse events associated with use of this device refer to the Clinical Evaluation Report HHPL-QA-CER-IVC.

"MEDSOURCE LABS, LLC DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE.
•Any device that is connected to this product must comply with ISO 80369-7 in order to achieve the intended performance of this product & to avoid leakage in the connection.

"The product should not be reprocessed as reprocessing may compromise the integrity of the device and /or lead to device failure.
"Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/or functional damage to device or packaging.
•The product is guaranteed sterile & non-pyrogenic if the package has not been damaged or unintentionally opened before use. If package is damaged or unintentionally opened before use, discard as per country's disposal regulation.
•Do not clean or re-sterilize the device as this compromise the device performance (functionality), integrity and biological features. This may increase the risk of cross contamination or severe deterioration in health and safety of patients.
•Store in cool & dry place.
•The product is sterile and for single use only. The product is non-pyrogenic.
•Do not expose to heat or direct sunlight.
•The product should be used immediately after opening the packaging.
•Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reactions or infections.

Disposal/Discard:
•Dispose of/Discard the used device in accordance with your country's Healthcare and Safety Regulations.
•Used sharps/needles should be disposed in sharps disposal container.
•Used product/catheter should be disposed in sanitary container or follow hospital protocol to prevent possible contamination and cross infection.

Fig. (3)



REF	Product Ref. No.		Keep dry
LOT	Batch Number		Fragile, handle with care
	Date of Manufacture		This way up
	Use-by-date		Quantity
2	Do Not Reuse		Non-pyrogenic
STERILE EO	Sterilized using Ethylene Oxide and Single Sterile Barrier System		Caution
	Consult Instructions for Use		Recyclable Packaging
	Manufacturer		

	Do Not Use if package is Damaged and consult instructions for use		Recyclable
2	Do not resterilize		Keep away from sunlight
LATEX	Not made with natural rubber latex	UDI	Unique Device Identifier
PHT	Not made with DEHP	MD	Medical Device
	Non- toxic/No Hazardous Substances	5° 30°	Temperature limit
	Importer		Distributor
EU REP	EU Rep	CE	Complies with EU directives

CE
0123

EU REP
Mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen GERMANY

Manufactured by:
Harsoria Healthcare Pvt. Ltd.
110 - 111, Phase - IV, Udyog Vihar
Gurgaon-122015, Haryana, India
Email: info@harsoria.com
Website: www.harsoria.com
For: MedSource Labs, LLC
8600 Shelby Court
Chanhassen, MN 55317 USA

Rx only

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