

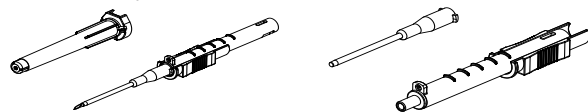
DISPOSABLE TELE

Safety IV Cannula without wings and without Injection Port

These instructions contain important information for use of the product. Read the entire contents of these instructions for use, including Warnings, cautions and instructions could result in death or serious injury to the patient and / or clinician failing to follow.

1. Description :

Each Disposable Safety IV Cannula consists of five separate components : (1) stainless steel introducer needle with plastic flash chamber (2) transparent contoured ribbed needle housing (3) transparent needle guard with primary and secondary push-off tabs, (4) catheter with translucent color-coded plastic hub, and (5) protective sheath (See illustrations 1 & 2)



The Disposable Safety IV Cannula is designed to minimize inadvertent needle stick injury. During needle retraction, a needle guard is locked over the introducer needle. after complete withdrawn of needle after successful veinpuncture.

Catheter gauge size and length are identified on the product packaging. The color of the catheter's plastic hub also identifies the gauge size.

GAUGE	14G	16G	17G	18G	20G	22G	24G	26G
COLOR	Orange	Grey	White	Green	Pink	Blue	Yellow	Violet

This device is intended for single use only and is sterile and non-pyrogenic. The materials used to manufacture this IV. Cannula are not contain natural rubber, Latex & PVC Free. Radiopaque I.V. Catheter

2. INDICATIONS :

- 1) A properly placed I.V. catheter provides access to a vein for the administration of solutions and medications with feature for active protection from accidental needle sticks.
- 2) 14G to 22G catheter may be used with power injectors up to 300 psi

3. CONTRAINDICATIONS :

None known.

4. WARNINGS :

- 1) Clinicians must follow Instructions for use. Failure to follow instructions could result in death or serious injury to the patient and/or clinician.
- 2) Extreme care should be taken not to cut the catheter and possibly cause an

INSTRUCTION FOR USE

embolus :

- Do not place scissors or sharp instruments near I.V. Catheters.
 - Never reinsert the introducer needle inside the catheter once the needle has been partially or completely withdrawn as it may pierce and/ or sever the catheter. If veinpuncture is not successful, discard both the needle and the catheter after engaging the safety mechanism.
- 4.3 To avoid accidental needle sticks:
- Do not bend the distal portion of the catheter/needle during insertion, threading, or removal of the catheter assembly during use.
 - In the unlikely event that the safety mechanism does not engage, dispose off needle immediately into an approved sharps container.

5. CAUTIONS:

- Patency must be established prior to use with power injectors. Use with power injector pressure greater than 300 psi may cause product leakage and/or damage to the product. Ensure that the injector is properly calibrated and will automatically stop at a pressure exceed 300 psi.
- Sterile, non-pyrogenic and non-toxic unless package is open , wet or damaged . Discard if open, wet or damaged.
- This device is for single use only. Do not reuse and do not re-sterilize.
- Do not Reuse. Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

6. PRECAUTIONS:

- This device is designed to reduce the risk of accidental needlesticks. However, care must be exercised when using any I.V. Catheter. In addition to these instructions for use, it is recommended that the health care professional follow the recommendations set forth by the CDC and OSHA standards (USA) for blood borne pathogens when starting, maintaining, or discarding any I.V. catheter to avoid the risk of exposure to blood.
- During catheter insertion, maintenance and removal follow current "Guidelines for the Prevention of Intravascular Catheter-Related Infections. Centers for Disease Control & prevention, Atlanta, GA(USA), Institutional policy and procedures and professional standard of care.
- Ensure firm securement of catheter to the patient. Improper securement

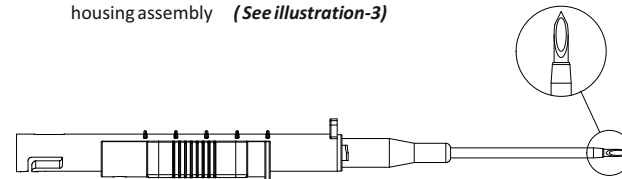
may lead to loss of vascular access.

- Ensure fluid administration/hub connection is tight in order to prevent leaking.
- The catheter is shorter than the introducer needle. Therefore, blood flashback may occur before the catheter tip is fully in the vein. If necessary, slightly advance the catheter and needle together to assure full catheter entry into the vein lumen. To avoid inadvertently puncturing the posterior wall of the vessel, lower the needle until it is parallel to the skin.
- If veinpuncture is unsuccessful, stabilize hub and retract the needle housing unit until it locks. Then remove the catheter and locked assembly together holding the hub to the guard, if necessary, prior to the disposal.

7. INSTRUCTION FOR USE :

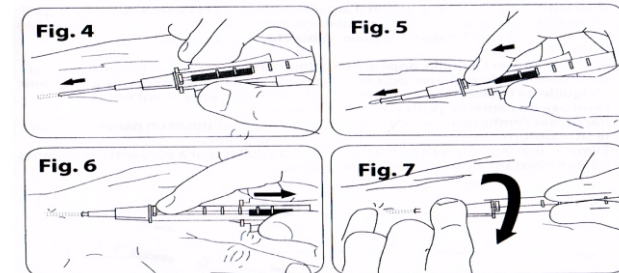
Due to the risk of blood borne pathogen exposure, follow universal precautions during placement, use and removal of I.V. catheter.

- Select and prepare site as per institutional policy, Apply tourniquet.
- Remove sheath in straight outward motion and inspect device. Ensure catheter hub and primary push-off tab are fully seated to the needle housing assembly (See illustration-3)



- Hold the device by the ribbed needle housing with thumb and fingers on opposite sides. Verify push-off tab and needle bevel are in the "up" position.
- Anchor the vein with gentle skin traction. Insert the needle into the skin and vein at an appropriate angle. (See. Fig. 4 below)
- Decrease angle and insert device slightly to assure catheter entry into vein.
- Holding the ribbed needle housing stable, place your finger on the primary push-off tab and thread the desired length of the catheter of the needle and into the vein. As you thread the catheter, the needle guard begins to cover the needle. (See. Fig.5 below)

- Keep your finger on the primary push-off tab to stabilize the device, then retract the ribbed needle housing until it securely locks into place. (See fig. 6 below)
- Remove the tourniquet.
- Before removing the steel needle, compress the vein at the tip of catheter to prevent spillage of blood. Remove needle by pulling needle straight back with a swift continuous motion parallel to the skin. (minimize rotation of needle) Plastic cage will automatically attach to needle tip, as needle tip exits catheter hub. (See. Fig. 7 below).
- Dispose of the shielded inner needle component immediately into the appropriate sharp container. Connect to administration set & secure.



REF	Reference No.	⊗	Do Not Reuse	STERILE	Sterilised By Ethylene Oxide Single Sterile Barrier System
LOT	Lot No./Batch No.	⊗	Do Not Resterilize	10°C ↑ 35°C	Temperature Limit
Manufacturer	Manufacturer	⊗	Non-Pyrogenic	i	Consult Instructions For Use
Date Of Manufacturing	Date Of Manufacturing	⚠	Caution	MD	Medical Device
Use By / Expiry Date	Use By / Expiry Date	⊗	Do Not Use If Package Is Damaged	EC REP	Authorised Representative In The European Community

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