

Size = A3(420X297mm), Black Print

TrueSafe Comfort® Blood Control Safety I.V. Catheter **English**

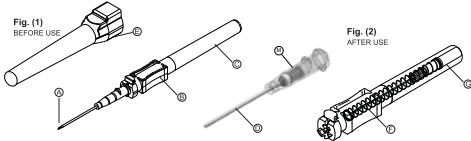
CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a registered physician. INTENDED USE: The MedSource TrueSafe Comfort® Blood Control Safety I.V. Catheter is indicated to sample blood or administer fluids intravenously. The MedSource TrueSafe Comfort® Blood Control Safety I.V. Catheter may be used on any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure, the solution being administered, and the duration of the therapy.

The following instructions contain important information regarding the safe use of this product. Please read the Instructions for Use contents entirely before using this product. Failure to properly follow warnings and instructions could result in serious injury or death to the patient and /or clinician.

Product Description:

The device TrueSafe Comfort® Blood Control Safety I.V. Catheter consists of major components as in fig. (1), fig. (2) and fig. (3), (A) Stainless Steel Needle, (B) Front chamber, (C) Gauge Chamber, (D) Catheter Cannula, (E) Safety Cap, (F) Stainless Steel Spring, (G) Flash Chamber, (H) Activation Button, (I) Catheter Hub, (J) Needle Bevel, (K) Canula Tip, (L) Rapid flashback needle.

(M) Blood Control Valve
The TrueSafe Comfort® Safety I.V. Catheter gauges are color coded for positive identification and range from 14G to 24G
ORANGE = 14G GREY = 16G GREEN = 18G PINK = 20G BLUE = 22G YELLOW = 24G



Warnings:

Clinicians must follow Instructions for Use. In addition to following the Instructions for Use, clinicians must be trained to ensure proper usage of the device. Failure to do either of these could result in death or serious injury to the patient and / or clinician. To avoid an accidental needle stick, use the device as described in the Instructions for Use and discard immediately into an approved sharps container.

Do not apply pressure during usage that causes the needle/catheter to flex.

In the unlikely event that the device does not function as described in the Instructions for Use, immediately dispose of the device in an approved sharps container.

Prior to insertion, caution needs to be taken to ensure that the catheter does not come in contact with any foreign objects.

Contact with a foreign object creates the potential for embolus.

Never reinsert the introducer needle inside the catheter. Reinsertion threatens the integrity of the catheter and could lead to embolus.

TrueSafe Comfort® Blood Control is intended for short-term use. Usage beyond this may lead to infection.

Cautions:

This device is in an unopened package and is sterile, non-toxic and non-pyrogenic.

Discard if open, wet, or damaged.

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

This product does not contain PVC. This product is not made with DEHP.

This device is Radiopaque.

This device is for single use only. Any attempt to re-sterilize and/or recondition the device will compromise the integrity of the device and may have an adverse affect on performance.

The valve is designed to provide fluid control to typical venous pressures. Venous pressures that exceed this range may result in fluid leakage from the valve.

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Precautions:

This device is designed to reduce needle stick occurrences. Care must always be exercised when using this product. In addition to the Instructions for Use provided, it is strongly recommended that the clinician follow the guidelines put forth by the Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA) standards (USA) for bloodborne pathogens when using this product.

During catheter insertion, maintenance, and removal follow current "Guidelines for the Prevention of Intravascular Catheter-Related Infections," CDC, Atlanta, GA (USA) Institutional policy and procedures, and professional standards of care.

Securely affix the catheter to the patient. Improper securement can result in loss of vascular access. A firm connection between the catheter hub and administration set is necessary to prevent leaking.

The introducer needle is longer than the catheter tube and will enter the vein or artery first. This can cause a blood flashback prior to the entrance of the catheter tube into the vein or artery. Advancing the catheter and needle together slightly will ensure intravascular access for the catheter. When advancing slightly, it is recommended to reduce the angle of approach in order to minimize the chance of puncturing the posterior wall of the vessel.

In the event of an unsuccessful venipuncture, stabilize the catheter hub and activate the safety mechanism. The safety position can be found by hearing a slight "click" sound and noticing the retraction of the needle into the gauge chamber via the spring.

Remove the catheter and properly dispose of both the spent catheter and locked Safety I.V. Catheter assembly.

There may be slight resistance when attaching and detaching the IV connector to the catheter hub in order to activate and deactivate the valve.

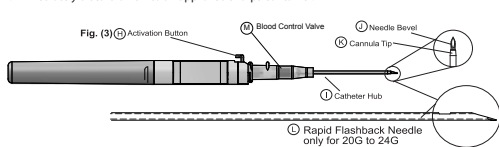
Instruction for use:

Due to the risk of bloodborne pathogen exposure, follow Universal Precautions during placement, use, and removal of TrueSafe Comfort® Blood Control Safety I.V. Catheter.

Clinicians must be trained in the practice of venipuncture and be aware of inherent dangers. Keep unshielded needles away from body and fingers at all times.

Aseptic technique, proper skin preparation and continued protection of the site are essential. Observe Universal Precautions on all patients.

- Remove safety cap in an outward motion and inspect catheter unit.
- Grasp device front chamber between thumb and fingers, verify the advancement tab and needle bevel are in the up position.
- Perform venipuncture.
- Observe blood return. **Sizes 20, 22, 24, GA: blood return will be visible through the catheter flash window Fig. (3). Lower and advance the catheter 1/8"**
- Keeping the device stable, advance the catheter off of the hub and into the vein.
- Before withdrawing the needle from the catheter, depress the activation button to activate the safety mechanism. The needle should retract fully into the gauge chamber.
- Observe valved hub carefully for any signs of leakage.
- Connect I.V. Administration line.
- Immediately discard unit into an approved sharps container.



REF	Product Ref. No.	☒	Keep dry
LOT	Batch Number	☒	Fragile, handle with care
☒	Date Of Manufacturing	☒	This way up
☒	Use By	☒	Quantity
☒	Do Not Reuse	☒	Non-pyrogenic
STERILE EO	Sterilised by Ethylene Oxide Gas	☒	Manufacturer
☒	Caution, Consult Accompanying Documents	☒	Authorized EC Representative in the European Community
☒	Consult Instructions for Use	☒	Recyclable Packaging
☒	Do Not Use if Package is Damaged	☒	Green Dot
☒	Do not resterilize	☒	Recyclable
☒	Keep away from sunlight		

Rx only

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