

DEVICE DESCRIPTION:

The Monarch Blood Collection Set is a sterile, single-use, winged needle with tubing and luer connector. Each Monarch Blood Collection device is individually wrapped in a blister pouch. Monarch Blood collection sets include configurations for three (3) needle gauges (21, 23, 25).

INDICATIONS FOR USE:

The Monarch Blood Collection Set is indicated for general medical use in healthcare facilities by medical professionals with the patient population to include both pediatric and adult patients. The device has a safety feature to prevent accidental needlestick injury during normal handling and disposal. The Blood Collection set is intended to be used with a vacuum blood collection tube for the collection of venous blood and is intended for short term iv infusion administration infusion.

WARNINGS:

1. Single Use Only. Do not reuse: Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only.
2. Do not use after the expiration date has passed.
3. Do not use if the packaging is punctured or damaged in any way.
4. Do not use in a Magnetic Resonance (MR) environment.
5. Mishandling this device may result in contaminated needlestick injury, which can cause infectious disease.
6. The device should be discarded immediately after use in a Sharps container, following institutional policy.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

PRECAUTION:

1. Misuse or mishandling of the device may result in exposure to blood or needlestick injury.
2. Follow facility protocol standard for infection control procedure.
3. This device is to be used by medical professionals only.
4. Vacuum tubes may vary in diameter size. Adaptors should be used to ensure the proper puncture of the vacuum tube following institutional policy.

	Manufacturer		Stored at Controlled Temperature
	Use-by date		Do not re-use
	Batch code		Sterilized using Ethylene oxide
	Importer		Distributor

	Unique Device Identifier		Date of manufacture
	Catalogue number		Consult instructions for use
	Do not use if package is broken		Non Pyrogenic
	Federal Law (USA) restricts the device to sale by or on the order of a physician		Caution

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 Made in India

INSTRUCTIONS FOR USE – SINGLE HAND ACTIVATION TECHNIQUE:

1. Visually inspect kit and confirm there is no damage present (no tears/punctures). If packaging appears damaged - do not use and dispose of per facility policy/protocol.
2. Peel blister pouch at marked location(s) and remove device from packaging.
3. Visually inspect kit and confirm there is no damage present to device/equipment (no cracks or breaks). If device appears to be damaged - do not use and dispose/report of per facility policy/protocol.
4. Attach the transfer device / holder (#2) is preattached and secured to backend female luer (#1) or syringe. For transfer device / holder confirm securement by pushing male luer the into the female luer or tighten by threading holder to female luer adapter.
5. Remove Needle Cover by lowering Tip of Needle Cover (red circle #1) and remove at horizontal position (red circle #2). CAUTION: Care should be taken to avoid needle contact by user.
6. Perform venipuncture draw per facility policy/protocol.
7. Collect blood into the vacuum tube by placing the vacuum tube (2) into the transfer device / holder (1) and pushing the center of vacuum tube stopper over the needle inside the transfer device / holder (1). Additional tubes may be used as appropriate. Follow facility policy/protocol.
8. Place gauze over the venipuncture site per facility policy/protocol.
9. Place index finger of predominant hand on top of the finger tab on the blood collection device.
 1. You can also hold the tubing with your thumb and a finger.
10. For a single hand activation (10a) retract the finger tab towards the distal part of the device. For a two hand activation (10b) secure the wings (1) and place your thumb and a finger on the tubing (2) to retract the finger tab towards the distal part of the device. Two “clicks” will be felt and heard. The first click is the door beginning to close and the second click is the safety activation that traps the needle inside the device Housing to prevent accidental needlesticks.
11. DO NOT ATTEMPT TO DISENGAGE SAFETY DEVICE BY PUSHING FINGER TAB & NEEDLE FORWARD. LEAVE FINGER TAB IN ACTIVATED POSITION AT DISTAL PART OF THE DEVICE. INJURY MAY OCCUR AS A RESULT OF MANIPULATING & DISENGAGING SAFETY DEVICE.
12. Apply digital pressure to the gauze and facility policy/protocol.
13. After needle activation, dispose in sharps containers following facility policy/protocol.

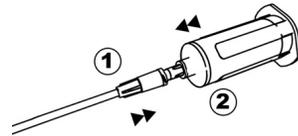
INSTRUCTIONS FOR USE – SHORT TERM IV INFUSION ADMINISTRATION (UP TO 6 HOURS):

1. Visually inspect kit and confirm there is no damage present (no tears/punctures). If packaging appears damaged - do not use and dispose of per facility policy/protocol.
2. Peel blister pouch at marked location(s) and remove device from packaging.
3. Visually inspect kit and confirm there is no damage present to device/equipment (no cracks or breaks). If device appears to be damaged - do not use and dispose/report of per facility policy/protocol.
4. Prepare venipuncture site per facility policy/protocol.
5. Attach IV tubing male connector or syringe to the back end female luer. Confirm there is no air in the product by priming in accordance with facility policy/protocol.
6. Remove Needle Cover. CAUTION: Care should be taken to avoid needle contact by user.
7. Perform the short term iv infusion administration per facility policy/protocol.
8. Place gauze over the venipuncture site per facility policy/protocol.
9. Place index finger of predominant hand on top of the finger tab on the blood collection device.
 - a. You can also hold the tubing with your thumb and a finger.
10. Gently retract the finger tab towards the distal part of the device. Initially, a slight resistance will be felt as the needle retracts onto the hub of the device.
 - a. Holding the tubing with your thumb and a finger you can retract the tubing towards the distal part of the device.
11. Two “clicks” will be felt and heard. The first click is the door beginning to close and the second click is the safety activation that traps the needle inside the device Housing to prevent accidental needlesticks.
12. Apply digital pressure to the gauze and facility policy/protocol.
13. After needle activation, dispose in sharps containers following facility policy/protocol.

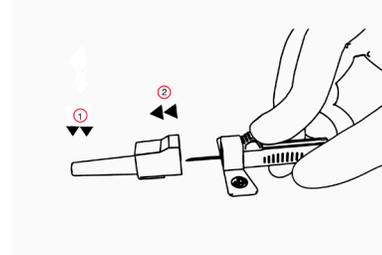
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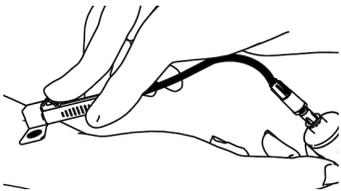
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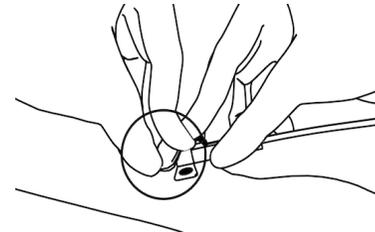
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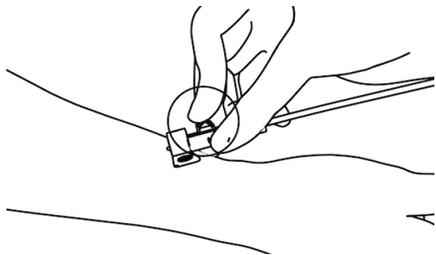
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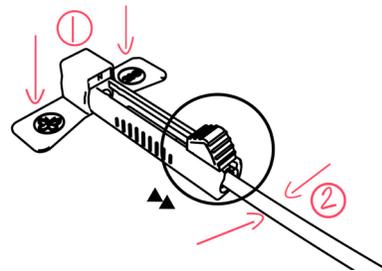
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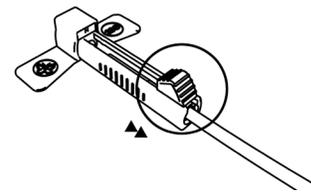
10a



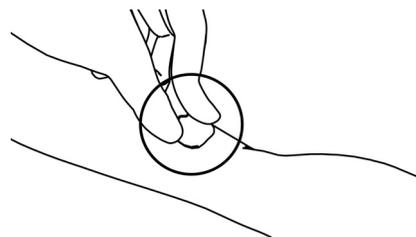
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