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NIPRO SafeTouch™

BLOOD COLLECTION SET

With Safety Device

<Instructions for Use>

Please read these instructions carefully before use.

Indications

Blood Collection Set is intended to be used to collect blood for various blood tests. The NIPRO SafeTouch Blood Collection Set helps to prevent accidental needle stick injuries.

Contraindications

The use of NIPRO SafeTouch Blood Collection Set is not itself a therapeutic procedure, and there is no particular contraindications.

Instructions for Use

1. Remove the NIPRO SafeTouch Blood Collection Set from its packaging.
2. Check to make sure that wing protector is securely locked into stopper, and that the multi-sample luer adapter is securely connected to luer connector. See Figure 1.
3. Assemble all components prior to venipuncture by attaching blood collection holder to butt end of multi-sample luer adapter. The blood collection holder is not included in the set. See Figure 2.
4. Remove needle cap by firmly holding wing. Be cautious with the exposed needle tip.
5. Insert needle into the disinfected puncture area.
6. Make sure that the needle tip is securely in the blood vessel by confirming blood flashback visibly in the wing protector and then immobilize the wing by taping.
7. Specimen collection into vacuum blood collection tubes can be made by accessing the multi-sample luer adapter as in standard venipuncture.

Activation of Safety Mechanism

The following procedures are used to activate the accidental needlestick prevention mechanism.

Pre-Removal Activation

1. After the completion of the blood collection, remove tape from the blood collection set. Apply digital pressure to the puncture area using sterilized gauze pad, and using the same hand, hold down the wing protector and/or the wings. See Figure 3.
2. With the other hand, release the lock by pressing in both sides of the stopper. See Figure 3.
3. NOTE: Do not apply undue pressure to the puncture site. Slide the stopper backwards until it becomes completely fixed with an audible or tactile click. See Figure 3.
4. Verify that the stopper is securely immobilized against the wing protector. Thus, the needle is completely retracted and protected in the wing protector. See Figure 4.
5. Maintain pressure on the puncture site according to facility protocol.
6. Promptly dispose of the set. [See Cautions 2]

Figure 1

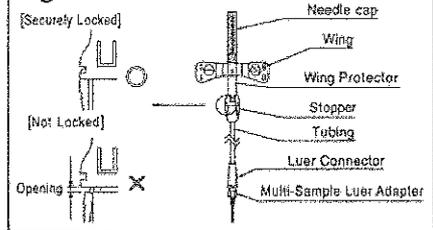


Figure 2

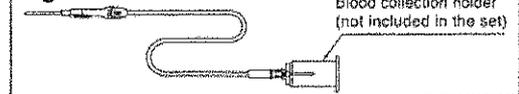


Figure 3

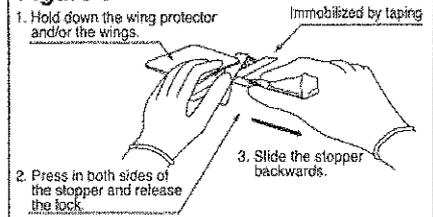
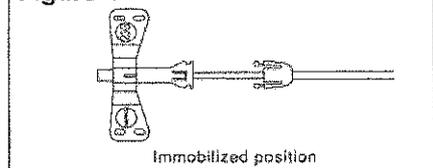


Figure 4



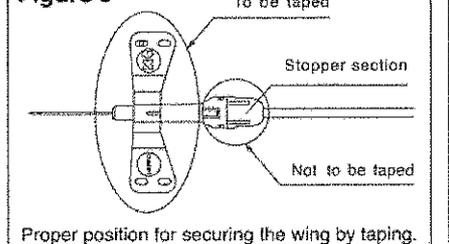
WARNINGS

1. The device will perform as intended when the Instructions are followed appropriately. Please refrain from carelessly releasing the lock, forcefully pulling the wing or such actions, since rough handling of the device may damage it.
2. Due to the risk of coming into contact with blood, please wear gloves and eye protector.
3. Do not release forcefully or destroy the accidental needlestick prevention mechanism after it has been activated.

CAUTIONS

1. When immobilizing the wing, be careful NOT TO COVER THE STOPPER WITH TAPE since taping the stopper prevents activating the safety mechanism. See Figure 5.
2. Due to the risk of blood dripping from its exposed tip, promptly dispose of the product in an approved disposal container. When separating the blood collection holder from the product, be careful of the multi-sample luer adapter as it is unprotected.
3. Immediately use the product after breaking package seal.
4. In the event that the packaging is damaged, do not use the product.
5. Store the product in a cool, dry environment away from direct sunlight, extreme temperature and humidity.
6. While using and during post-use disposal, pay close attention to prevent accidental needlestick.
7. The product is for single use only. DO NOT REUSE.
*Reuse or reprocessing of a single use device may lead to contamination and compromised device function or structural integrity.

Figure 5



GUARANTEE

1. Our SafeTouch Blood Collection Set is manufactured under strict quality control and quality is assured. We shall not be responsible for injury caused to a patient or any person or damage to any object that is attributed to transport, storage, and usage in your institution.
2. If a patient or any person is injured or any object is damaged when using our SafeTouch Blood Collection Set, we shall not be responsible for the injury or damage unless we are clearly identified as being at fault.
3. If a patient or any person is injured or any object is damaged when re-using our SafeTouch Blood Collection Set, we shall not be responsible for the injury or damage of any nature.
4. We shall not be responsible for any injury or damage caused if our SafeTouch Blood Collection Set after the expiry date mentioned on the packages.

Symbols used for labeling

- See Instructions for Use
- Single use only.
- Sterilized with Ethylene oxide gas
- Expiry date
- Lot number



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