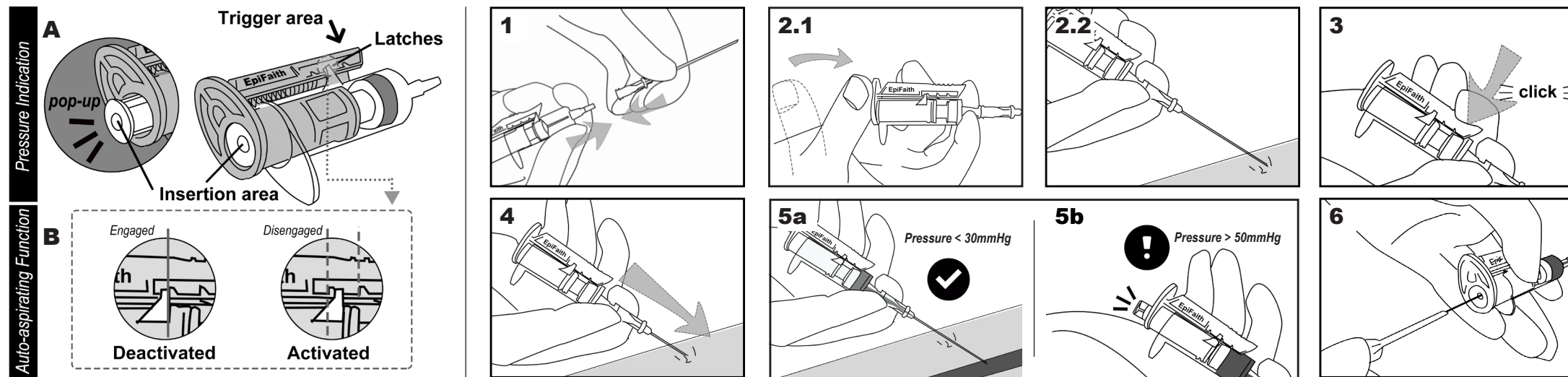


INSTRUCTIONS FOR USE



Indications for use

The EpiFaith CV is intended for use in central venous catheter placement procedure, which is designed to facilitate guidewire-assisted catheter placement and is compatible with guidewires ranging from 0.025" (0.64mm) to 0.038" (0.96mm) along with their appropriate introducer needles. The device provides a visual cue when it hits a vessel with >50mmHg of pressure. The EpiFaith CV will be sold sterile individually packaged, and as part of a sterile kit.

Neonates and infants shall be excluded from the intended population.

Contraindications and Restrictions on use

CAUTION

The EpiFaith CV must be used by a trained physician familiar with anatomical landmarks, central line placement technique and its associated complications. Each patient (especially patient has **abnormal blood pressure**, such as **hypertension** or **hypotension**) must be thoroughly and independently evaluated by a trained physician prior to its use. In some conditions, reliable differentiation of vessel type may not be achievable

from color or pressure.

Trained physicians should be aware of complications including but not limited to: arterial puncture, guidewire malposition, air embolism, vessel wall perforation, bacteremia, septicemia, hematoma, dysrhythmias, nerve damage, pneumothorax, hemothorax etc.

CAUTION

Extra care and considerations should be exercised when guidewire is being passed. Even if the needle has correctly anchored in the vessel, the guidewire may still puncture the wall, leading to serious complications mentioned above.

Warnings

This is a single-use, sterilized medical device. Do not reuse, reprocess, or re-sterilize. Reusing the device creates serious risk of injury, infection, and death. Do not use if the device package is damaged or has exceeded its labeled expiration date. Physicians should visually confirm unobstructed blood flow through the device during placement, as clots and debris may otherwise obstruct the channel, causing malfunction.

Directions

CAUTION

The procedure should be carried out **sterilely**.

1 Attach the EpiFaith CV to the introducer needle (Fig. 1).

2 Engage the plunger by pushing it to the end of the syringe. (Fig. 2.1)

Insert the entire device (EpiFaith CV and its attached introducer needle) into tissue. (Fig. 2.2)

CAUTION

Ensure the plunger is fully engaged inside the syringe, as any room for air (inside the EpiFaith CV, between the plunger and its syringe tip) will risk injection of air.

3 Press the trigger area to activate auto-aspiration (Fig. 3).

Note: by pressing down on the trigger area, auto aspiration is activated. See Fig. B for a close-up view of an activated vs a deactivated EpiFaith CV.

CAUTION

Do not push or pull the plunger or restrict its movement in any way

once the trigger is activated. Auto-aspiration will not work properly otherwise.

4 Adjust and advance the needle slowly until flash (Fig. 4).

CAUTION

Never advance the device/needle if auto-aspiration is not activated. In some situations, debris may enter the device and deactivates auto-aspiration.

Physicians should re-activate this function by pressing down on the trigger area again before making any further moves.

5 Stop advancing the needle when flash is observed (Fig. 5a).

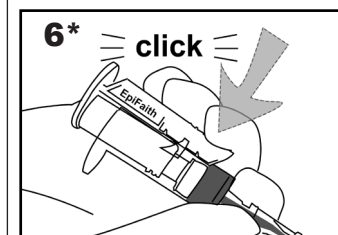
Examine the top of the EpiFaith CV, where one would insert the guidewire. If the pressure within the vessel is lower than 30mmHg, the insertion mechanism will not "pop-up"/protrude from the plunger (see Fig A and Fig 5a). If the pressure within the vessel is higher than 50mmHg, the insertion area will "pop-up", thus providing a visual cue to the physician that the vessel being accessed is likely an artery (Fig. 5b).

CAUTION

The insertion area will gradually pop-up when pressure exceeds 30mmHg, and become fully protruded from the plunger when pressure hits 50mmHg. Pause and confirm whether or not the pop-up mechanism has fully deployed before proceeding to the next step. Also confirm the needle position when the pop-up mechanism is deployed (Fig. 5b).

6 Insert the guidewire from the top insertion area into device and advance into the vessel to desirable depth (Fig 6). Firmly hold the guidewire in place when removing the EpiFaith CV/needle complex.

Note: if the guidewire can not be easily inserted, the physician should withdraw the guidewire completely and re-attempt. The trigger area can be pressed again to re-activate auto-aspiration, assuming the device has yet to be fully filled with blood (Fig 6*).



Storage

Protect from sunlight.

Disposal

Follow local protocols regarding the proper disposal of the equipment.

Failure to dispose of the device correctly could lead to serious infections.

If an incorrect disposal method is used, the outcome may be harmful to a third party or the environment.

Date of last revision: Oct 2022



Caution



Do Not Reuse



Batch Code



Manufacturer



Sterilized using ethylene oxide



Catalogue number



Do not use if package is damaged.



Non-pyrogenic



Consult instructions for use



Do Not Resterilize



Use-by date



Date of Manufacture



Requires prescription in the United States.



Keep away from sunlight



Quantity