EpiFaith® CV

For safety central venous catheterization

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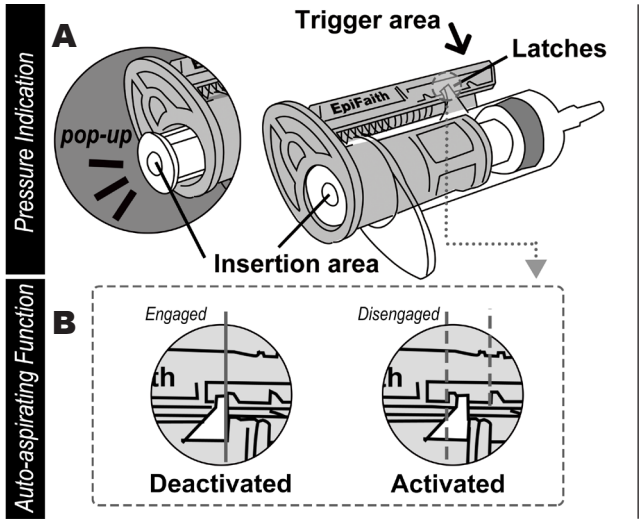
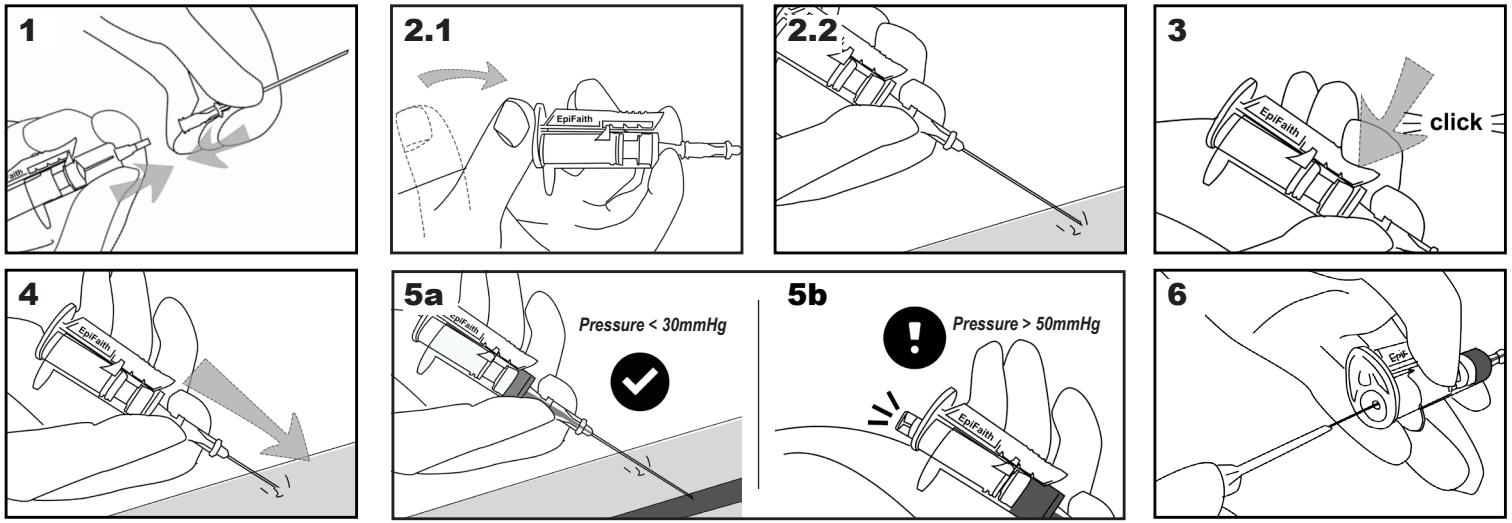
INSTRUCTIONS FOR USE





Indications for use

The EpiFaith CV 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.

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 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.

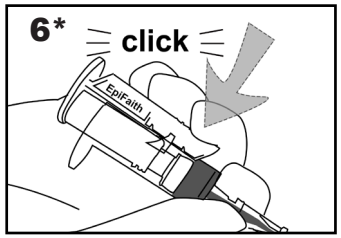
5 Stop advancing the needle when flash is observed (Fig. 5a).
Examine the top of the EpiFaith CV, where one would insert the guidewire. If the pressure within the vessel is lower than 30mmHg, the insertion mechanism will not "pop-up"/protrude from the plunger (see Fig A and Fig 5a). If the pressure within 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 withdrawal 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: May 2021

Caution	Do Not Reuse	LOT	Batch Code	Manufacturer	STERILE EO	Sterilized using ethylene oxide	REF	Catalogue number		Do not use if package is damaged.	Non-pyrogenic
Consult instructions for use	Do Not Resterilize		Use-by date	Date of Manufacture	EC REP	Authorised Representative in the European Community		Keep away from sunlight		Quantity	