

SAFELET™ CATH

IV CANNULA

<Instructions for Use>

Prior to use, please read the Instructions for Use carefully.

Indications

The device is a general device not intended for a specific medical condition. The device is to be used by healthcare professionals with specialized knowledge, such as doctors, medical technicians, or nurses, etc.

Intended Purpose

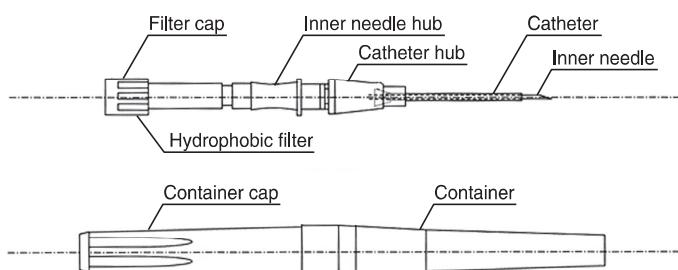
The device is intended to secure vascular access by connecting to an infusion line, such as an infusion set or transfusion set, in order to administer medication or blood into the body.

Contraindications

- There are no recognized contraindications for the use of the device.

Shape and Structure

<Name of components>



Clinical Benefits

The device enables the administration of medication or blood into the body by connecting to an infusion line such as an infusion set, providing benefits to the patient such as relief of symptoms. Relief of symptoms depend on the medicinal fluid being injected.

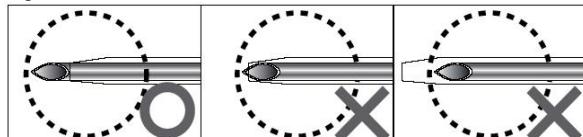
Cautions

- Do not re-use.
- Use with caution in children, pregnant women, and the elderly.
- When removing the device from the container, pull it in a straight direction. Pulling in a slanted direction may damage the tip of the inner needle.
- Do not use if the catheter protrudes beyond the tip of the inner needle. (See Fig. 1.)
- Puncture the site holding or supporting the inner needle hub. Holding another part while puncturing, or not supporting the inner needle while puncturing, will cause the inner needle to move during the puncture, preventing a good puncture.
- When pulling out the inner needle, pull it out straight without bending the catheter. In case it is determined that vascular access has not been secured while pulling out the inner needle, pull out both the inner needle and catheter together and dispose them both.
- Once an inner needle has been pulled out from the catheter, do not under any circumstance re-insert it into the catheter. In addition, under the conditions that an inner needle has been pulled out partially, do not move the inner needle back and forth within the catheter. There is a risk that the catheter inner surface may be scratched, or the inner needle might poke through, damaging the catheter, and a fragment may remain in the patient.
- Be careful of the adhesion of blood or medication onto the connecting parts. The connecting parts may loosen, etc.
- Re-use of the device may lead to infection by contamination.
- Not to be used for high-pressure injection. The device may break.
- Constantly monitor for damage to the device, loose connections, leakage, air inclusion, and clogging during use.
- Be careful not to pull out, push in, or bend the connecting part of the catheter and catheter hub with excessive force. There is a risk of detachment, damage, or elongation of the catheter.
- Do not use if package is damaged.
- Stop the use of the device if phlebitis or extravasation due to the catheter is observed after placing the catheter.
- After placing the catheter, if it is not secured enough, leakage or accidental removal may be caused by misalignment of the catheter. Constantly confirm the catheter's condition.
- As this device is made of plastic, avoid subjecting it to vibration or any impact during transportation and operation.
- Do not recap the device. Recapping may result in needle sticking. Also, if the container is incorrectly recapped at an angle, the needle tip may pierce the container.
- Dispose of the device in an approved biohazard container as per facility protocol.
- Any incidents shall be reported to the manufacturer and the competent authority of your State.
- If the device is exposed to abnormal conditions (for example, high temperature and humidity) or if it is unintentionally opened before use, do not use the device.

Instructions for Use

- Open by twisting the container cap and breaking the label along the perforation line.
- Take off the container cap, and pull the device straight out of the container.
- Confirm that the hydrophobic filter is securely attached to the inner needle hub.
- Confirm that the inner needle and catheter are matched together in the correct position. (See Fig. 1.)
- With the bevel of the inner needle facing upwards (confirm using the marking), puncture the disinfected site on the skin.
- If the tip of the catheter enters the blood vessel, back-flow of blood (flashback) will occur.
- If flashback is observed, secure the inner needle hub in place using your fingers, and advance the catheter to the required depth.
- Support the catheter hub and take out the inner needle.
- Connect an infusion set etc. to the inserted catheter hub and secure it with tape.

Fig. 1.



Connection with other devices

The device connects to medical devices (infusion set, etc.) that connect the inside and outside of the body through a catheter hub.

Symbols used for labeling

 Sterilized using ethylene oxide

 Contains hazardous substances