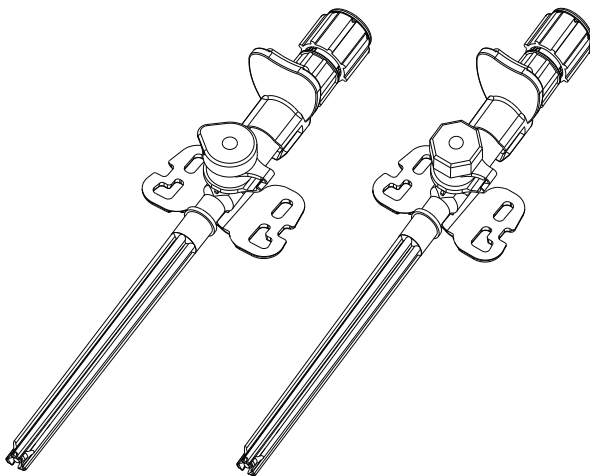


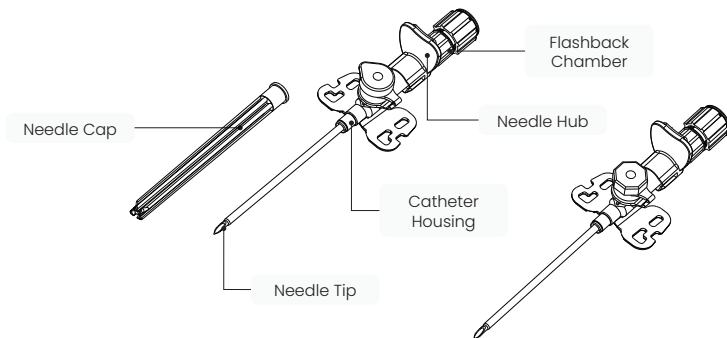
INSTRUCTIONS FOR USE

KAWANA™ SAFETY

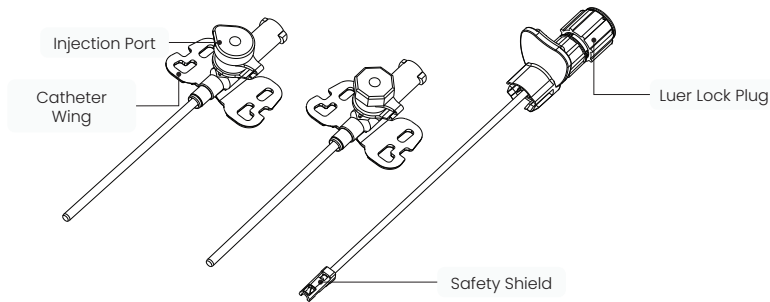
Peripheral IV Catheter



Before Removal of Needle



After Removal of Needle



Description

The device is an over-the-needle catheter for short-term use. This IFU is for the safety model of the device. It is a single-use device with two capillary variants – Fluorinated Ethylene Propylene (FEP) and Polyurethane (PUR), embedded with radio-opaque stripes. These are available in different gauges – G14, G16, G18, G20, G22 and G24 that specify the flow rate, coded by the colours orange, grey, green, pink, blue and yellow respectively for easy identification of gauge type. The device has a female 6% conical taper (luer) at the catheter housing to enable a fluid administration set or related equipment to be connected to the patient venous system via a matching male taper. It is typically assembled with a dedicated introduction needle. It has an injection port with a unidirectional valve, which shall be covered by a flip cap. It also has wings for fixation. It comes in blister packaging and is sterilized using ethylene oxide. In general, the dwell time for this device is 72-96 hours as these are intended for short-term use.

Intended Purpose

Peripheral IV catheter is intended to be used for administration of medications, fluids, transfusion of blood and blood products as well as blood sampling.

Indications for Use

- Fluid administration: These are frequently used for the administration of fluids, such as saline or other intravenous medications. This is common in situations where oral intake is insufficient of contraindicated.

- Medication administration: Many medications, including antibiotics, pain relievers, and other therapeutic agents can be administered through peripheral IV lines.
- Blood transfusion: It can be used for the transfusion of blood or blood products.
- Emergency situations: In emergency situations where rapid access to the circulatory system is necessary to administer life-saving medications or fluids.

Intended Patient Population

It shall be used on neonates, paediatric and adult patients (all age groups) as this device is available in gauges from G14 to G24.

Intended Users

It shall be used by all Clinicians (Physicians – doctors, registered nurses, nurses, pharmacy professionals, other specialists, operators over 3 years of experience) who are competent to perform the PIVC insertion and maintenance.

Contraindications

- Not to be used in patients with known hypersensitivity to any of the materials used in the device.
- Local skin infection, trauma, and burns.
- Scorched sites, infected sites.
- Occluded vein.
- Needed for long-term venous access (consider the central venous access if venous access is required for more than 4 days).
- Deep venous Thrombosis on the affected limb or Lymphedema.
- Presence of Arteriovenous Fistula or graft in the extremity.

- Previous infiltration and extravasation at the chosen site.

Cautions

- Before placing the device, the punctured site needs to be disinfected. When starting and maintaining the device, avoid the risk of exposure to contaminated blood.
- The product shall be used immediately after opening the packaging to ensure product sterility.
- Do not bend the needle before use, during advancement, or removal. A bent needle can damage the catheter safety mechanism functionality.
- Do not use scissors or other sharp objects when removing fixation dressing as it may damage the catheter.

Warnings

- Do not use the product if the seal is tampered with or damaged unintentionally.
- Do not resterilize the device as it may increase the EO residuals in the product.
- Do not reuse the same device for multiple pricking in case of failure to access the vein in the first attempt with the same patient.
- Reuse of the product can cause a change in physical characteristics like damage to the tip of the needle, catheter, splitting of the catheter, and blockage of needle path. Besides, it could contribute to infection, allergy, and other blood-related transfusion diseases like HIV, AIDS, Hepatitis, etc.
- Do not reintroduce the steel needle into the catheter after withdrawal as it may lead to cut-off.

- Depending on how long the cannula is left in situ on the type and number of infusions or injections administered and on individual predisposition, thrombophlebitis may occur in the accessed vein. Hence, the punctured site should be checked at regular intervals.
- Read the instructions before using the device to prevent infiltration caused by improper gauge size selection, dislodgement, or incorrectly inserted IV.
- Dispose of the device after use in accordance with the applicable local, state, and federal laws and regulations. If not disposed of properly, it may lead to environmental pollution, and any infectious diseases.

Limitations

- Large blood transfusion.
- Administration of highly viscous fluids, irritant fluids, and drugs as those require a large vein for administration. In such cases, central venous access is necessary.

Undesirable Side Effects

Infiltration, Extravasation, Phlebitis, Occlusion, Catheter dislodgement, Infection, Damage to veins and injection site, Air embolism, Blood clots, Hematoma formation, Bleeding, Nerve injury.

Raw Materials Used

Polypropylene, FEP (Fluorinated Ethylene Propylene) or PUR (Polyurethane), Methyl Methacrylate-Acrylonitrile-Butadiene-Styrene, and Polystyrene, Stainless Steel, High-density Polyethylene, Low-density Polyethylene, Acrylic Copolymer, Silicone.

Clinical Benefits

First insertion success, Safe/fast IV infusion, Passive safety shield or no needlestick injury, Excellent handling and patient satisfaction, Ease of insertion, Reduction of blood leakage and blood contamination.

Performance Characteristics

- The material used in the device has a low coefficient of friction thereby smoothening the insertion.
- The needle bevel design minimizes the penetration force for the ease of catheterization.
- It is made of biocompatible material. Hence, it has a long indwelling time.
- Appropriate detachment force and pull strength support successful venous access.
- Desired flow rates can be achieved with a specified gauge size.

Storage

Recommended storage conditions are between 10°C to 40°C. Keep dry and away from sunlight.

How It is Supplied

Pentamaster MediQ Sdn. Bhd. supplies these devices in a sealed peel pack that has been ETO sterilized. One inner box has 50 primary packs. Four such inner boxes are packed in a master carton.

Expiration Date

The use-by date on the primary package is the sterility expiration date. This device should not be used after the indicated sterility expiration date.

Duration of Use

Change according to the CDC guidelines and/or hospital or institutional protocols.

Reporting

Any serious incident that occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Competent Authority

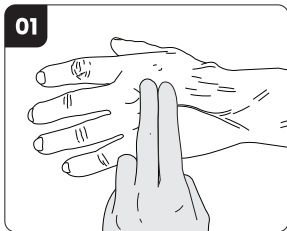
Name : DE/CA20, Bezirksregierung Düsseldorf
Dezernat 24
Address : Cecilienallee, 2, Düsseldorf, Germany
Email : dez24.mpg@brd.nrw

General Instructions for Using PIVC in Combination with Other Devices

User's Medical experience/expertise is important for using a safe combination of the PIVC with other devices like syringes, and infusion lines.

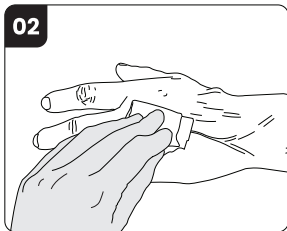
- For safe combination/attachment Infusion Line accessory: A proper and secure union with IV. Line and match with rigid 6% luer taper male fitting (with or without luer lock) of infusion accessory. The attachment is to be done by push fitment and clockwise rotation at a 90-degree angle to the IV cannula hub.
- Syringes: Open the injection port and attach the syringe conus with a slight twisting movement and inject medicaments/fluids using the syringe via the integrated injection port.
- It is also safe to use infusion pumps and extension tubing, among other devices that come into indirect contact with the PIVC.

01



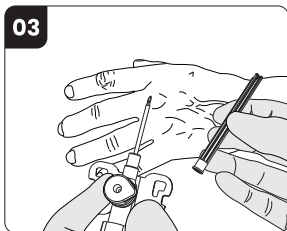
Identify the veins at the back of the hand which are easy to access and have good blood flow. Tap the back of hand to view the veins.

02



Disinfect the puncture site upon identifying the veins.

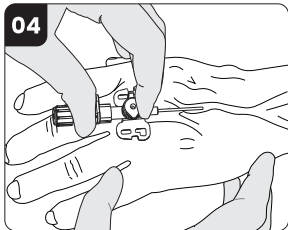
03



Remove the needle cap from KAWANA™ Safety.

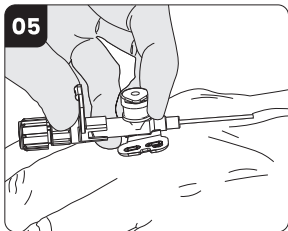
NOTE: KAWANA™ Safety can be used on the back of the hand or arm depending on the Clinician and/or Indication.

04



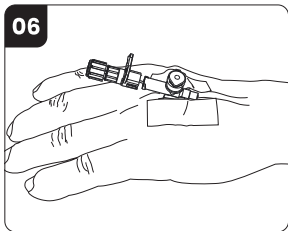
Approach vein slowly at low angle. Puncture a suitable vein. If venipuncture is successful, blood will immediately be visible inside the flashback chamber. Observe the flashback of blood to know when the needle is in the vein.

05



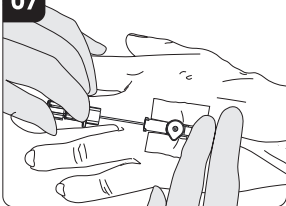
Upon flashback visualization, lower KAWANA™ Safety's position almost parallel to the skin. Advance the capillary further into the vein, while slightly withdrawing the steel needle. The catheter flashback will appear, indicating that the catheter has been safely and successfully inserted into the vein.

06



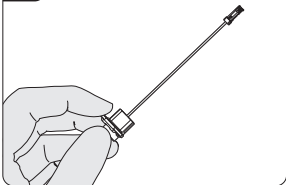
Using adhesive tape, fix the catheter housing's wing onto the skin. The steel needle should stay in the vein.

07



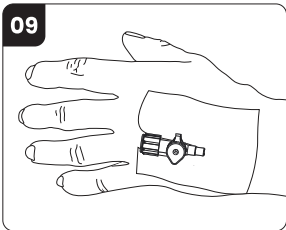
Before removing the steel needle, use one hand to compress the vein at the tip of capillary with the middle finger, to prevent spillage of blood. At the same time press the catheter housing's injection port with the index finger to prevent capillary dislodgement during needle removal.

08



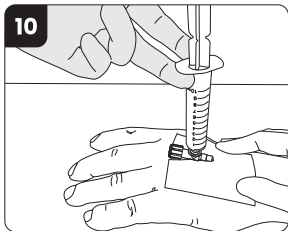
Remove the needle using another hand by pulling the needle straight back. Metal safety clip will automatically attach to the needle tip as it exits the catheter housing. Dispose of needle immediately into sharps container.

09



Connect to infusion line and cover puncture site with a sterile dressing. At times when it is not connected, close the opening of the catheter housing with luer lock plug.

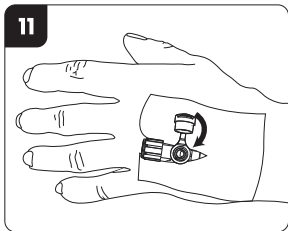
10



Drugs, fluids or medicament can be injected without a cannula via the integrated injection port.

- i. Open the injection cap.
- ii. Attach syringe conus with a slight twisting movement.
- iii. Inject/administer drugs/fluids or medicament using syringe via the integrated injection port.
- iv. Valve opens and closes automatically.

11



Close the injection cap after injection/administration of drugs or fluids is done.

NOTE: Based on equivalent and similar devices data of PIVC, no evidence of incompatibility or limitations in the choice of medicinal products to be administered.

EN | EXPLANATION OF SYMBOLS



Consult instructions for use



Batch code



Catalogue number



Date of manufacture



Use-by date



Manufacturer



Authorized representative



Medical device



Caution



Do not re-use



Sterilized using ethylene oxide



Single sterile barrier system



Single sterile barrier system with protective packaging outside



Do not resterilize



Do not use if package is damaged



Keep away from sunlight



Keep dry



Temperature limit



EUROPECERT UG (haftungsbeschränkt)

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support@europecert.eu

MediQ

Eco-Excellence. Trusted Quality.



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