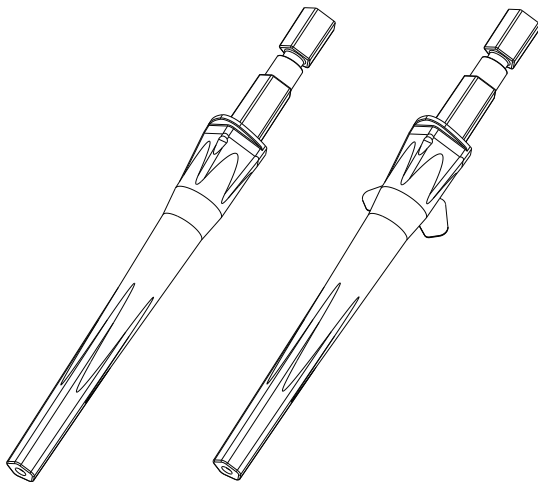


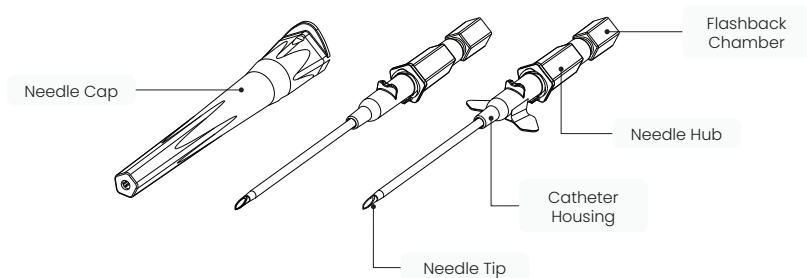
INSTRUCTIONS FOR USE

YOLANDA™ SAFETY IV Catheter

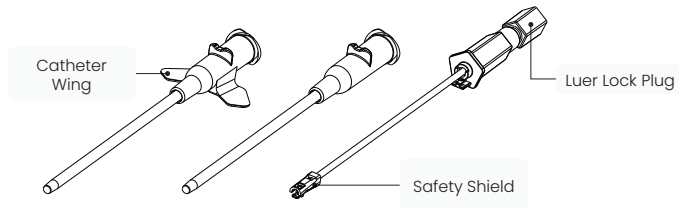


MediQ
Eco Excellence, Trusted Quality.

Before Removal of Needle



After Removal of Needle



Description

The YOLANDA™ Safety IV Catheter is an indwelling peripheral over-the-needle catheter intended to obtain intravascular access for short-term use. It is designed for single use and is available as a safety model to minimize inadvertent needlestick injuries. The catheter is manufactured using Fluorinated Ethylene Propylene (FEP) or Polyurethane (PUR) capillary material with embedded radio-opaque stripes and is available in multiple gauges to provide the required flow rates. The catheter housing incorporates an ISO 80369-7 female 6 % conical taper (Luer) to allow connection to compatible fluid administration sets or related equipment via a matching male taper.

Both wingless and winged (to support secure fixation on the patient) configurations are available. The device is supplied sterile, non-pyrogenic, non-toxic and sterilized using ethylene oxide. It is intended for short-term use, with a typical dwell time of 72–96 hours.

Intended Purpose

The YOLANDA™ Safety IV Catheter is intended to sample blood, monitor blood pressure, or administer fluids and blood intravenously.

Indications for Use

- Fluid and medication administration: The YOLANDA™ Safety IV Catheter is intended for short-term vascular access for the administration of infusion solutions, blood products, and pharmaceutical preparations, in accordance with the Summary of Product Characteristics (SPC) of the drug or solution.

- Blood sampling and monitoring: The device may be used to sample venous or arterial blood and to monitor blood pressure.
- Subcutaneous infusion therapies: The YOLANDA™ Safety IV Catheter is also indicated for subcutaneous infusion therapies, according to the SPC of the drug or solution.
- Facilitation of vascular access device placement: The YOLANDA™ Safety IV Catheter may be used to facilitate the placement of vascular access devices such as guidewires, central venous catheters (CVC), peripherally inserted central catheters (PICC), and midline catheters into the vascular system.
- Emergency situations: In emergency situations where rapid access to the circulatory system is necessary to administer life-saving medications or fluids.

Intended Patient Population

The catheter may be used for patients of all age groups, including neonates, paediatric, and adult patients, with consideration given to the adequacy of vascular anatomy, the appropriateness of the procedure being performed, the solution being infused, and the duration of therapy.

Intended Users

The catheter is intended to be used by qualified healthcare professionals who are trained and competent in the insertion and maintenance of peripheral IV Catheters, in accordance with applicable national regulation.

Contraindications

The YOLANDA™ Safety IV Catheter is not to be used in patients with known hypersensitivity to any of the materials used in the device.

Cautions

- Before placing the device, the punctured site shall be disinfected. When starting or maintaining the device, adhere to aseptic technique and avoid the risk of exposure to contaminated blood.
- The product shall be used immediately after opening the packaging to ensure product sterility. Use only if the packaging is intact.
- Do not bend the needle before use, during advancement, or during removal. A bent needle may damage the catheter or impair the safety mechanism functionality.
- Do not use scissors or other sharp objects when removing fixation dressings, as this may damage the catheter.
- If blood is present, flush the device according to institutional protocols.
- Verify adequate collateral circulation prior to arterial puncture, if applicable.
- Care shall be taken to avoid kinking, obstructing, or damaging the catheter during connection to infusion devices or accessories.
- For use with power injectors, ensure secure luer lock connections and verify catheter integrity prior to power injection.

Warnings

- Do not use the product if the seal is tampered with or unintentionally damaged.

- Inspect the needle before use. Do not use if the needle shows signs of corrosion, rust, or discoloration, as this may cause pain, injury, or infection to the patient.
- Do not resterilize the device, as this may increase ethylene oxide (EO) residuals and compromise device safety.
- Do not use the product after the use-by (expiration) date printed on the packaging. Use of an expired product may compromise sterility, performance, or safety, and may increase the risk of infection.
- Do not reuse the device. Reuse or reprocessing presents a risk of contamination, infection, and impaired functionality, and may result in serious injury or infection transmission.
- Do not reuse the same device for multiple puncture attempts if venous access is not achieved on the first attempt.
- Reuse of the product may cause changes in physical characteristics, including damage to the needle or catheter, catheter splitting, or blockage of the needle path, and may contribute to infection, allergy, or blood-borne disease transmission (e.g. HIV, Hepatitis).
- Do not reintroduce the steel needle into the catheter after withdrawal, as this may lead to catheter shearing or cut-off.
- Do not attempt to bypass or disable the safety mechanism. If the safety mechanism has not been activated, keep the needle tip away from the body and fingers at all times and immediately dispose of the device in an approved sharps container.

- Depending on dwell time, type and number of infusions, and patient predisposition, thrombophlebitis may occur. The puncture site shall be inspected regularly.
- Read the instructions before use to prevent infiltration due to improper gauge selection, dislodgement, or incorrect insertion.
- Dispose of the device immediately after use in accordance with applicable local, state, and national regulations. Improper disposal may result in injury, infection risk, or environmental contamination.
- When used with power injectors, exceeding recommended flow rates or pressure limits may result in catheter failure, dislodgement, or infiltration.

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, leakage, phlebitis, thrombophlebitis, thrombosis, catheter occlusion, catheter dislodgement, catheter fracture or catheter cut-off, bloodstream infection, local infection, inflammation, damage to veins and injection site, injury to adjacent structures during insertion, vascular spasm, embolic complications, air embolism, blood clots, hematoma formation, bleeding, edema, erythema, pain, cellulitis, nerve injury, nerve palsy, pseudoaneurysm,

arteriovenous fistula, ischemia due to arterial occlusion, injury to tendon sheaths or adjacent structures, systemic side effects such as acute cardiac failure or hyponatremia, and infection related to subcutaneous infusion therapies.

Raw Materials Used

Polypropylene, FEP (Fluorinated Ethylene Propylene) or PUR (Polyurethane), Methyl Methacrylate-Acrylonitrile-Butadiene-Styrene, Stainless Steel, Acrylic Copolymer, Silicone.

Clinical Benefits

For preventing repeated IV pricks while providing emergency treatment, 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, clinically well accepted and easy for healthcare professionals to use.

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

The duration of use shall be in accordance with the Centers for Disease Control and Prevention (CDC) guidelines and/or applicable hospital or institutional protocols and shall be dependent on the applied therapy in accordance with the Summary of Product Characteristics (SPC) of the drug or solution. The insertion site should be checked frequently and at regular intervals, and the catheter should be removed in the event of local or systemic signs of infection.

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.

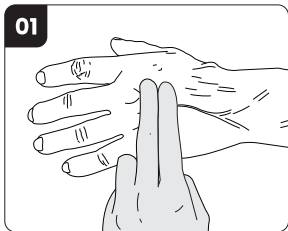
Competent Authority

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

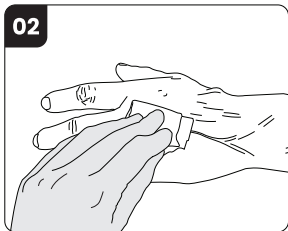
General Instructions for Using PIVC in Combination with Other Devices

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

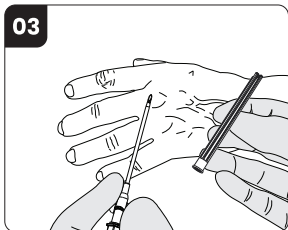
- For safe combination/attachment Infusion Line accessory: A proper and secure union with IV. Line and match with rigid 6% luer taper male fitting (with or without luer lock) of infusion accessory.
- Syringes: Syringes may be connected via appropriate luer-compatible injection ports, needle-free connectors, or compatible adapters for administration of fluids or medicaments.
- It is also safe to use infusion pumps and extension tubing, among other devices that come into indirect contact with the PIVC.

01

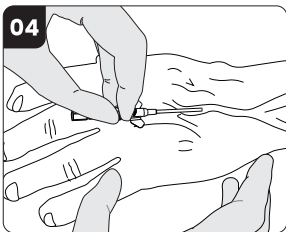
Identify the veins at the back of the hand which are easy to access and have good blood flow. Tap the back of hand to view the veins.

02

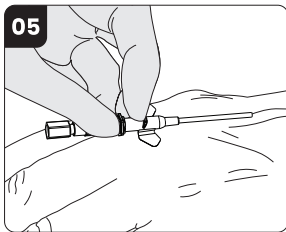
Disinfect the puncture site upon identifying the veins.

03

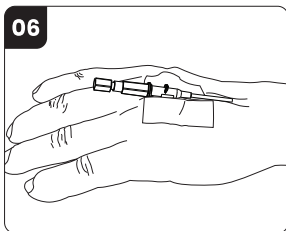
Remove the needle cap.



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.

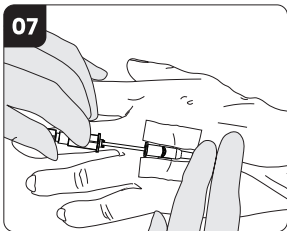


Upon flashback visualization, lower entire catheter's position almost parallel to the skin. Advance the capillary further into the vein, while slightly withdrawing the steel needle. The catheter flashback will appear, indicating that the catheter has been safely and successfully inserted into the vein.



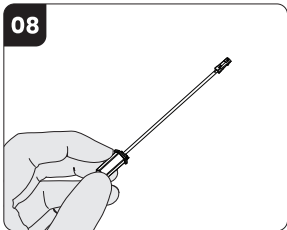
Using adhesive tape, fix the catheter housing onto the skin. The steel needle should stay in the vein.

07



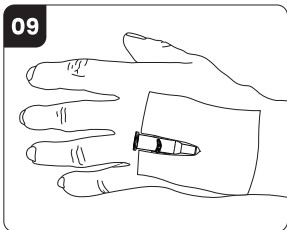
Before removing the steel needle, use one hand to compress the vein at the tip of capillary with the middle finger, to prevent spillage of blood. At the same time press the catheter housing with the index finger to prevent capillary dislodgement during needle removal.

08



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

09



Immediately connect to tubing or adapter.

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 re-sterilize



Do not use if package is damaged



Keep away from sunlight



Keep dry



Temperature limit



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