KIMAL
delivering healthcare innovation

MIDLINE
Mid term peripheral inserted catheter

Instructions for Use

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Οδηγίες Χρήσης

INTENDED USE

Sterile single use device indicated to be placed peripherally in the upper arm veins for use in attaining access to the venous system for short term use (<30days) and for the specific purpose:

- Infusion of
  - All intravenous fluids that are appropriate for short peripheral IV infusion.
  - Infusates that are Less than 10% Dextrose.
  - Infusates that are Less than 5% Protein.
  - Infusates that are between pH 5 and 9 have an osmolarity less than 600 mOsm/L
  - Power Injection of contrast media at a maximum 300psi
- frequent blood sampling

WARNING

- **This product is sterile and for single use only. Do not re-use, reprocess or re-sterilise. Do not use catheter or accessories if any sign of damage is visible.**
- **Reprocessing or re-sterilisation of the set may damage the catheter and affect its integrity which may, when re-used, lead to severe deterioration in health and safety of patients.**
- **The catheter does not have any metallic components and can be exposed to various environmental conditions including thermal ignition source (during MRI) as long as no metal component is attached to it.**
- **For high pressure injection applications, only utilize lumen indicated for such applications. Lumen not indicated for high pressure applications can result in inter-lumen crossover or rupture with potential for injury.**
- **Since upper arm veins run deeper than veins used for insertion and likely targets for short peripheral IV catheters, complications from the infusion may not be recognized until a severe reaction has occurred. Therefore, certain medications that are likely to be damaging to the vein generally should not be infused through Midline catheters. Therapies not appropriate for midline catheters include continuous vesicant therapy and medications including; Vancomycin, Nafcillin, Primaxin, Phenergan (promethazine), and Dilantin (phenytoin) as well as any agent that is hyperosmolar (> 600 mOsm/L) or very acidic of basic.**
- **The catheters should not be cut to alter their length unless the procedure requires it.**
- **The catheters should be in place no longer than 30 days from the date of insertion.**
- **The insertion technique has a significant influence on the complications and outcome of the patient. Insertion must be performed by a competent and experienced catheter insertion team. Inexperienced personnel should not be permitted to perform the insertion except under the direct supervision of an experienced physician or surgeon.**
- **Be sure that you are familiar with the possible complications and emergency measures are known and available if occur.**
- **Do not advance the guidewire or catheter if unusual elastic resistance is encountered. Do not insert or withdraw the guidewire forcibly from any component. The wire could break or unravel, in which case both the catheter and guidewire must be removed simultaneously.**
- **In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter immediately.**

DEVICE DESCRIPTION

Peripherally Inserted venous catheters (Midline catheters) are radiopaque and made from polyurethane. The catheter tube can be single, dual, or multi-lumen. Midline catheters are longer than peripheral IV catheters and shorter than peripherally inserted central catheters (PICC) which extend into the vena cava. This device provides an alternative to short peripheral IVs for certain treatments. Pressure resistant Midline catheters (identified by purple colour) and indicated for use with power injection of contrast media.
Catheters are supplied with four kit types for direct puncture following; Seldinger technique (using either IV Seldinger Kit or Micro-Access Over Needle Peel-away), Modified Seldinger technique (using Over Dilator Peel-away) or Catheter only with externally sourced insertion kit.

Kit components

Each Midlines Catheter Set for Modified Seldinger technique consists of a unique Midline catheter and the following accessories:

- 1 × Introducer needle
- 1 × Standard syringe
- 1 × Nitinol guidewire with a straight flex tip
- 1 × Peel-away sheath micro-introducer
- 1 × Scalpel
- 1 × Unifix Lok
- 1 × Transparent adhesive

Each Midlines Catheter Set for Seldinger technique consists of a unique Midline catheter and the following accessories:

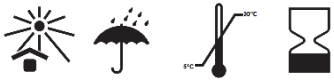
- 1 × Standard syringe
- 1 × Nitinol mandrel with a straight flex tip
- 1 × Over the needle peel-away sheath introducer
- 1 × Scalpel
- 1 × Unifix Lok
- 1 × Transparent adhesive

Depending on the type of the catheter, different variations of accessories are provided in the sets. Dimensions of the components are indicated on the product label.

How supplied

All contents are supplied sterile and non-pyrogenic in unopened and undamaged packaging. The device is sterilised by ethylene oxide. Do not use catheter if sterile package has been damaged or has been opened. Do not re-use or re-sterilise the device.

Storage



Protect from direct sunlight, any source of heat, and moisture. Store and expose only within the specified temperature limit. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that catheters are used prior to expiration date on package label.

RELATIVE CONTRAINDICATIONS

The inserter of the catheter shall apply its clinical judgement prior to the insertion of the catheter. Instances where catheter might not be suitable, and not exhausted list, are:

- In patients with bleeding disorders
- When the presence of another device related infection, bacteraemia or septicaemia is known or suspected
- If severe chronic obstructive lung disease exists
- If previous episodes of venous thrombosis or vascular surgical procedure at the prospective insertion site have occurred
- Local tissue factors which may prevent proper devices stabilisation and/or access, like allergic reaction, or any dermatological disease
- History of mastectomy at the insertion site

WHICH VEIN TO CANNULATE?

Cephalic, Basilic or the median Cubital veins. Basilic is the preferred insertion site for peripherally inserted venous catheters. Placement above antecubital fossa is recommended.

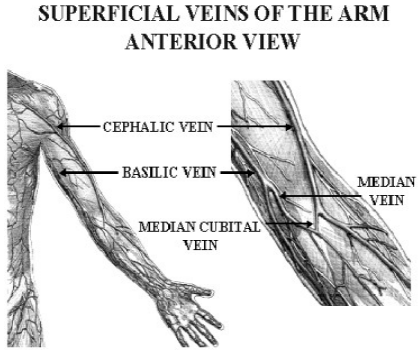


Figure 1

WARNING

- **Placement at or below antecubital fossa may result in phlebitis**

METHOD OF INSERTION

General preparation to obtain vascular access

The basic preparation and equipment which are required for venous cannulation are the same regardless of the route or technique chosen. Clinicians who insert central catheters should be taught the technique by an experienced colleague.

WARNING

- **Do not apply excessive force in placing or removing catheter as it may result in catheter breakage. If placement or withdrawal cannot be easily accomplished, an X-ray should be obtained and further consultation requested.**
- **Do not secure, staple, or suture directly to outside diameter of catheter body or extension lines as this may increase the risk of damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.**

PRECAUTION

- **Ultrasound should be used in the placement of catheters.**
- **Do not use absolute alcohol or acetone based product on the catheter. 2% chlorhexidine or iodine based solution is recommended as antiseptic solution.**
- **It is not recommended to use antimicrobial ointments or solutions on catheters as it may cause degradation of catheter materials.**
- **Do not use sharp instruments near the extension line or tubing. Do not use scissors to remove dressing, as this could possibly cut or damage the catheter. Do not suture through any part of the catheter. Catheter tubing can tear when subjected to excessive force or rough edges.**
- **Check ingredients of prep sprays and swabs before using. Some disinfectants used at catheter insertion site contain solvents which can attack the catheter material. Alcohol and**

acetone can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between catheter stabilization device and skin.

- **Take care when instilling drugs containing high concentration of alcohol.**
- **Do not use syringes smaller than 10ml to minimize the risk of pressure induced damage to catheter.**
- **Continuously monitor catheters for:**
  - **Desired flow rate.**
  - **Security of dressing.**
  - **Adherence of stabilization device to skin and connection to catheter.**
  - **Correct catheter position; use centimetre markings to identify if catheter position has changed.**
  - **Secure connections.**

PREPARING FOR INSERTION

PRECAUTION

- **Clinicians should use aseptic techniques and dress in protective clothing.**

1) Drape puncture site.

2) Perform a local anaesthetic as needed.

CATHETER INSERTION INSTRUCTIONS

WARNING

- **Do not insert stiff end of guidewire into vessel as this may result in vessel damage.**
- **Do not cut guide wire to alter length.**
- **Do not withdraw guidewire against needle bevel to minimize the risk of possible severing or damaging of guidewire.**
- **If any resistance is felt then the needle should be pulled out with the wire still inside and the procedure repeated. This reduces the risk of entangling of the guide wire or its end being cut off by the needle tip.**
- **Do not leave the dilator in place to minimize the risk of possible vessel wall perforation.**
- **Do not apply undue force on guidewire to minimize the risk of possible breakage.**
- **Do not apply excessive force in placing or removing catheter as it may result in catheter breakage.**
- **If placement or withdrawal cannot be easily accomplished, an X-ray should be obtained and further consultation requested.**
- **Site selection should avoid areas of pain on palpation, veins that are compromised (e.g., bruised, infiltrated, phlebitic, sclerosed, or corded)**
- **Repeated over-tightening of bloodlines, syringes and caps will reduce connector life and could lead to potential connector failure. Inspect the catheter frequently for nicks, scrapes and cuts, etc. which could impair catheter performance.**

PRECAUTION

- **The colour of blood observed is not always a reliable indicator of venous access.**
- **Do not withdraw tissue dilator until the sheath is well within the vessel to minimize the risk of damage to sheath tip.**
- **Sufficient guide wire length must remain exposed at hub end of sheath to maintain the firm grip on guide wire.**
- **Catheter clamp must not to be clamped until stylet or guide wire is removed.**
- **The colour of blood is not always a reliable indicator of venous access.**

- **Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site of peripheral venous catheters because of the potential risk to promote fungal infections and antimicrobial resistance.**

Modified Seldinger – Using over dilatory peel away sheath

1) Reapply tourniquet and replace sterile gloves.
2) Locate vein for insertion and use image guidance if available.
3) Insert introducer needle into vein and check for pulsatile flow. Pulsatile flow is usually an indicator of inadvertent arterial puncture.
4) Insert soft tip of guide wire through introducer needle into vein. Advance guide wire to desired depth.
5) Hold guidewire in place while removing introducer needle and always maintain firm grip on guidewire.
6) Enlarge puncture site if necessary, by using scalpel positioned away from the guidewire to enlarge the puncture site.
7) Thread tapered tip of peel-away sheath dilator assembly over guidewire. Advance assembly with slight twisting motion to a depth sufficient to enter vessel. Dilator may be partially withdrawn to Further facilitate advancement of sheath into the vessel. A slight twisting motion of the peel-away might help sheath advancement.
8) Hold the sheath in place; withdraw guide wire and dilator as one unit.
9) Insert Catheter through peel-away sheath.
10) If resistance is met while advancing catheter. retract and/or gently flush while advancing.
11) Before reaching pre- established insertion length, withdraw peel-away sheath over catheter until free from venepuncture site.
12) Grasp tabs of peel-away sheath and pull apart away from catheter until sheath splits down entire length.
13) Advance catheter to final position.
14) Verify Catheter tip placement by checking catheter placement with syringe and aspirating through distal lumen until free flow of venous blood is observed.
15) Flush lumen(s) to completely clear blood from catheter. Use catheter clamps, if provided, to occlude lumen(s)
16) Cleanse insertion site per hospital protocol.
17) Ensure insertion site is dry before applying dressing.
18) Secure catheter in place by suture fixation or using adhesives.

Direct puncture – Using IV Seldinger Insertion Kit

1) Apply tourniquet and replace sterile gloves.
2) Flush and prime the catheter with saline
3) Locate vein for insertion and use image guidance if available.
4) Insert the introducer needle/cannula into the vein and be sure that the flow is not pulsatile. Pulsatile flow is usually an indicator of inadvertent arterial puncture.
5) Remove the needle from the cannula, leaving the cannula in place
6) Place the guide wire through the cannula to the desired depth, if resistance is felt please check with a consultant physician
7) Remove the cannula over the wire, leaving the wire in place

8) Widen the hole with the scalpel if necessary, ensure the scalpel cuts away from the guide wire

9) Thread the catheter over the guide wire to the desired depth, if resistance is met while advancing catheter, retract and/or gently flush while advancing

10) Remove the guide wire and continue with step 13 of the modified seldinger insertion instructions

Direct puncture - Using over needle peel away sheath.

1) Apply tourniquet and replace sterile gloves

2) Locate vein for insertion and use image guidance if available.

3) Insert the over needle peel-away sheath into vein and be sure that the flow is not pulsatile. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

4) Hold the sheath in place, withdraw the needle.

5) Continue with step 9 of the modified seldinger insertion instructions

CONTRAST MEDIA INJECTION

WARNING

- **The lumen indicated "pressure" is the only lumen to be used for powerful injection. Do not attempt to use the other lumen(S) in this procedure as it may result in catheter rupture and high risk to the patient.**
- **Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.**
- **Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.**
- **Use of lumens not marked "Pressure" for power injection of contrast media may cause failure of the catheter.**
- **Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may lead to catheter failure.**
- **Exceeding the maximum flow rate of the flow rate ML/SEC printed on the extension line or the maximum pressure of power injectors of 300 psi may result in catheter failure and/or catheter tip displacement.**

PRECAUTION

- **Check before using the pressure MIDLINE (identified by purple suture wing) catheter for contrast media injection.**

1) Attach a 10 ml or larger syringe filled with sterile normal saline.

2) Aspirate for adequate blood return and vigorously flush the catheter with the full 10 ml of sterile normal saline.

3) Detach the syringe

4) Attach the power injection device to the catheter pressure tube marked "pressure"

5) Contrast media should be warmed to body temperature prior to power injection.

6) Use only lumens marked "Pressure" for power injection of contrast media.

7) Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum flow rate of 5 ml/sec.

8) Disconnect the power injection device.

9) Flush the catheter with 10 ml of sterile normal saline, using a 10 ml or larger syringe. In addition, lock each lumen of the catheter with heparinized saline. Usually, one ml per lumen is adequate.

USE OF NEEDLE-FREE CONNECTORS

1) Prior to accessing the haemostatic valves, swab the silicone seal in accordance with facility protocol (Figure 2).

Figure 2

2) To attach a Male Slip Luer (Figure 3) or a Male Luer Lock (Figure 4) to the haemostatic valve, grasp the clear polycarbonate body of the connector and push the luer/syringe straight into the silicone valve by using a twisting motion.

Figure 3

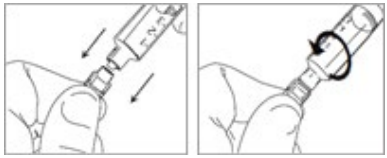


Figure 4

3) Flush the lines after each use, in accordance with facility protocol, using a push-pause and positive pressure disconnection technique.

4) To disconnect from the valve, grasp the valve and twist the syringe or blood tubing set connector clockwise until loose, then pull away from the valve connector. The valve closes and seals once a connector is removed, therefore capping is optional.

Equipment required for venous access

- Ultrasound imaging
- Sterile dressing
- Syringes and needles
- Sterile pack and antiseptic solution
- Appropriate catheter
- Local anaesthetic (e.g. 5 ml lignocaine 1% solution)
- Saline or heparinised saline to prime and flush all lumens on the line after insertion
- Shaving equipment for the area if very hairy (especially if femoral access is required)
- Suture in case of fixation by suturing is determined (e.g. 2/0 silk on a straight needle)

POSSIBLE COMPLICATIONS

The table below lists some of the possible complications that can occur during the early and late stages of venous cannulation.

Table 3 – Potential early and late complications

Early		Late
Arterial puncture	Air embolism	Venous thrombosis
Bleeding	Catheter embolus	Infection

PREVENTION AND TREATMENT OF CATHETER DYSFUNCTION

Causes of early catheter dysfunction

- Mechanical compression (pinch off syndrome)
- Malposition of catheter tip
- Kinks
- Catheter migration
- Patient position, especially if the catheter has not been well positioned and secured
- Loss of catheter integrity by infection

Methods that should be used to treat dysfunctional or non-functional catheter include

- Repositioning of a malpositioned catheter.
- Use of thrombolytics, as per hospital protocol.
- All catheter-related infections, except for catheter exit-site infections, should be addressed by initiating parenteral treatment with an antibiotic(s) appropriate for the organism(s) suspected. Definitive antibiotic therapy should be based on the organism(s) isolated.
- Catheters should be exchanged as soon as possible and within 72 hours of initiating antibiotic therapy in most instances, and such exchange does not require a negative blood culture result before the exchange. Follow-up cultures are needed 1 week after cessation of antibiotic therapy.

CARE OF CENTRAL VENOUS CATHETER

- Use an aseptic technique when inserting the catheter and any subsequent injections or changing fluid lines.
- Replace dressing according to organizational policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised e.g. dressing becomes damp, soiled, loosened, or no longer occlusive.
- Transparent semipermeable membrane dressing should be changed every **week**.
- Gauze and tape should be changed every 2 days.
- Label dressing with type, size, and length of catheter; date and time.
- Maintain Catheter Patency:
- Maintaining venous catheter patency should done in accordance with hospital policies, procedures, and practice guidelines. The personnel who care for patients with venous catheters must be knowledgeable about effective management to prolong catheters dwell time and prevent injury.
    - Solution and frequency of flushing a venous access catheter should be established in hospital policy.
    - Catheter patency is established and maintained by flushing intermittently via syringe with heparinized saline or 0.9% sodium chloride. Continuous drip is preferred.

PRECAUTION

- **Assess patient for heparin sensitivity. Heparin-induced thrombocytopenia has been reported with the use of heparin flushing solutions.**
- **The volume of flush solution should be equal to at least twice the priming volume of the catheter.**
- **When using any venous catheter for intermittent infusion therapy, proper flushing using a positive pressure flushing technique will help prevent occlusion.**
- **All valves, if used, need is to be properly swabbed with an appropriate antiseptic before being accessed.**
- **Keep the entry site covered with a dry sterile dressing.**
- **Ensure the line is well secured to prevent movement (this can increase risks of infection and clot formation). It is also recommended that the tip position is monitored to ensure correct positioning.**
- **Change the catheter if there are signs of infection at the site.**
- **Remember to remove the catheter as soon as it is no longer needed. The longer the catheter is left in, the greater the risks of sepsis and thrombosis.**
- **It is recommended changing according to hospital protocols to reduce the risks of catheter related sepsis and thrombosis. However, providing that the catheter is kept clean (sterile**

injections and connections) and there are no signs of systemic sepsis, routine replacement may not be necessary. Repeated cannulation to change lines on a routine basis, rather than based on clinical need, can increase the risks to the patient.

- **When changing the dressing, if using an alcohol based cleaning solution, ensure the site is dry by either waiting for 20 to 30 seconds or by drying with a clean, sterile swab before applying a dressing.**
- **For lumens not in use check at least once a day their patency by aspirating the lumen and flushing it with saline solution using a push-pause flushing followed by a positive disconnection.**

CATHETER

Remove any dressing and suture material. It is recommended that the patient is in a supine or Trendelenburg position. Ask the patient to inhale and fully exhale afterwhich they should hold their breath. Remove the catheter with a steady pull and apply firm pressure to the puncture site for at least 5 minutes to stop the bleeding. Excessive force should not be needed to remove the catheter. If it does not come out, try rotating it whilst pulling gently. If this still fails, cover it with a sterile dressing and ask an experienced person for advice.

CATHETER DISPOSAL

Used catheters should be disposed of in a sanitary container or according to hospital protocol to prevent possible contamination and cross infection.

DESCRIPTION OF THE MARKING SYSTEM

In order to achieve the required length, the catheter tube is reversely marked with numerical values every centimetre between 2 and 5 centimetres from the hub and then every 5 centimetres thereafter with dots every 1cm in between.
Example for 40cm long:

Hub **2 3 4 5 • • • • 10 • • • • 15 • • • • 20 • • • • 25 • • • • 30 • • • • 35 • • • • 40** tip
Illustration purposes only, not to scale.

SUMMARY SAFETY AND CLINICAL PERFORMANCE (SSCP)

The Summary of Safety and Clinical Performance (SSCP) can be referenced on the Eudamed public website (https://ec.europa.eu/tools/eudamed) or can be requested directly from Kimal (regulatory_department@kimal.co.uk)

BASIC UDI

The basic UDI for the Midlines range of Catheters is 5032932KSP-200J8.

SERIOUS ADVERSE EVENTS

If a serious adverse event occurs, please report it to Kimal at vigilance@kimal.co.uk and to your national competent authority.

EC REP

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