VYGON
Value Life

MID & LONG TERM VASCULAR ACCESS

leaderflex, smartmidline & lifecath midline

FAQ

INTRAVASCULAR THERAPIES

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Disclaimer

Use of Vascular Access Devices can result in harm to patients and adverse outcomes. Vygon (UK) accepts no liability for the consequences of any actions taken where the following guidance is not taken, or the details within the associated IFU (Instructions for Use) not adhered to.

Purpose

This document has been designed to provide information to clinicians using **leaderflex**, smart**midline**™ or life**cath** midlines in practice. Where possible, the information provided has been gathered from research evidence. However, where this is not available, information is provided using expert opinion and from RCN or INS guidelines.

- Information regarding insertion and care and maintenance of midlines is provided during device insertion sessions and specific training sessions available from Vygon (UK)
- Support literature regarding insertion, care and maintenance, along with Patient Information for midlines are also available from Vygon (UK)

Frequently Asked Questions

Q1: What is the difference between a Midline and an Extended Dwell Catheter (EDC)?

The terminology around these devices remains unclear clear. According to the book 'Vessel Health and Preservation' (Moureau, 2019)...

Extended Dwell Catheter:

'An extended dwell cannula is a peripheral cannula measuring less than 8cm but designed with a longer cannula (3-7.5cm) to facilitate ultrasound-guided placement, deeper vein access and longer dwell (Gorski, 2016). Placement varies but is preferred in the veins of the forearm or upper arm with a catheter long enough to ensure at least two-thirds of the catheter length will reside in the vein after insertion. Infusate considerations and dwell time are the same as with peripheral cannula (Gorski, 2016). EDC may, at times, be considered a midline catheter depending on length and placement location'.

Midline Catheter

'A midline catheter is a longer peripheral cannula most commonly inserted into the upper arm via the basilic, cephalic or brachial veins, with the internal terminal tip located below the level of the axilla, distal to the shoulder (Gorski, 2016; Moureau and Chopra, 2016; Adams et al., 2016). Midline catheter length ranges from 8cm up to 20cm. A midline should not extend to the axillary vein or enter the chest. As with short peripheral IV catheters, midline catheters are not used if the osmolarity of prescribed solution is greater than 900mOsm or the solution is considered irritating or vesicant. Haemodilution, which aids in protecting the vein from damage caused by irritating solutions, occurs at a lower rate in the smaller peripheral veins; therefore, irritating medications are not recommended for non-central placement. Characteristics of certain medications and their level of irritation can be mitigated with dilution resulting in lower concentrations of the irritant. Insertion of a midline catheter is performed in a sterile manner. Midline catheters are available in different lengths, materials (i.e. silicone or polyurethane) and differing insertion methods (i.e. over the needle peelaway, accelerated Seldinger, Seldinger)'.

RCN definition of a midline

A midline catheter for adults is defined as one that is between 3 and 8 inches (7.5cm–20cm) in length. Midline catheters are used for the administration of blood, fluid and medication when the therapy is expected to last between 1-4 weeks. They may be used where patients present with poor peripheral venous access and when the use of a central venous catheter is contraindicated. The midline catheter provides venous accessibility along with an easy, less hazardous insertion at the antecubital fossa (Denton, 2016).

The optimal dwell time for the removal of midline catheters is unknown; ongoing and frequent monitoring of the access site should be performed (O'Grady et al., 2011) alongside manufacturer's guidelines.

Device Classification

CE Marking is the medical device manufacturer's claim that a product meets the essential requirements of all relevant European Medical Device Directives. The Directives outline the safety and performance requirements for medical devices in the European Union (EU).

The technical file submitted to support the CE Marking covers various aspects of the design and manufacture of the device which relate to risk. One of the key elements of this file is a statement about intended use that will, normally, include details about the length of time the device is intended to be in situ. This is particularly important for IV access devices and establishes the classification of that device and, thus, the regulatory route that is followed in applying the CE mark.

In broad terms, **Short-term IV access devices** (normally intended for use for not more than 29 days) are classified as **Class IIa (medium risk)**.

Long-term IV access devices (normally intended for use for more than 29 days) are classified as **Class III (high risk)**.

Every Class III medical device technical file is reviewed by an independent expert working for a designated Notified Body and must be authorised by that Notified Body before a company can place their device on the market. This review will include assessment of the claims and of the evidence used to support those claims.

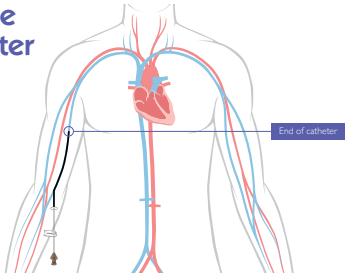
Vygon (UK) leader**flex** and smart**midline devices are Class IIa products**. They are intended for short-term use i.e. they should be used for not more than 29 days.

Vygon (UK) life**cath** midlines **are Class III products**. They are intended for short or long-term use, as clinically required. They can be left in situ for extended periods of time and dwell time can be for the full duration of the treatment, even when it exceeds 29 days.

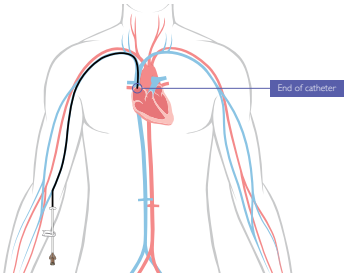
Q2: What is the difference between a midline / EDC and a Peripherally Inserted Central Catheter (PICC)?

The tip of a midline / EDC terminates before the axillary vein. Therefore, it has the same limitations as a peripheral cannula.

Midline Catheter



PICC



INS guidelines (Gorski, 2016)
Ensure appropriate midline catheter tip location:

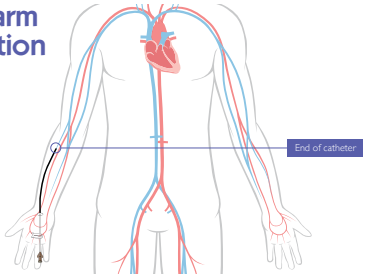
- Adults and older children: at the level of the axilla and distal to the shoulder
- Neonate / paediatric scalp vein placement: jugular vein above the clavicle
- Neonate / paediatric lower extremity vein placement (before walking age): in the leg with the tip below the inguinal crease.

The tip of a PICC terminates in the superior vena cava / top of right atrium.

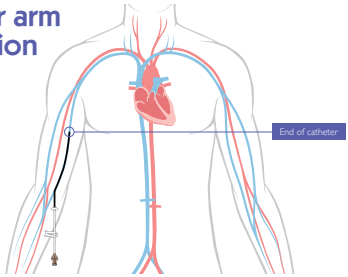
Q3: Where on the body can these devices be inserted?

They can be inserted in the veins of the forearm or in the upper arm provided the veins are of adequate length and not inserted at an area of flexion.

Forearm insertion



Upper arm insertion



Q4: What medications can I give through these devices?

As midline / EDC catheters are peripherally sited devices, they have the same indications as for peripheral cannulas.

Drug which have vesicant properties should be given with caution.

Royal College of Nursing (RCN) Guidelines

'Therapies which are not appropriate for certain peripheral cannulae and / or midlines include continuous vesicant chemotherapy, parenteral nutrition solutions and / or medications with osmolarity greater than 900 mOsm/L (INS, 2016). These aspects should not be considered in isolation and a risk assessment that includes vein assessment, duration and environment of therapy as well as pH and osmolarity is important prior to any site and device selection' (Gorski, 2016; Hallam et al., 2016).

Standards:

- Consider infusate characteristics in conjunction with anticipated duration of treatment (e.g. 1-4 weeks)
- Consider a midline catheter for medications and solutions such as antimicrobials, fluid replacement and analgesics with characteristics that are well tolerated by peripheral veins
- Do not use midline catheters for continuous vesicant therapy, parenteral nutrition, or infusates with an osmolarity greater than 900 mOsm/L
- Use caution with intermittent vesicant administration due to risk of undetected extravasation
- The administration of Vancomycin for less than six days through a midline catheter was found to be safe in one study (Caparas and Hu, 2014)
- Avoid the use of a midline catheter when the patient has a history of thrombosis, hypercoagulability, decreased venous flow to the extremities, or end-stage renal disease requiring vein preservation.

Parental Nutrition (PN) via a Midline / EDC

ESPEN (The European Society for Clinical Nutrition and Metabolism) recommends that peripheral parenteral nutrition (given through a short peripheral cannula or through a midline catheter) should be used only for a limited period of time, and only when using nutrient solutions whose osmolarity does not exceed 850 mOsm/L). Vygon (UK) fully support the most recent ESPEN guidelines and can advise that Vygon (UK) midline devices, including **leaderflex**, can be used for the infusion of peripheral parenteral nutrition (osmolarity not exceeding 850 mOsm/L).

Q5: Can I take blood from these devices?

Research Evidence

Vygon (UK) have found that blood sampling is possible through any of the midline devices, including the 2Fr. However, the success of blood aspiration is dependent on the technique. Because of the material, the device can collapse on aspiration, so a slow aspiration technique is required. The use of a vacutainer can be useful. The use of a tourniquet above the intended access site can help, as can using a smaller syringe (3ml).

Q6: Can I transfuse blood through these devices?

RCN Infusion Standards

Midline catheters are used for the administration of blood, fluid and medication (Denton, 2016). There is no minimum or maximum size of cannula for administration of blood / blood components. The cannula size used should depend on the size of the vein and the speed at which the transfusion is to be infused (BCSH, 2009).

INS Infusion Standards

Short peripheral catheters: Use 20 to 24 gauge based on vein size and patient preference. When rapid transfusion is required, a larger-size catheter gauge is recommended (14-18 gauge) (Gorski, 2016).

Vascular Clinical Expert Opinion

Because the devices are longer in length than typical peripheral cannulas and often used in patients with challenging access, they are an ideal device for blood sampling.

EDC's and midlines have been used sucessfully for blood transfusion, irrespective of the length or lumen size. Catheter clearance (push / pause turbulent flush) is important, plus bio**nector** TKO, if possible is useful to keep the device patent.

Q7: What do I do if the device becomes blocked?

Firstly, check for kinkage, which can occur at the entry site. Clamp the catheter and change the needle free device. Attempt to gently aspirate and flush with normal saline. Do not attempt to flush with force if there is resistance.

RCN Infusion Standards

The HCP should understand the predisposing factors and preventative strategies and be able to assess the catheter for suspected occlusion (INS, 2016). The HCP should assess the catheter for a potential cause of the occlusion – thrombotic, non-thrombotic or mechanical – and report / manage this in line with local policies and procedures. See guidelines by (Denton, 2016; Gorski, 2016)

Q8: Can I use urokinase / cathflo in these devices?

No research evidence exists, however urokinase has been used successfully to clear midlines and EDC's. Usually only half the amount that is used for a PICC is required for midlines.

To help prevent device occlusion, ensure adequate care and maintenance training is available and that all staff responsible for using the devices are competent in care and maintenance procedures.

Q9: Do I need to use heparin to 'lock' these devices?

Background

To maintain catheter patency, vascular access devices are routinely 'locked' between uses. Locking of a vascular access device involves injecting a fluid into the device in order to maintain device patency.

INS Standards

There is insufficient evidence to recommend the solution for locking midline catheters.

The following information refers specifically to the use of heparin with central venous catheters. Please refer to your local Hospital Trust IV Policy with regard to maintaining patency of EDC's and midline vascular access devices.

Risks Associated with Heparin Use:

- The risk of errors in the dosage of heparin prompted the labelling of heparin as a "high alert" medication (NPSA, 2008)
- Heparin administration may also lead to heparin-induced thrombocytopenia and hypersensitivity to heparin. These are severe adverse effects of heparin, even after exposure to small quantities of heparin from catheter flushing (Loveday et al., 2014)
- Moreover, an intrinsic risk of heparin is infection because heparin stimulates S. aureus biofilm formation (NPSA, 2008)
- Heparin can interfere with blood test results if present in the VAD (Toft, 2007)
- Heparin is also associated with drug incompatibilities (NPSA, 2008)
- Heparin interfering with blood test results if it is present in the VAD or cannula (Toft, 2007).

Evidence to Support the Replacement of Heparin with 0.9% Normal Saline

Cochrane Review: The meta-analysis in this review found:

- Very low quality evidence to suggest that heparin resulted in fewer central venous catheter (CVC) occlusions
- Low quality evidence found heparinised saline does not have a significant impact on duration of CVC patency
- No difference between normal saline and heparinised saline was seen for secondary outcome of sepsis (López-Briz, et al., 2018).

NICE CG 139 (Recommendation 1.4.4.6) states: "preferably, a sterile 0.9% sodium chloride injection to flush and lock catheter lumens" (NICE, 2012).

Royal College of Nursing (RCN) Infusion Standards state: "Sterile 0.9% sodium chloride should be used to flush and lock catheter lumens that are accessed frequently" (Denton, 2016).

EPIC3 guidelines state: "Use sterile normal saline for injection to flush and lock catheter lumens that are accessed frequently" (Loveday et al., 2014).

Infusion Nurses Society (INS) Standards of Practice state: "Lock CVCs with either heparin 10 units per mL or preservative-free 0.9% sodium chloride (USP), according to the directions for use for the VAD and needleless connector" (Gorski, 2016). They support this with the following statement: "Randomized controlled trials have shown equivalent outcomes with heparin and sodium chloride lock solutions for multiple-lumen non-tunnelled CVADs, peripherally inserted central catheters (PICCs), and implanted ports while accessed and when the access needle is removed" (Halm, 2008; Goh, Teo and Masagoes. 2011; Tully et al, 2011).

Benefits of Using 0.9% Saline

Using 0.9% saline in place of heparin to lock devices may result in savings in nursing time, supplies, and costs for the patient and / or the institution and / or the society.

Vygon (UK) therefore recommend that there is no role for routine use of heparinised saline lock for the purpose of locking midlines. Sodium chloride 0.9% is suitable for locking midlines. Nevertheless, there are no functional reasons why heparin cannot be used with our range of VADs. This decision will ultimately be guided by local policies and procedures. Vitally, clinicians caring for people with a VAD should remain aware of the importance of adequate flushing and locking techniques to help reduce incidences of catheter occlusion (Denton, 2016; Gorski, 2016).

Q10: Should I aspirate the device before I use it?

The HCP should aspirate midlines and central venous access devices to check blood return to confirm patency, assess catheter function and prevent complications prior to administration of medications and / or solutions (INS, 2016) (Denton, 2016).

In the absence of a blood return for midlines and central venous access devices, an attempt should be made to flush the device; if resistance is met force should not be applied. For midlines and all central venous access devices, the HCP should take further steps to assess patency of the device prior to administration of medications and / or solutions, for example diagnostic tests (INS, 2016). The relevant algorithm should be followed for checking blood return from a central venous access device.

Vascular Clinical Expert Opinion

It could be argued that EDC's do not require aspiration and blood return checking prior to use. Like short peripheral catheters, patency is confirmed if administration of fluids and medication is possible with no adverse issues such as pain, swelling, leakage etc (Gorski, 2016). Do not attempt to deliver medications if there is any resistance felt, if the patient experiences pain during administration or if there is swelling or leaking at the site when the device is in use.

Q11: Do I need to measure the arm circumference?

Vascular Clinical Expert Opinion

It can be useful to measure the circumference of the arm where the tip terminates. If measured on insertion any increase in size would be recognised and action taken to check for thrombosis. Any increase in arm (or hand) size should also be investigated.

Q12: I have a device that is leaking at the device exit site, why is this happening and what should I do?

Vascular Clinical Expert Opinion

It is thought that leakage from the device access site can be a sign of vein occlusion such as the formation of thrombosis. When fluid is injected into the device it is not able to pass this obstruction. This results in retrograde flow and subsequent leakage from the exit site of the device. Thrombosis can be due to the following:

Catheter to Vein Ratio

Evidence suggests that the catheter inserted into a vein should not take up more than one third of the lumen of the vein. If a catheter lumen is too large it can result in a reduced blood flow which is turbulent. In addition, it can result in mechanical vein irritation.

Catheter Tip Position

A midline / EDC tip should terminate at or before the level of the axilla or armpit and not at or beyond the shoulder. The reason is that the motion of the shoulder joint can cause mechanical irritation to the wall of the vein. This eventually results in device occlusion as the blood flow around the catheter reduces.

Research Evidence

Evidence for midlines is scarce, however there are some studies relating to PICCs that should be considered:

- The incidence of symptomatic upper limb venous thrombosis associated with midline catheter: Prospective observation. (Lisova et al., 2018). Conclusion: The negative consequences of ULVT may be limited using a shorter midline catheter (8 cm, mini-midline) rather than a 20cm device that terminated beyond the axillary vein.

- Evans et al., (2010) observed that increasing catheter size is associated with increased DVT risk
  - 0.4% symptomatic thrombosis rate for 4Fr PICCs
  - 8.8% symptomatic thrombosis rate for 6Fr PICCs
  - 0.6% with single-lumen catheters
  - 2.9% with double lumen and
  - 8.8% with triple lumen

A three-year, prospective, observational study, which showed that an increase in the use of single-lumen PICCs compared with use of smaller 5Fr triple-lumen PICCs was associated with significant decrease in the rate of PICC-related thrombosis (Evans et al., 2013)

In a retrospective analysis, Grove et al (2000) showed no thrombosis for PICCs <3Fr and 9.8% rate of thrombosis for 6Fr PICCs.

Q13: Can midlines be used for CT contrast / power injections?

Contrast media can be used in any CT compatible device up to the PSI limit indicted for that particular device. Our smart**midlines** have specific pressure flow rates labelled on each device and these must be adhered to. The PSI varies by device so it is important to check this prior to using any vascular access device for the delivery of drugs under pressure and to ensure an adequate vein purchase (at least half of the device situated within the vein lumen).

Device	Length (cm)	Maximum pressure	Maximum flow rate (viscosity 11.8cvP)
smart**midline** 2Fr	4	150psi	1.5mL/s
smart**midline** 2Fr	6	150psi	1.5mL/s
smart**midline** 2Fr	8	150psi	1mL/s
smart**midline** 2Fr	10	150psi	1mL/s
smart**midline** 2Fr	15	150psi	0.5mL/s
smart**midline** 2Fr	20	150psi	0.5mL/s
smart**midline** 3Fr	6	100psi	1.5mL/s
smart**midline** 3Fr	8	100psi	1.5mL/s
smart**midline** 3Fr	10	100psi	1.5mL/s
smart**midline** 3Fr	12	100psi	1mL/s
smart**midline** 3Fr	15	100psi	1mL/s
smart**midline** 3Fr	20	100psi	1mL/s
smart**midline** 4Fr	12	300psi	5mL/s
smart**midline** 4Fr	15	300psi	5mL/s
smart**midline** 4Fr	20	300psi	5mL/s
smart**midline** 4Fr	25	300psi	5mL/s

EDC / Midline maintenance:

- Consider the clinical need for the vascular access device and remove if no longer required
- Use at least a standard ANTT in all aspects of catheter management
- The device should be flushed after every use and at established intervals to promote and maintain patency and to prevent the mixing of incompatible medications and / or solutions
- Use a syringe no smaller than 10mL to flush the device
- Use a push / pause technique to achieve catheter clearance
- Ensure a positive pressure clamping sequence is used (maintain positive pressure whilst clamping, always clamp before removing syringe)
- Secure catheter with a Grip-**Lok**™ securement device and cover with a semi-permeable transparent dressing e.g. IV3000
- It is recommended that a bio**nector** TKO™ is used to prevent catheter occlusion
- Clean the bio**nector** TKO™ with chlorhexidine 2% in 70% alcohol for at least 15 seconds
- 'Scrub the Hub' and allow to fully dry before use
- Use Posiflush XS pre-filled syringe for flushing, Chloraprep for sterilisation and biopatch discs on the catheter as per local guidelines
- Change the dressing, Grip-**Lok**™ securement and bio**nector** TKO™ every seven days
  - Consider potential allergic reactions and sensitives to chlorhexidine and dressings and seek alternatives if required
- Measure arm circumference at least once per shift and more often should there be an increase. Take additional steps and investigate if there are signs of thrombosis
- Document care and maintenance in care bundle
  - Perform and record vital signs check at least once per day. Be aware of signs of infection.

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