



Midline Catheter Product

Venous Access | Critical Care

ARROW®

Table of Contents

<i>Product Description</i>	1	Procedural Pause	8
Indications / Contraindications	1	Preparing for Midline Insertion.	8
<hr/>		Prep Puncture Site.	9
<i>Midline Catheter Warnings and Precautions</i>	1	Prepare All Equipment	9
General	1	Trim Catheter	9
Catheter	2	Flush Catheter	9
Placement Wire & Guidewire / SWG	2	<hr/>	
Tissue Dilator	3	<i>Catheter Insertion Instructions</i>	9
Peel-Away Sheath over Tissue Dilator	3	Gain Initial Venous Access.	9
Possible Complications.	3	Place Sheath	10
<hr/>		Advance Catheter.	10
<i>Accessory Component Instructions</i>	3	Placement Wire Use	10
Catheter Stabilization Device	3	Verify Catheter Tip Placement	11
Catheter Trimmer.	4	Complete Catheter Insertion.	11
Dressing	4	<hr/>	
Echogenic Needle	5	<i>Documentation</i>	11
Luer-Activated Connector.	5	<hr/>	
Maximal Barrier Drape	5	<i>Care and Maintenance</i>	11
Protected Needle.	7	Dressing	11
SharpsAway II™ Locking Disposal Cup	7	Catheter Patency	11
Sharps-Protected Peel-Away Sheath over Needle	7	<hr/>	
<hr/>		<i>Catheter Removal Instructions</i>	12
<i>Pre-Midline Insertion & Patient Assessment Activities</i>	8		

For convenience, procedural and general Warnings and Precautions are listed at the beginning of the instructions. Please review all content before performing the procedure.

For reference literature concerning patient assessment, clinician education, insertion techniques and potential complications associated with this procedure refer to Arrow International, Inc. website: www.arrowintl.com



Caution



Do not reuse



Do not resterilize



Sterilized by ethylene oxide



Do not use if package is damaged



Not made with natural rubber latex



Consult instructions for use



Temperature limits - upper and lower

Arrow International, Inc.

© 2008 Arrow International, Inc. All rights reserved. Printed in the USA.

An issued or revision date for these instructions is included for user information. If two years have elapsed between this date and product use, the user should contact Arrow International, Inc. to see if additional product information is available.

Revision Date: April 2016

Rx only.

Midline Catheter Product

Product Description

The Arrow® Midline Catheter is a peripherally inserted intravenous catheter manufactured with medical grade, flexible polyurethane. The Arrow® Midline is designed with a non-tapered catheter body and softens *in-situ* to be less traumatic to the vessel. The kit components assist the clinician in maintaining maximal sterile barrier precautions (where provided).

Indications:

The Arrow® Midline Catheter permits venous access to the peripheral circulation. It offers an alternative method of intravenous access for select adult and pediatric patients.

Contraindications:

None known.

Midline Catheter

Warnings and Precautions:

General Warnings and Precautions

Warnings:

1. Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.
2. Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.
3. Practitioners must be aware of clinical conditions that may limit use of Midlines including but not limited to: dermatitis, cellulitis, and burns at or about the insertion site, previous ipsilateral venous thrombosis, radiation therapy at or about insertion site, contractures, mastectomy, and potential use for AV fistula.
4. Practitioners must be aware of the potential for entrapment of guidewire by any implanted device in circulatory system (i.e., vena cava filters, stents). Review patient's history before catheterization procedure to assess for possible implants. Care should be taken regarding length of guidewire inserted. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to reduce risk of guidewire entrapment.
5. Catheter tip must be located in central circulation when administering > 10% glucose solution, total parenteral nutrition, continuous vesicant therapy, infusates with pH less than 5 or greater than 9, and infusates with an osmolality above 600 mOsm/L, or any medication known to be irritating to vessels proximal to the vena cava.
6. Use only securely tightened Luer-Lock connections with any Venous Access Device (VAD) to guard against inadvertent disconnect.
7. Use Luer-Lock connectors to help guard against air embolism and blood loss.
8. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

Cautions:

1. Do not use if package has been previously opened or damaged.
2. Do not alter the catheter, guidewire, or any other kit/set component during insertion, use, or removal (except as instructed).
3. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.
4. Assess patient for heparin sensitivity. Heparin-Induced Thrombocytopenia (HIT) has been reported with the use of heparin flush solutions.
5. Do not use topical antibiotic ointment or creams on insertion sites (except when using dialysis catheters) because of their potential to promote fungal infections and antimicrobial resistance.
6. Verify midline catheter placement by x-ray when advancing catheter in smaller patients, or in such a manner that tip location may be advanced beyond the shoulder. Although catheters are radiopaque, on smaller gauge catheters it may be necessary to inject contrast medium to visualize the tip.
7. Seek appropriate consultation if practitioner is inexperienced in utilizing this product in a child. Indications for use in children are the same as adults; however, insertion techniques are often modified according to the growth and development of a child.
8. Do not rely on blood aspirate color to indicate venous access.
9. Do not reinsert needle into introducer catheter to reduce risk of catheter embolism.
10. Maintain insertion site with regular meticulous redressing using aseptic technique.

11. Engage safety and/or locking feature of scalpel (where provided) when not in use to reduce risk of sharps injury.
12. Perform hand hygiene:
 - before and immediately after all clinical procedures
 - before donning and after removal of gloves
13. Properly handle and dispose of sharps in sharps container in accordance with US OSHA or other governmental standards for blood borne pathogens and/or hospital/institutional policy.
14. Keep hands behind needle at all times during use and disposal.
15. Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to Human Immunodeficiency Virus (HIV) or other blood borne pathogens.
9. Do not clamp extension line(s) when placement wire is in catheter to reduce risk of placement wire kinking.
10. Practitioners should remove slide clamp(s), where provided, when not in use. Slide clamp(s) may be inadvertently removed and aspirated by children or confused adults.

Cautions:

1. 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.
 - Acetone: Do not use acetone on catheter surface.
 - Alcohol: Do not use alcohol to soak catheter surface or to restore catheter patency.

Take care when instilling drugs containing high concentration of alcohol. Allow insertion site to dry completely prior to applying dressing.

2. Ensure catheter patency prior to injection. Do not expose midline catheter to pressures above 50 psi to reduce risk of pressure induced damage to catheter. Common sources of potentially high pressure include:
 - syringes smaller than 10 mL (a fluid filled 1 mL syringe can exceed 300 psi)
 - certain radiographic procedures
 - infusion pumps with occlusion pressure limits above 50 psi
3. Remove catheter clamp and fastener (where provided) prior to attempting a catheter exchange procedure.
4. Continuously monitor indwelling catheter for:
 - desired flow rate
 - security of dressing
 - adherence of stabilization device to skin and connection to catheter
 - correct catheter position; use centimeter markings to identify if catheter position has changed
 - secure Luer-Lock connection(s)

Catheter Warnings and Precautions

Warnings:

1. Only utilize catheters indicated for high pressure injection applications for such applications. Utilizing catheters not indicated for high pressure applications can result in inter-lumen crossover or rupture with potential for injury.
2. Do not apply excessive force in placing or removing catheter. Excessive force can cause catheter breakage. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.
3. Do not secure, staple, and/or suture directly to outside diameter of catheter body or extension lines to reduce risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.
4. Do not cut catheter to alter catheter length unless procedure requires it.
5. Do not attach catheter clamp and fastener (where provided) until either guidewire or placement wire is removed.
6. Do not use scissors to remove dressing to reduce risk of cutting catheter.
7. Open catheter clamp prior to infusion through lumen to reduce risk of damage to extension line from excessive pressure.
8. Do not attempt to advance or reinsert placement wire (where provided) into catheter through the septum, if placement wire has been removed prior to catheter insertion. Attempting placement wire advancement or reinsertion increases risk of damaging catheter or wire.

Placement Wire & Guidewire / SWG Warnings and Precautions

Warnings:

1. Do not cut guidewire to alter length.
2. Do not withdraw guidewire against needle bevel to reduce risk of possible severing or damaging of guidewire.
3. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation and bleeding.

4. Do not apply undue force on guidewire to reduce risk of possible breakage.
5. Do not apply excessive force in removing guidewire or catheter. If withdrawal cannot be easily accomplished, a visual image should be obtained and further consultation requested.
6. Do not cut guidewire with scalpel.
 - Position cutting edge of scalpel away from guidewire.
 - Engage safety and/or locking feature of scalpel (where provided) once cutaneous puncture site is enlarged, to reduce risk of cutting the guidewire (refer to Figure 19).
7. Do not attempt to advance placement wire through septum.
8. Do not cut placement wire when trimming catheter to reduce risk of foreign embolism.
9. Remove placement wire and Luer-Lock sidearm assembly as a unit (refer to Figure 20). Failure to do so may result in wire breakage.

Cautions:

1. Maintain a firm grip on guidewire at all times. Keep sufficient guidewire length exposed at hub for handling purposes. A non-controlled guidewire can lead to wire embolism.
2. Check that there is no wire in cut catheter segment, after trimming catheter. If there is any evidence that placement wire has been cut or damaged, catheter should not be used.

Tissue Dilator Warnings

Warnings:

1. Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.
2. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation and bleeding.

Peel-Away Sheath over Tissue Dilator Precaution

Caution:

1. Do not withdraw tissue dilator until the sheath is well within the vessel to reduce risk of damage to sheath tip. Sufficient guidewire length must remain exposed at hub end of sheath to maintain a firm grip on guidewire.

Possible Complications (but not limited to):

- ♦ air embolism
- ♦ catheter embolism
- ♦ bleeding / hemorrhage
- ♦ bacteremia
- ♦ thrombosis
- ♦ hematoma
- ♦ vessel erosion
- ♦ exit site infection
- ♦ nerve injury
- ♦ catheter tip malposition
- ♦ occlusion
- ♦ septicemia
- ♦ inadvertent arterial puncture
- ♦ fibrin sheath formation
- ♦ phlebitis

Accessory Component Instructions

Review the list of components that will be utilized before beginning the Arrow® Midline Catheter insertion procedure. Kits / Sets may not contain all accessory components detailed in this section. Become familiar with instructions for individual component(s) before beginning the actual procedure.

Catheter Stabilization Device:

A catheter stabilization device should be used in accordance with manufacturer's instructions for use.

⚠ Caution: Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.

- Cleanse and prep anticipated dressing site per hospital/institutional protocol.
- Apply skin prep (where provided) to coat skin and maximize adherence.
- Allow to dry thoroughly.
- Position catheter stabilization device appropriate distance from catheter insertion site to permit ease of insertion site care and maintenance.
- Secure catheter to the catheter stabilization device.
- Remove paper backing from catheter stabilization device pad and press onto dry, prepared skin.
- Complete sterile insertion site dressing according to established hospital/institutional protocol.
- Document dressing application on patient's chart.
- Replace dressing per hospital/institutional protocol. Catheter stabilization device should be replaced at least every 7 days to ensure maximum adherence.

Refer to individual manufacturer's instructions for more information and specific detailed instructions.

Catheter Trimmer:

A catheter trimmer is a one time use trimming device.

Warning: Do not attempt to advance placement wire through septum.

Warning: Do not cut placement wire when trimming catheter to reduce risk of foreign embolism.

Caution: Check that there is no wire in cut catheter segment, after trimming catheter. If there is any evidence that placement wire has been cut or damaged, catheter should not be used.

NOTE: There should be very limited resistance when cutting catheter with supplied trimmer. Any greater resistance is likely to be caused by the placement wire – which has not been sufficiently retracted. If so, do not use catheter.

- Retract placement wire 1-1/2 inches minimum (4 cm) behind where catheter is to be cut. The placement wire is to be withdrawn through septum (refer to Figure 1).

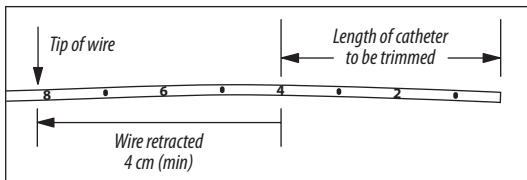


Figure 1

- Kink proximal end of placement wire at connector with side-port (refer to Figure 2) to reduce risk of placement wire extending beyond distal tip of catheter during insertion.

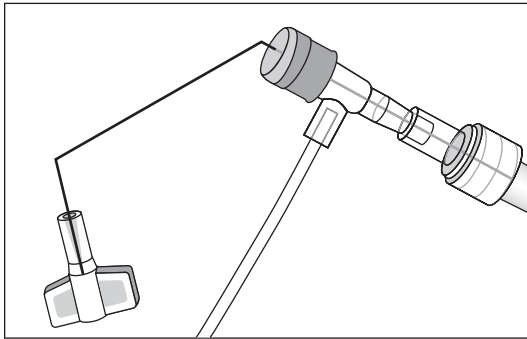


Figure 2

- Peel back contamination guard exposing catheter portion to be trimmed. Using trimming device, cut catheter straight across (90° to catheter cross-section) to maintain a blunt tip.

Dressing:

A transparent dressing should be used in accordance with manufacturer's instructions for use.

- Prepare site. Allow all preps to dry completely.
- Peel liner from dressing to expose adhesive.
- Adhere center of transparent window over insertion site, while holding notched portion off the skin (refer to Figure 3).

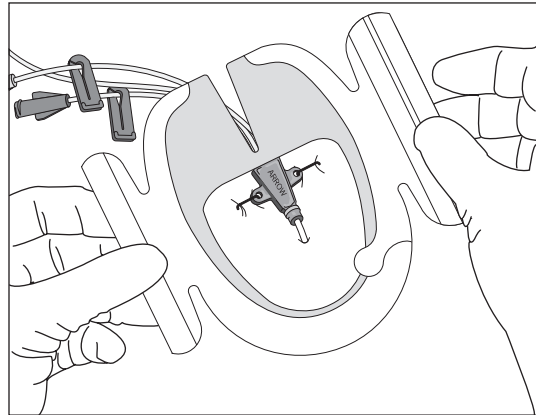


Figure 3

- Overlap softcloth tabs under catheter to form a tight seal around catheter hub and extension line(s) (refer to Figure 4).

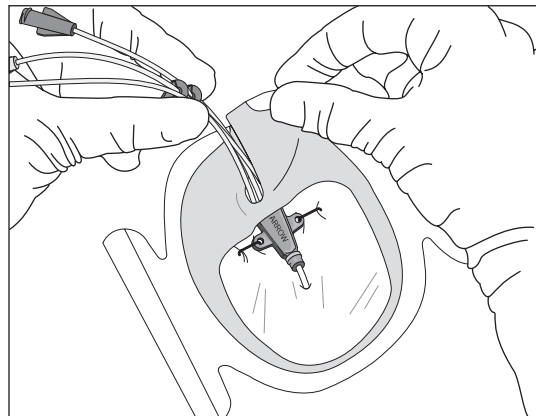


Figure 4

- Press dressing into place.
- Slowly remove frame while smoothing down dressing edges. Smooth dressing from center toward edges, use firm pressure to enhance adhesion (refer to Figure 5).

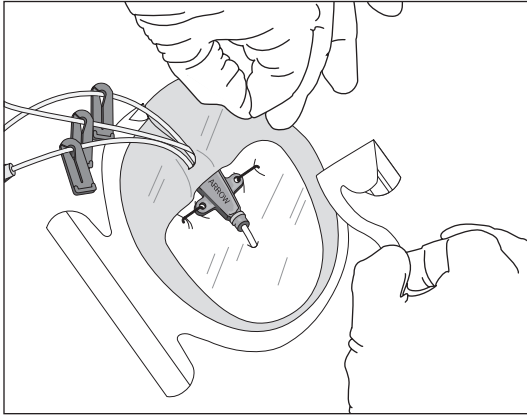


Figure 5

- Use sterile tape strips to secure hub, extension line(s), and/or tubing (refer to Figure 6).

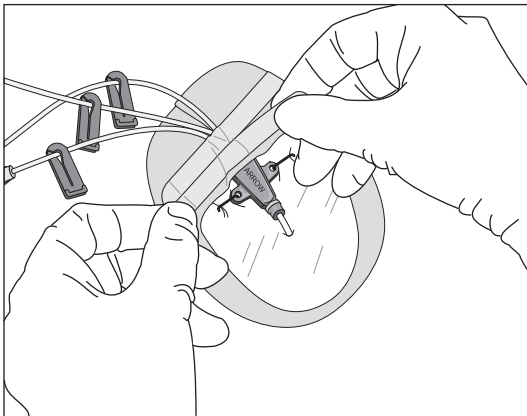


Figure 6

- Label dressing according to protocol.

Refer to individual manufacturer's instructions for more information and specific detailed instructions for dressing removal (not included).

Echogenic Needle:

An echogenic needle is used to provide greater needle visibility under ultrasound. The needle tip is enhanced for approximately 1 cm for clinician to identify exact needle tip location when puncturing the vessel under ultrasound.

Luer-Activated Connector:

A luer-activated connector is used to reduce risk of accidental disconnects and potential for air embolism.

- ⚠ **Caution:** Do not use needles in connector unless specifically indicated.
- ⚠ **Caution:** Do not cap connector unless specifically indicated.
- ⚠ **Caution:** Check for clamping requirement to prevent fluid movement prior to connector disconnect and use.

General Guidelines for Connector Use:

Use aseptic technique.

- Remove connector from packaging.
- Inspect for integrity.
- If applicable:
 - prime in accordance with hospital/institutional protocol
 - expel air
- Disinfect desired extension set or venous access device; make sure to rotate swab to ensure cleaning of threads.
- Attach connector to desired extension set or venous access device.
- Secure connector. If using a rotating luer connector, make sure that the spin collar is tightened.
- Position connector to achieve the most comfortable position on the patient's skin.
- Access: Swab connector with desired disinfectant in accordance with hospital/institutional and connector manufacturer protocol.
- Utilize only fully primed syringe or administration set.
- Disconnect from venous access device or administration set, grasp connector/cap and twist until loose.
- Flush after each use with normal saline or in accordance with hospital/institutional protocol.
- Repeat above steps for subsequent connections.

Refer to individual manufacturer's instructions for specific connector details, including priming volumes, dead space, and flow rates.

Maximal Barrier Drape:

Drape(s) provide a maximal sterile barrier. Follow CDC Category 1A Recommendation.

- Drape provided is either:
 - single extra-large drape with fenestration
 - two-piece drape consisting of an arm drape with fenestration and a body drape (body drape is used to appropriately drape torso and upper-lower extremities)
- Unfold the Maximal Barrier Drape:
 - Peel off fenestration backing (refer to Figure 7).

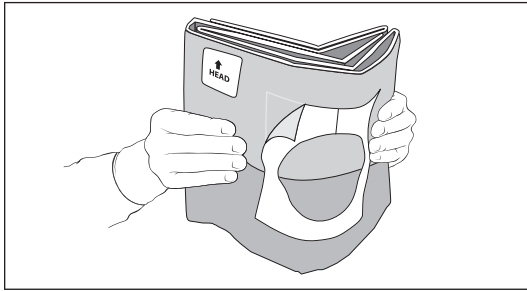


Figure 7

- Position fenestration over intended insertion site (refer to Figure 8).

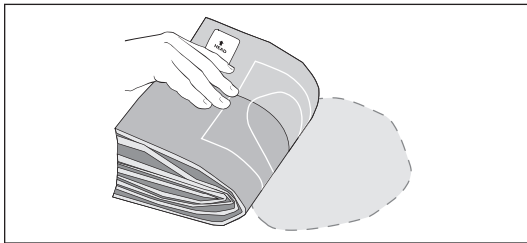


Figure 8

- Unfold width (refer to Figure 9).

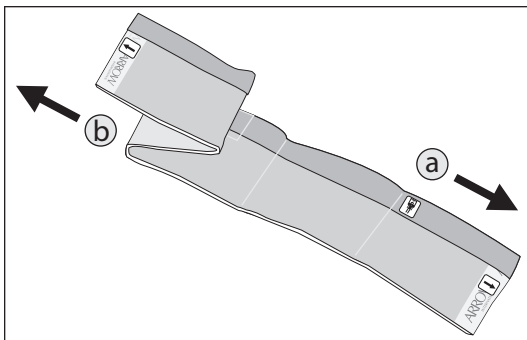


Figure 9

- Unfold towards head (refer to Figure 10).

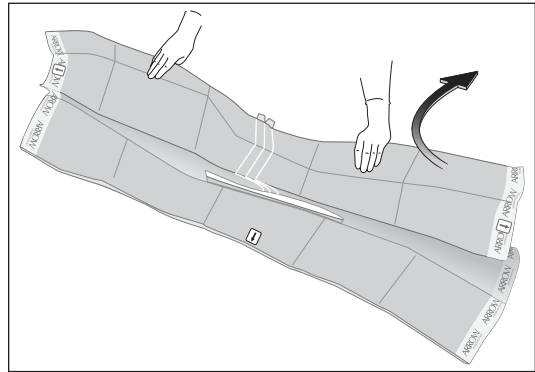


Figure 10

- Unfold towards hand (refer to Figure 11).

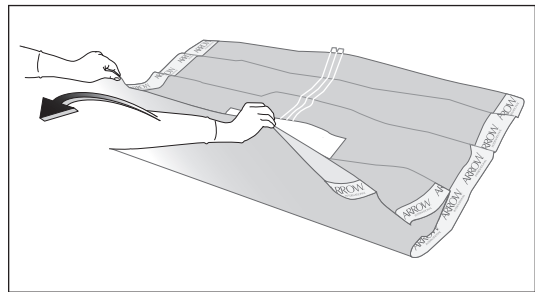


Figure 11

- Perform sterile procedure.
- Tear along seam to remove drape (refer to Figure 12).

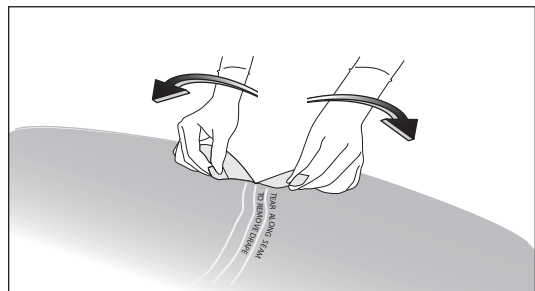


Figure 12

Protected Needle:

A protected needle should be used in accordance with manufacturer's instructions for use.

- ⚠ Warning:** Keep hands behind needle at all times during use and disposal.
- ⚠ Caution:** Use all needles in accordance with OSHA and hospital/institutional safety protocols.
- ⚠ Caution:** Do not attempt to override or defeat the safety locking mechanism of a protected needle.
- ⚠ Caution:** Discard in an approved sharps collector in accordance with applicable regulations and hospital/institutional policy.

General Guidelines for Protected Needle Use:

- Aspirate medication into syringe using aseptic technique.
- If necessary to transport filled syringe to point of administration, use safe, passive recapping technique to cover needle before transport to point of use. In accordance with OSHA standards, such recapping must be accomplished by a one-handed technique, i.e., do not hold needle shield during recapping process.
- Administer injection following established technique.
- Immediately activate needle protection device upon withdrawal from patient. For greatest safety, use a one-handed technique and activate away from self and others (see Figure 13).

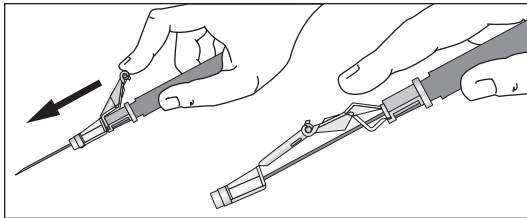


Figure 13

- Visually confirm needle tip is completely covered. If unable to activate, discard immediately into approved sharps collector.
- Activation of protective mechanism may cause minimal splatter of fluid that may remain on needle after injection.
- Discard after single use.

SharpsAway II™ Locking Disposal Cup:

The SharpsAway II™ Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

- ⚠ Caution:** Do not attempt to remove needles that have been placed into SharpsAway II™ Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.
- ⚠ Caution:** Do not re-use needles after they have been placed into the foam SharpsAway® system. Particulate matter may adhere to needle tip.

- Using one-handed technique, firmly push needles into disposal cup holes (refer to Figure 14).

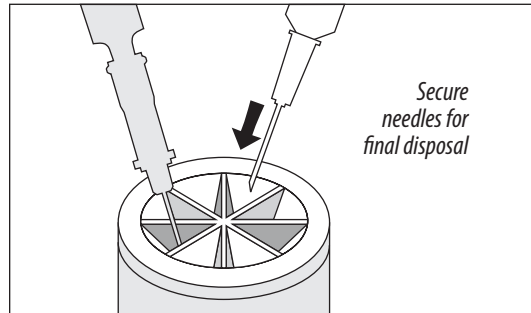


Figure 14

- Once placed into disposal cup, needles will be automatically secured in place so that they cannot be reused.
- Discard entire cup, at completion of procedure, into an approved sharps container.
- Where provided, a foam SharpsAway® system may be utilized by pushing needles into foam after use.

Sharps-Protected Peel-Away Sheath over Needle:

- ⚠ Warning:** Keep hands behind needle at all times during use and disposal.
- ⚠ Warning:** Never reinsert needle into sheath, to reduce risk of possible sheath embolism.
- ⚠ Caution:** Listen for audible click and resulting tactile sensation to confirm needle protection mechanism is activated. Visual inspection can confirm needle tip is enclosed in the translucent plastic cap.

For Direct Puncture Technique:

- One-handed technique:
 - Advance sharps-protected peel-away sheath over needle introducer into vein to a desired length by using index finger on push-off tab to stabilize needle protector while pulling back on needle hub until needle protector activates over needle bevel (refer to Figure 15).

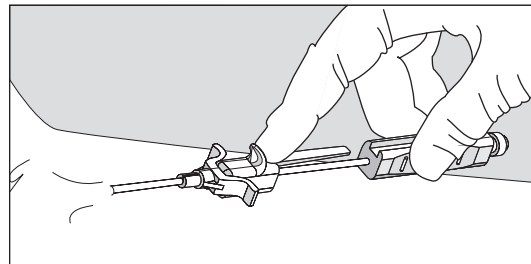


Figure 15

- Two-handed technique:
 - Firmly hold needle hub with one hand while using other hand on push-off tab to advance introducer sheath to a desired length. Use index finger or thumb on push-off tab to stabilize needle protector. Then pull back needle hub until needle protector activates over needle bevel (refer to Figure 16).

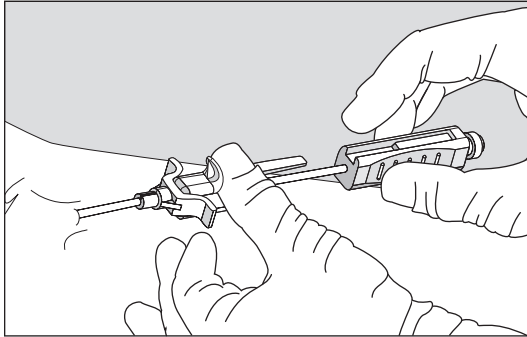


Figure 16

Pre-Midline Insertion & Patient Assessment Activities

A Suggested Procedure:

Warning: Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.

Clinical assessment of patient must be completed to ensure no contraindications exist e.g. allergies. This device is not recommended for use in the presence of device related infections or previous/current thrombosis.

Caution: Perform hand hygiene:

- before and immediately after all clinical procedures
- before donning and after removal of gloves

A procedural checklist is included in many Arrow® products. Check individual product labeling to see if one is included.

Procedural Pause:

- Verify physician order:
 - Confirm correct patient.
 - Confirm correct diagnosis.
 - Confirm correct procedure.

Physician order must include post placement assessment of catheter tip placement (direct visualization technique or other method in compliance with hospital/institutional protocol).
- Educate patient: Explain procedure to patient. Make sure information is presented with respect to patient's level of understanding, culture, and language.

- Have informed consent signed, if required.
- Identify insertion vein:
 - Apply tourniquet above anticipated insertion vein.
 - Identify appropriate vein for insertion. Use direct visualization technologies, e.g. ultrasound or fluoroscopy, if available; and assess vein health.

NOTE: Midlines are typically inserted into basilic, brachial, or cephalic veins (refer to Figure 17).

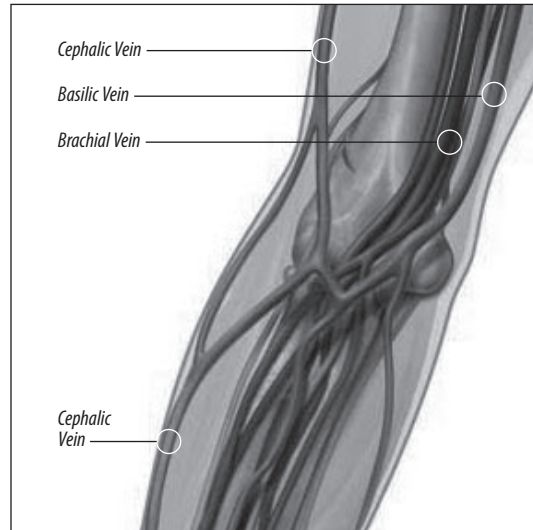


Figure 17

- Pediatric: The most suitable vein depends on size and maturity of child.
- Release tourniquet and leave in place beneath the arm.
 - Position patient as appropriate for insertion site:
 - Extend arm laterally 45 to 90 degrees from trunk.
 - Prepare work area.

Preparing for Midline Insertion:

- Clinicians should use sterile technique, maximal sterile barrier precautions throughout the procedure, and dress in protective clothing:
 - mask
 - sterile gown
 - hair cover
 - eye protection
 - sterile gloves

Caution: Perform hand hygiene:

- before and immediately after all clinical procedures
- before donning and after removal of gloves

⚠ Caution: Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to Human Immunodeficiency Virus (HIV) or other blood borne pathogens.

⚠ Caution: Properly handle and dispose of sharps in sharps container in accordance with US OSHA or other governmental standards for blood borne pathogens and/or hospital/institutional policy.

Prep Puncture Site:

1. Prep puncture site with appropriate antiseptic/agent.
2. Drape puncture site.

See unfolding instructions for Maximal Barrier Drape (where provided) under Accessory Component Instructions section.

3. Perform skin wheal using desired needle and local anesthetic.
4. Dispose of needle.
 - In kits where provided, the SharpsAway II™ Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

See SharpsAway II™ Locking Disposal Cup under Accessory Component Instructions section.

⚠ Caution: Do not attempt to remove needles that have been placed into SharpsAway II™ Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.

⚠ Caution: Do not re-use needles after they have been placed into the foam SharpsAway® system. Particulate matter may adhere to needle tip.

Prepare All Equipment:

Prepare Catheter with Placement Wire for Insertion, where provided (refer to Figure 18).

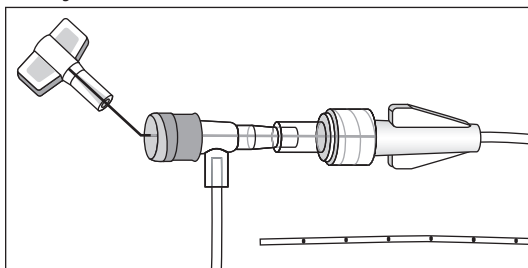


Figure 18

- Add desired luer-activated connector.
- Remove catheter tip protector.

Trim Catheter:

If necessary, review detailed instructions for Catheter Trimmer device under Accessory Component Instructions section.

1. Peel back contamination guard exposing catheter portion to be trimmed.

2. Using the trimming device, cut catheter straight across (90° to catheter cross-section) to maintain a blunt tip.

NOTE: There should be very limited resistance when cutting catheter with supplied trimming device. If using a catheter with a placement wire, any greater resistance is likely to be caused by the placement wire which has not been sufficiently retracted. If so, do not use catheter.

3. Inspect cut surface for clean cut and no loose material.

⚠ Warning: Do not cut placement wire when trimming catheter to reduce risk of foreign embolism.

⚠ Caution: Check that there is no wire in cut catheter segment, after trimming catheter. If there is any evidence that placement wire has been cut or damaged, catheter should not be used.

Flush Catheter:

1. Attach syringe to sidearm and flush distal lumen with sterile saline solution. Leave syringe in place.
2. Flush remaining lumen(s) with sterile saline solution, to establish patency and prime lumen(s).
3. Clamp or attach luer-activated connector(s) to extension line(s) to contain saline within lumen(s).

Catheter Insertion Instructions

1. Reapply tourniquet and replace sterile gloves.
2. Locate vein for insertion:
 - Use image guidance, if available.
 An echogenic needle is included for access.
3. Insert introducer needle into vein.
4. Check for pulsatile flow.

⚠ Warning: Pulsatile flow is usually an indicator of inadvertent arterial puncture.

⚠ Caution: Do not rely on blood aspirate color to indicate venous access.

Gain Initial Venous Access:

See Sharps-Protected Peel-Away Sheath over Needle for Direct Puncture Technique under Accessory Component Instructions section.

1. Insert soft tip of guidewire through introducer needle into vein. Advance guidewire to desired depth.

⚠ Warning: Do not cut guidewire to alter length.

⚠ Warning: Do not withdraw guidewire against needle bevel to reduce risk of possible severing or damaging of guidewire.

2. Remove needle:
 - Hold guidewire in place while removing introducer needle.

⚠️ Caution: Maintain firm grip on guidewire at all times. Keep sufficient guidewire length exposed at hub for handling purposes. A non-controlled guidewire can lead to wire embolism.

3. Enlarge cutaneous puncture site with cutting edge of scalpel, if necessary, positioned away from guidewire.

⚠️ Warning: Do not cut guidewire to alter length.

⚠️ Warning: Do not cut guidewire with scalpel.

- Position cutting edge of scalpel away from guidewire.
- Engage safety and/or locking feature of scalpel (where provided) once cutaneous puncture site is enlarged, to reduce risk of cutting the guidewire (refer to Figure 19).

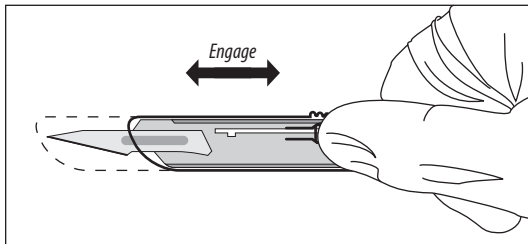


Figure 19

Place Sheath:

1. Thread tapered tip of peel-away sheath/dilator assembly over guidewire. Grasping near skin 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 sheath can help advancement.

⚠️ Caution: Do not withdraw tissue dilator until the sheath is well within the vessel to reduce risk of damage to sheath tip. Sufficient guidewire length must remain exposed at hub end of sheath to maintain a firm grip on guidewire.

2. Check sheath placement by holding sheath in place, withdraw guidewire and dilator sufficiently to allow venous blood flow. Holding sheath in place, remove guidewire and dilator as a unit.

⚠️ Warning: Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.

⚠️ Warning: Do not apply undue force on guidewire to reduce risk of possible breakage.

Advance Catheter:

⚠️ Warning: Do not apply excessive force in placing or removing catheter. Excessive force can cause catheter breakage. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.

1. Remove catheter tip protector.
2. Insert catheter through peel-away sheath.
 - Retract and/or gently flush while advancing catheter if resistance is met.
 - Contamination guard will peel away as catheter is advanced through peel-away sheath.
3. Stop advancing catheter 5 inches (13 cm) before reaching pre-established insertion length.
4. Withdraw peel-away sheath over catheter until free from venipuncture site.
5. Grasp tabs of peel-away sheath and pull apart, away from catheter, until sheath splits down entire length.
6. Advance catheter to final indwelling position.

Placement Wire Use (where provided):

⚠️ Caution: Do not clamp extension line(s) when placement wire is in catheter to reduce risk of placement wire kinking.

1. Complete catheter insertion.
2. Remove placement wire.

⚠️ Warning: Remove placement wire and Luer-Lock sidearm assembly as a unit (refer to Figure 20). Failure to do so may result in wire breakage.

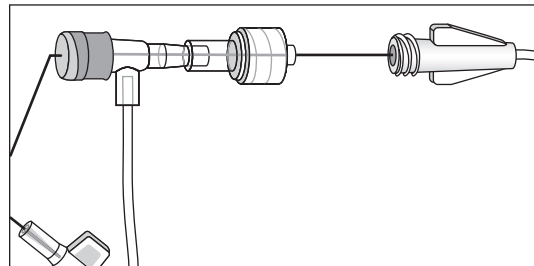


Figure 20

⚠️ Warning: Do not attach catheter clamp and fastener (where provided) until either guidewire or placement wire is removed.

3. Examine tip of placement wire after removal to ensure wire has not been altered (refer to Figure 21).

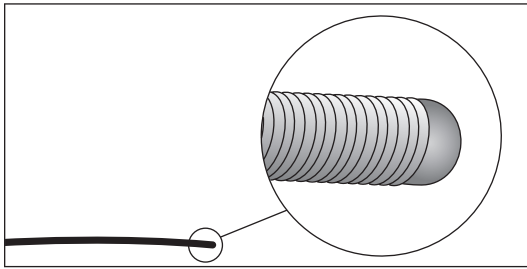


Figure 21

Verify Catheter Tip Placement:

- Check catheter placement with syringe by aspirating through distal lumen until free flow of venous blood is observed.

⚠️ Caution: Do not rely on blood aspirate color to indicate venous access.

Complete Catheter Insertion:

1. Flush lumen(s) to completely clear blood from catheter.
2. Connect all extension line(s) to appropriate Luer-Lock line(s) as required. Unused port(s) may be “locked” through luer-activated connector(s) using standard hospital/institutional protocol.
 - Slide clamps are provided on extension lines to occlude flow through each lumen during line and luer-activated connector changes.

⚠️ Warning: Practitioners should remove slide clamp(s), where provided, when not in use. Slide clamp(s) may be inadvertently removed and aspirated by children or confused adults.

3. Cleanse insertion site per hospital/institutional protocol.
4. Ensure insertion site is dry before applying dressing. Apply skin protectant as needed.

⚠️ Caution: Do not use topical antibiotic ointment or creams on insertion sites (except when using dialysis catheters) because of their potential to promote fungal infections and antimicrobial resistance.

5. Secure catheter: Use a catheter clamp, fastener, catheter stabilization device or sterile tape strips where provided.

Documentation

Hospitals/institutions must establish a permanent medical record that documents the entire procedure, based upon their policy, procedures, and Best Practices. The actual format can differ from institution to institution. Report any product defects/failures to organization risk management, manufacturers, and appropriate regulatory agencies.

Documentation generally includes (but is not limited to) the following information:

1. Device specifics:
 - type, brand and lot number
 - length and size of Venous Access Device (VAD)
 - internal/external catheter length
 - trimmed catheter or not
2. Procedure specifics:
 - time out or procedural pause
 - informed consent, as required
 - date, time of insertion, insertion site, number and site attempts, inserter’s identification
 - use of visualization and guidance technologies
 - site preparation and technique
3. Patient assessment and response:
 - pertinent dx, assessment, vital signs
 - understanding of procedure, patient’s response to procedure
 - complications and barriers to care
4. Therapy specifics:
 - type of therapy, drug dose, rate, time
 - route and method of administration
 - laboratory specimen collected

Monitor patient for post catheter insertion complications.

Care and Maintenance

Dressing:

Replace dressing according to hospital/institutional policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised e.g. dressing becomes damp, soiled, loosened, or no longer occlusive.

⚠️ Caution: Maintain insertion site with regular meticulous redressing using aseptic technique.

Catheter Patency:

Maintain catheter patency according to hospital/institutional policies, procedures, and practice guidelines. All personnel who care for patients with catheters must be knowledgeable about effective management to prolong catheter’s dwell time and prevent injury.

⚠️ Caution: Perform hand hygiene:

- before and immediately after all clinical procedures
- before donning and after removal of gloves

- Solution and frequency of flushing a venous access catheter should be established in hospital/institutional policy.

- Establish and maintain catheter patency by:
 - flushing intermittently via syringe with heparinized saline or preservative-free 0.9% sodium chloride
 - continuous drip
 - positive pressure device
- Amount of heparin depends on:
 - physician preference,
 - hospital/institutional protocol,
 - patient condition

⚠ Caution: Assess patient for heparin sensitivity. Heparin-Induced Thrombocytopenia (HIT) has been reported with use of heparin flush solutions.

- Volume of flush solution should be:
 - equal to at least twice the priming volume of the catheter and any add-on devices

NOTE: Catheter priming volume is printed on product packaging.

- Properly flush (heparinization) using a positive-pressure flushing technique to help prevent occlusion, when using any VAD for intermittent infusion therapy.

NOTE: Neutral as well as positive displacement valve systems have also been shown to help prevent occlusion.

- Properly cleanse all valves with an appropriate antiseptic before being accessed.
- The SASH or SAS method of flushing will help eliminate occlusions due to incompatible solutions:
 - Saline • Administer drug • Saline • Heparin (if used)

Catheter Removal Instructions

1. Perform catheter removal:
 - following order of authorized prescriber
 - in accordance with hospital/institutional policies, procedures, and practice guidelines
2. Remove catheter immediately upon patient assessment for:
 - suspected contamination i.e. when catheters are inserted during a medical emergency or if adherence to aseptic technique cannot be ensured

- unresolved complication(s)
- discontinuation of therapy
- source of infection

3. Remove dressing.

⚠ Warning: Do not use scissors to remove dressing, to reduce risk of cutting catheter.

4. Open catheter stabilization device retainer wings and remove catheter from catheter stabilization device posts.

5. Remove catheter by slowly pulling it parallel to skin. If resistance is met when removing, catheter should not be forcibly removed and physician should be notified.

⚠ Caution: Do not exert excessive force while removing catheter; to reduce risk of catheter breakage.

6. Upon removal of catheter:

- measure and inspect
- ensure entire catheter length has been removed

7. Apply direct pressure to site until hemostasis is achieved.

8. Apply alcohol swab to catheter stabilization device adhesive and gently lift pad off of skin (if applicable).

9. Dress insertion site. Apply sterile air occlusive dressing and assess site every 24 hours until site is epithelialized.

10. Document catheter removal procedure on patient's chart per hospital/institutional protocol.

Include:

- catheter condition
- length of catheter removed/presence of intact catheter tip
- patient's tolerance of the procedure
- any interventions needed for removal

For reference literature concerning patient assessment, clinician education, insertion techniques and potential complications associated with this procedure refer to Arrow International, Inc. website: www.arrowintl.com

2400 Bernville Road, Reading, PA 19605 USA

| 1-800-523-8446

1-610-378-0131

| www.arrowintl.com

A-02041-100C (4/16)

ARROW[®]
INTERNATIONAL