

Pressure Injectable CVC Product

Venous Access | Critical Care

ARROW®

Arrow International, Inc.

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An issued or revision date for these instructions is included for user information. In the event 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.

Issued Date: September 2009

Rx only.

Table of Contents

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

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Pressure Injectable Central Venous Catheter (CVC) Product

Product Description

The Arrow® Pressure Injectable CVC is a central venous catheter manufactured with medical grade, flexible polyurethane. A Pressure Injectable CVC may vary from two to four noncommunicating lumens. The catheter has a soft Blue FlexTip® that is more pliable than the catheter body. Lumens are connected to separate color-coded extension lines which have hubs on the end that are standard Luer-Lock. Centimeter markings referenced from the tip are placed along length of indwelling catheter body to facilitate proper positioning. The kit components assist the clinician in maintaining maximal sterile barrier precautions (where provided).

Indications:

The Arrow® CVC is indicated to provide short-term (< 30 days) central venous access for treatment of diseases or conditions requiring central venous access including, but not limited to:

- multiple infusions of fluids, medications, or chemotherapy
- infusion of fluids that are hypertonic, hyperosmolar, or have divergent pH values
- frequent blood sampling or blood/blood component infusions
- infusion of incompatible medications
- central venous pressure monitoring
- lack of usable peripheral IV sites
- replacement of multiple peripheral sites for IV access
- injection of contrast media
 - When used for pressure injection of contrast media, do not exceed the maximum indicated flow rate for each catheter lumen. The maximum pressure of power injector equipment used with pressure injectable CVC may not exceed 400 PSI.

Contraindications:

None known. See additional labeling for product specific contraindications.

Central Venous Catheter

Warnings and Precautions:

Do not place the catheter into or allow it to remain in the right atrium or right ventricle (refer to Figure 1).



Figure 1

General Warnings and Precautions

Warnings:

1. Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.
2. Practitioners must be aware of complications associated with central vein catheters including but not limited to: cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, catheter occlusion, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma, hemorrhage, and dysrhythmias.
3. Do not place Central Venous Catheter (CVC) or Peripherally Inserted Central Catheter (PICC) into or allow them to remain in the right atrium or right ventricle. X-ray exam or other method in compliance with hospital/institutional protocol must show catheter tip located in right side of mediastinum in the Superior Vena Cava (SVC) above its junction with right atrium and parallel to vessel wall and its distal tip positioned at a level above either azygos vein or carina of the trachea, whichever is better visualized. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it. Improper advancement of guidewire into the heart has also been implicated in causing cardiac perforation and tamponade. For femoral vein approach, catheter should be advanced into vessel so catheter tip lies parallel to vessel wall and does not enter right atrium.

4. Ensure catheter tip has not entered the heart or no longer lies parallel to vessel wall by performing an x-ray exam or other method in compliance with hospital/institutional protocol. If catheter position has changed, immediately re-evaluate.
5. 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 minimize the risk of guidewire entrapment.
6. Choose appropriate sized catheter for size of vessel to be cannulated.
7. 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.
8. Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. Air embolism can occur with these practices.
9. Use only securely tightened Luer-Lock connections with any Central Venous Access Device (CVAD) to guard against inadvertent disconnect.
10. Use Luer-Lock connectors to help guard against air embolism and blood loss.
11. Pulsatile flow is usually an indicator of inadvertent arterial puncture.
8. Temporarily shut off remaining port(s) through which solutions are being infused before blood sampling.
9. Blood aspirate color is not always a reliable indicator of venous access.
10. Do not reinsert needle into introducer catheter to reduce risk of catheter embolism.
11. Maintain insertion site with regular meticulous redressing using aseptic technique.
12. Activate safety feature of safety scalpel (if provided) when not in use to minimize the risk of sharps injury.
13. Perform hand hygiene before and immediately after all clinical procedures and before and after donning and removal of gloves.
14. 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.
15. Hands must remain behind the needle at all times during use and disposal.
16. Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens.

Cautions:

1. The product is designed for single use only.
2. Do not resterilize or reuse.
3. Do not use if package has been previously opened or damaged.
4. Do not alter the catheter, guidewire, or any other kit/set component during insertion, use, or removal (except as instructed).
5. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.
6. Assess patient for heparin sensitivity. Heparin-Induced Thrombocytopenia (HIT) has been reported with use of heparin flush solutions.
7. Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site of central venous catheters because of the potential risk to promote fungal infections and antimicrobial resistance.

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 minimize the 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.
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 minimize the risk of cutting catheter.

7. Open catheter clamp prior to infusion through lumen to minimize the risk of damage to extension line from excessive pressure.
8. 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.
9. Do not routinely replace central venous catheters solely for the purpose of reducing incidence of infection.
10. Do not use guidewire techniques to replace catheters in patient suspected of having catheter-related infection.
11. Residual catheter track remains an air entry point until completely sealed, occlusive dressing should remain in place for at least 24 - 72 hours dependent upon amount of time catheter was indwelling.

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 use syringes smaller than 10 mL (a fluid filled 1 mL syringe can exceed 300 psi), to minimize the risk of intraluminal leakage or catheter rupture.
3. Remove catheter clamp and fastener (where provided) prior to attempting a catheter exchange procedure.
4. Do not exert excessive force while removing the catheter, to minimize the risk of catheter breakage.
5. 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)
6. Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.

7. Inject a small amount of radiopaque dye to locate catheter tip if difficulty is encountered in visualizing the catheter tip.

Guidewire / SWG Warnings and Precautions

Warnings:

1. Do not cut guidewire to alter length.
2. Do not withdraw guidewire against needle bevel to minimize the 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. Passage of guidewire into the right heart can cause dysrhythmias, right bundle branch block, and a perforation of vessel, atrial, or ventricular wall.
5. Do not apply undue force on guidewire to minimize the risk of possible breakage.
6. 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.
7. Do not cut guidewire with scalpel.
 - Position cutting edge of scalpel away from guidewire.
 - Activate safety feature of safety scalpel (where provided) once cutaneous puncture site is enlarged, to minimize the risk of cutting the guidewire (refer to Figure 28).
8. Do not aspirate with guidewire in place or air will enter syringe.

Caution:

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. If resistance is encountered when attempting to remove guidewire after catheter placement, guidewire may be kinked about tip of catheter within vessel (refer to Figure 29).

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.

Pressure Injection Warnings and Precautions

Warnings:

1. Assess each patient for appropriateness of a pressure injection procedure. Pressure injection procedures must be performed by trained personnel well versed in safe technique and potential complications.
2. Obtain a visual image to confirm catheter tip position prior to each pressure injection.
3. Ensure patency of each lumen of catheter prior to pressure injection to minimize the risk of catheter failure and/or patient complications.
4. Discontinue pressure injections at first sign of extravasation or catheter deformation. Follow hospital/institutional protocol for appropriate medical intervention.

Cautions:

1. Do not exceed ten (10) injections or catheter's maximum recommended flow rate located on product labeling and catheter luer hub to minimize the risk of catheter failure and/or tip displacement.
2. Warm contrast media to body temperature prior to pressure injection to minimize the risk of catheter failure.
3. Pressure limit settings on injector equipment may not prevent over pressurizing an occluded or partially occluded catheter.
4. Use appropriate administration set tubing between catheter and pressure injector equipment to minimize the risk of catheter failure.
5. Follow the contrast media manufacturer's specified instructions for use, contraindications, warnings, and precautions.

Possible Complications (but not limited to):

- ♦ cardiac tamponade secondary to vessel wall, atrial or ventricular perforation
- ♦ pleural injury
- ♦ air embolism
- ♦ catheter embolism
- ♦ bleeding / hemorrhage
- ♦ bacteremia
- ♦ thrombosis
- ♦ hematoma
- ♦ fibrin sheath formation
- ♦ vessel erosion
- ♦ mediastinal injury
- ♦ nerve injury
- ♦ thoracic duct laceration
- ♦ occlusion
- ♦ septicemia
- ♦ inadvertent arterial puncture
- ♦ dysrhythmias
- ♦ exit site infection
- ♦ catheter tip malposition

Accessory Component Instructions

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

Arrow Advancer™:

Arrow Advancer™ is used to straighten "J" Tip of Spring-Wire Guide (SWG) for introduction of guidewire into Arrow® Raulerson Syringe or a needle.

- Using your thumb, straighten the "J" by retracting SWG into the Arrow Advancer™ (refer to Figures 2 and 3).

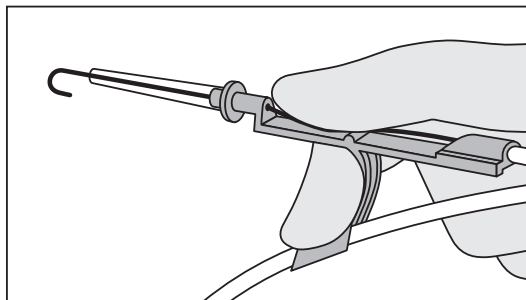


Figure 2

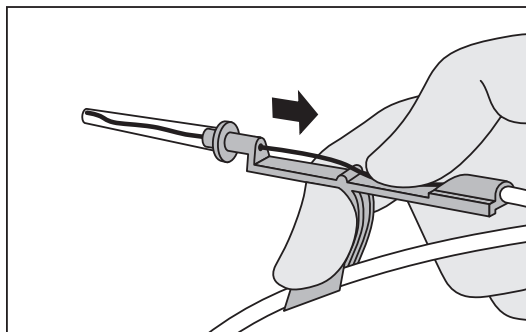


Figure 3

- When tip is straightened, SWG is ready for insertion. Centimeter marks on SWG are referenced from "J" Tip: one band indicates 10 cm, two bands 20 cm, and three bands 32 cm.
- Place tip of Arrow Advancer™ – with "J" retracted – into the hole in rear of Arrow® Raulerson Syringe plunger (refer to Figure 4) or introducer needle.

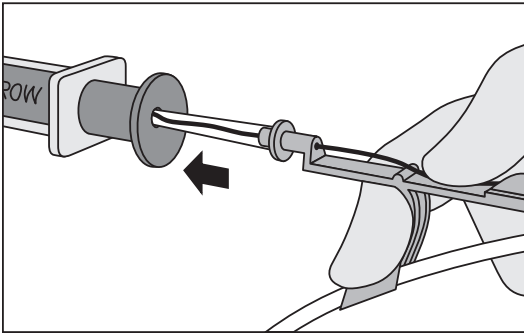


Figure 4

- Advance SWG into Arrow® Raulerson Syringe approximately 10 cm until it passes through syringe valves (refer to Figure 5) or into introducer needle.

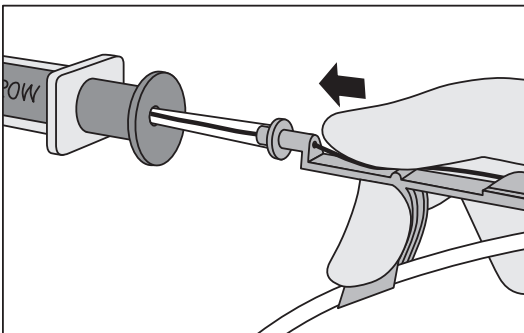


Figure 5

- Raise thumb and pull Arrow Advancer™ approximately 4 - 8 cm away from Arrow® Raulerson Syringe or introducer needle. Lower thumb onto Arrow Advancer™ and while maintaining a firm grip on SWG, push assembly into syringe barrel to further advance SWG. Continue until SWG reaches desired depth (refer to Figure 6).

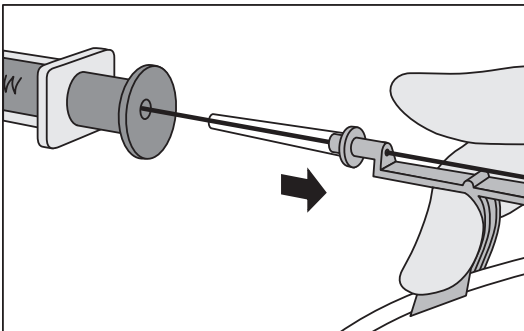


Figure 6

Simple Straightening Tube Technique:

The straightening tube portion of the Arrow Advancer™ can be disconnected from the unit and used separately.

- Separate Arrow Advancer™ tip or straightening tube from blue Arrow Advancer™ unit.
- Prepare for insertion by sliding plastic tube over “J” to straighten, if “J” Tip portion of SWG is used.
- Advance SWG in routine fashion to desired depth.

Arrow® Raulerson Syringe:

Arrow® Raulerson Syringe is used in conjunction with Arrow Advancer™ for SWG insertion.

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

Warning: Do not aspirate with guidewire in place or air may enter syringe.

Caution: Blood aspirate color is not always a reliable indicator of venous access.

Caution: Do not reinfuse blood to minimize the risk of blood leakage from rear (cap) of syringe.

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.

- Insert introducer needle attached to Arrow® Raulerson Syringe into vessel and aspirate.
 - Vessel may be prelocated with a 22 Ga. locator needle.
 - For pressure wave form transduction, a separately packaged transduction probe is available.
- Straighten SWG “J”.
- Advance SWG through Arrow® Raulerson Syringe into vessel to desired depth.
- Hold SWG in place and remove introducer needle and Arrow® Raulerson Syringe.

Catheter Clamp and Fastener:

Catheter Clamp and Fastener are used to secure catheter when an additional securement site other than catheter hub is required for catheter stabilization.

- After SWG has been removed and necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter making sure catheter is not moist, as required, to maintain proper tip location (refer to Figure 7).

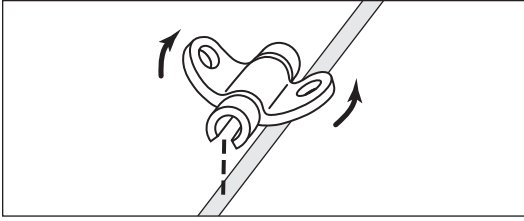


Figure 7

- Snap rigid fastener onto catheter clamp (refer to Figure 8).

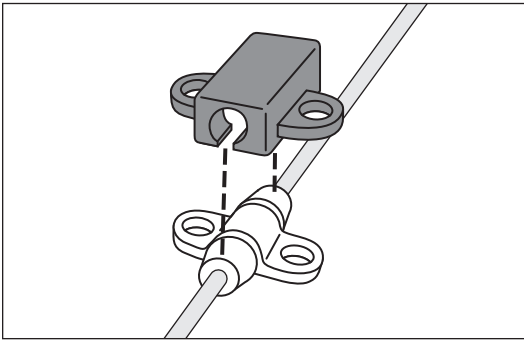


Figure 8

- Secure catheter to patient by stapling or suturing catheter clamp and fastener together to skin, using side wings to minimize the risk of catheter migration (refer to Figure 9).

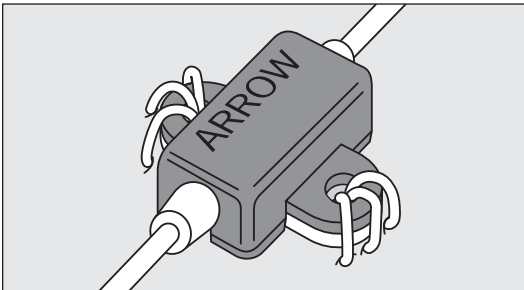


Figure 9

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 by using the primary suture hub.
- Place suture hub wings over posts and press down (refer to Figure 10). Snap retainer wings to closed position to secure suture hub (refer to Figure 11).

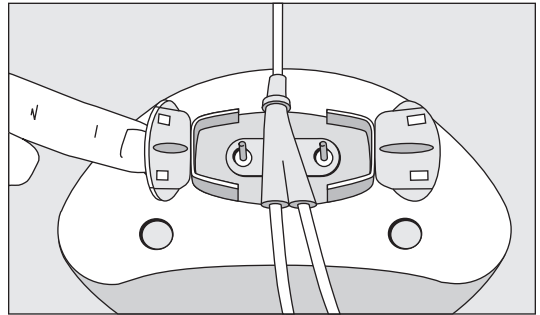


Figure 10

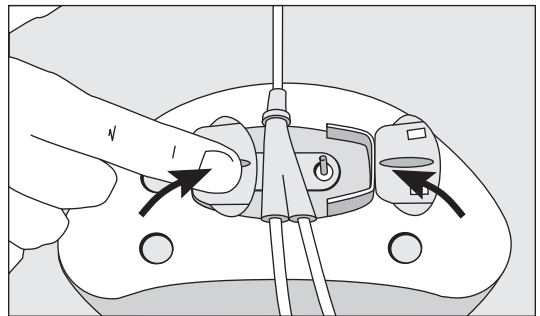


Figure 11

- Remove paper backing from one half of catheter stabilization device pad and press onto dry, prepared skin. Repeat process for other half.
- 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.

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 12).

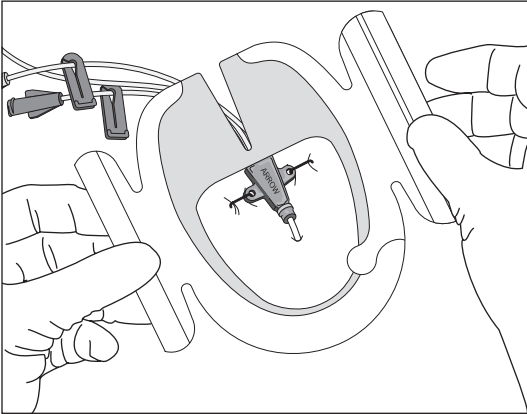


Figure 12

- Overlap softcloth tabs under catheter to form a tight seal around catheter hub and lumens (refer to Figure 13).

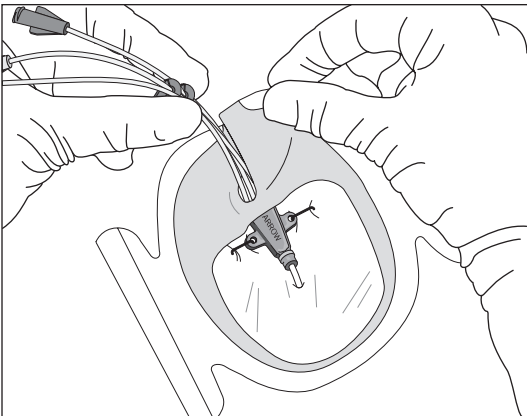


Figure 13

- 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 14).

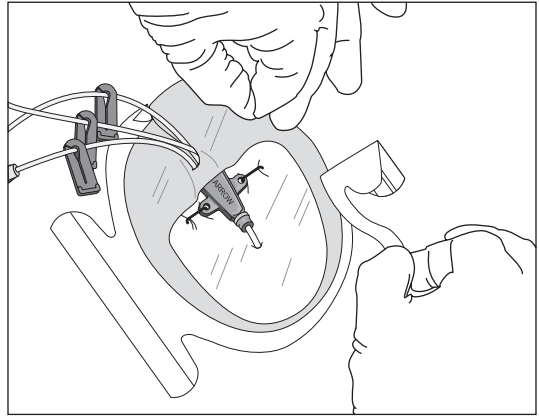


Figure 14

- Use sterile tape strips to secure hub, lumens, and/or tubing (refer to Figure 15).

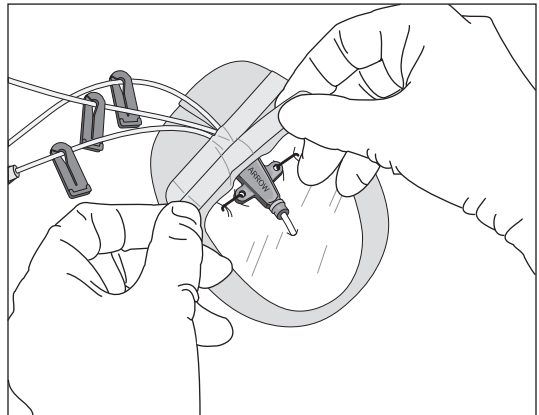


Figure 15

- 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.

Guidewire / SWG:

Kits/Sets are available with a variety of guidewires/SWG. Guidewires are provided in different diameters, lengths, and tip configurations for specific insertion techniques. Become familiar with the guidewire(s) to be used with the specific technique before beginning the actual CVC insertion procedure.

Image guidance may be used to gain initial venous access.

Luer-Activated Connector:

A Luer-Lock connector is used to minimize the 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 septum and 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 the CDC Category 1A Recommendation.

- Unfold the Maximal Barrier Drape:
 - Peel off fenestration backing (refer to Figure 16).

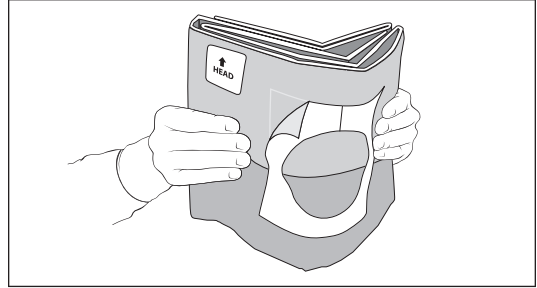


Figure 16

- Position fenestration over intended insertion site (refer to Figure 17).

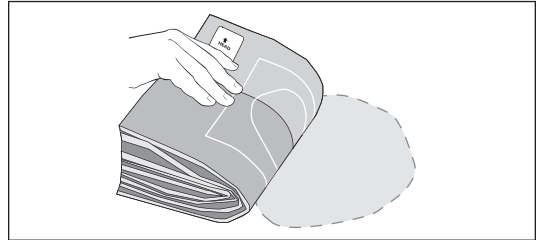


Figure 17

- Unfold width (refer to Figure 18).

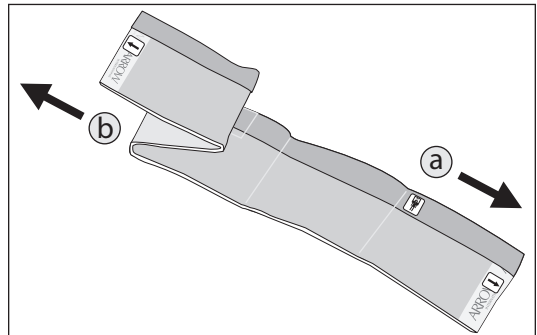


Figure 18

- Unfold towards head (refer to Figure 19).

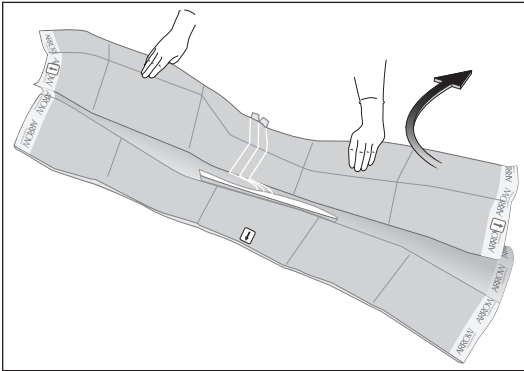


Figure 19

- Unfold towards hand (refer to Figure 20).

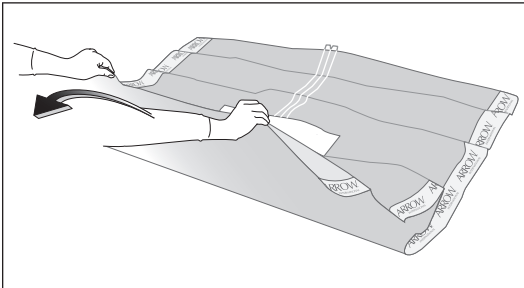


Figure 20

- Perform sterile procedure (refer to Figure 21).

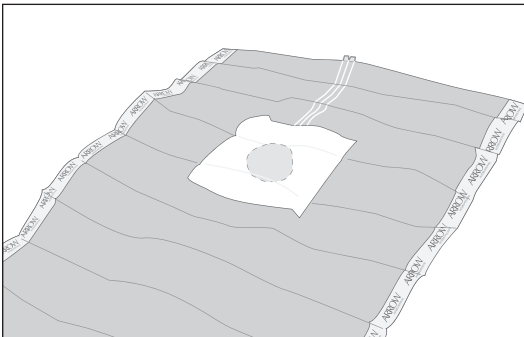


Figure 21

- Removal procedure: Tear along seam (refer to Figure 22).

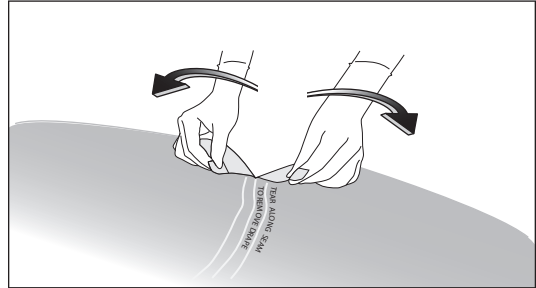


Figure 22

Protected Needle:

See individual manufacturer's instructions for product use, when used as a single product and not as a kit component.

Warning: Hands must remain behind needle at all times during use and disposal.

Caution: Make sure all needles are used 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 by pushing lever arm completely forward until needle tip is fully covered (see Figure 23).

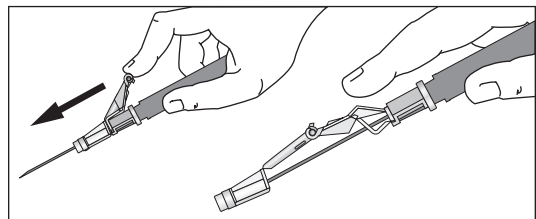


Figure 23

- Visually confirm lever arm has fully advanced and needle tip is 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.
- After single use, discard in an approved sharps collector in accordance with applicable regulations and hospital/institutional policy. For greatest safety, use a one-handed technique and activate away from self and others.

SharpsAway II™ Locking Disposal Cup:

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

- Using one-handed technique, firmly push needles into disposal cup holes (refer to Figure 24).

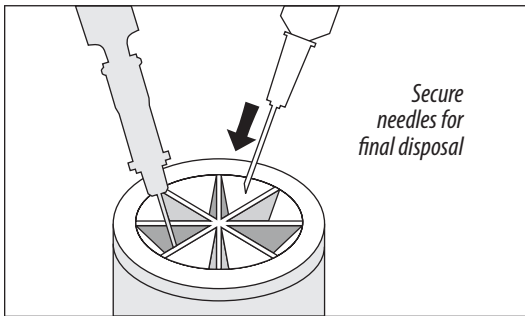


Figure 24

- 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.

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.

- Where provided, a foam SharpsAway® system may be utilized by pushing needles into foam after use.

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

Staple Anchoring Device:

Staples offer an alternative for catheter stabilization.

Warning: Do not secure, staple, and/or suture directly to outside diameter of catheter body or extension lines to minimize the risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.

- Position thumb and index finger of dominant hand on indented surface of staple anchoring device.
- Pass staple point through eye of catheter suture hub (refer to Figure 25).

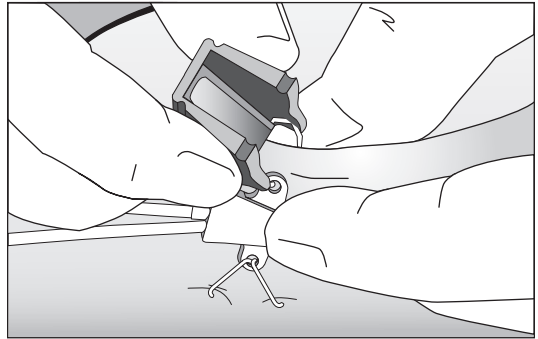


Figure 25

- Tent skin and position with hub eye between staple opening.
- Firmly squeeze anchoring device together to close staple and secure catheter to skin (refer to Figure 26).

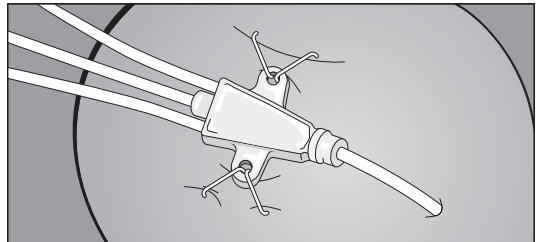


Figure 26

- Repeat procedure through other suture eyes, if applicable.
- Discard anchoring device upon completion.

Pre-CVC 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.

Perform hand hygiene as required.

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



Procedural Pause:

1. 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).
2. Educate patient: Explain procedure to patient. Make sure information is presented with respect to patient's level of understanding, culture, and language.
3. Have informed consent signed, if required.
4. Identify insertion vein:
 - Identify appropriate vein for insertion.
 - Use direct visualization technologies, e.g. ultrasound or fluoroscopy, if available; and assess vein health.
5. Position patient as appropriate for insertion site:
 - Subclavian or jugular approach: Place patient in slight Trendelenburg position as tolerated to reduce the risk of air embolism and enhance venous filling.
 - If femoral approach is used, place patient in supine position.
6. Prepare work area.

Preparing for Catheter Insertion:

- Perform hand hygiene as required:
 - before and immediately after all clinical procedures
 - before and after donning and removal of gloves

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

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

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 (25 Ga. or 22 Ga.) with 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.

Flush Catheter:

1. Flush each lumen with sterile saline solution, to establish patency and prime lumen(s).
2. Clamp or attach injection site cap(s) to extension line(s) to contain saline within lumen.
3. Leave distal extension line uncapped for SWG passage.

Warning: Do not cut catheter to alter length.

Catheter Insertion Instructions

Gain Initial Venous Access:

Warning: Do not leave open needles or uncapped, undamped catheters in central venous puncture site. Air embolism can occur with these practices.

1. Insert introducer needle or catheter/needle with attached syringe or Arrow® Raulerson Syringe (where provided) into vein and aspirate.

NOTE: If larger introducer needle is used, vessel may be pre-located with 22 Ga. locator needle and syringe.

See Arrow® Raulerson Syringe under Accessory Component Instructions section.

2. Remove locator needle.

Caution: Blood aspirate color is not always a reliable indicator of venous access.

Caution: Do not reinsert needle into introducer catheter to reduce risk of catheter embolism.

Verify Venous Access:

Because of the potential for inadvertent arterial placement, one of the following techniques should be utilized to verify venous access:

1. Central Venous Waveform:
 - Insert fluid primed blunt tip pressure transduction probe into rear of plunger and through valves of the Arrow® Raulerson Syringe and observe for central venous pressure waveform.
 - ◇ Remove transduction probe if using Arrow® Raulerson Syringe.

- Observe for central venous pressure waveform obtained by a calibrated pressure transducer attached directly to the introducer needle/catheter (refer to Figure 27).

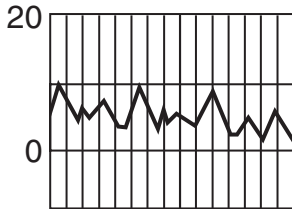


Figure 27

- Pulsatile Flow (if hemodynamic monitoring equipment is not available):
 - Use transduction probe to open syringe valving system of Arrow® Raulerson Syringe and observe for pulsatile flow.
 - Disconnect syringe from needle and observe for pulsatile flow.

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

Guidewire / SWG Insertion:

- Straighten “J” of SWG by using a straightening tube or Arrow Advancer™ (where provided).

See Arrow Advancer™ under Accessory Component Instructions section.

- Insert tip of SWG into plunger of Arrow® Raulerson Syringe or into introducer needle.
- Advance SWG through Arrow® Raulerson Syringe or introducer needle into vein to desired depth.
 - Advancement of “J” Tip through Arrow® Raulerson Syringe may require a gentle rotating motion.
 - Advance SWG until triple band mark reaches rear of Arrow® Raulerson Syringe plunger.
- Use centimeter markings on SWG as a reference to assist in determining how much guidewire has been inserted.

NOTE: If guidewire has three sets of markings, they will be located as follows:

- One band - 10 cm from “J” Tip
- Two bands - 20 cm from “J” Tip
- Three bands - 32 cm from “J” Tip

NOTE: When guidewire is used in conjunction with the Arrow® Raulerson Syringe (fully aspirated) and a 2-1/2 inch introducer needle, the following positioning references can be made:

- 20 cm mark entering back of plunger = guidewire tip is at end of needle
- 32 cm mark entering back of plunger = guidewire tip is approximately 10 cm beyond end of 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.

Warning: Do not aspirate with guidewire in place or air may enter syringe.

Caution: Do not reinfuse blood to minimize the risk of blood leakage from rear (cap) of syringe.

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

- Remove introducer needle and Arrow® Raulerson Syringe (or catheter) while holding SWG in place.
- Use centimeter markings on SWG to adjust indwelling length according to desired depth of indwelling catheter placement.
- Enlarge cutaneous puncture site with cutting edge of scalpel, where provided, positioned away from SWG.

Warning: Do not cut guidewire to alter length.

Warning: Do not cut guidewire with scalpel.

- Position cutting edge of scalpel away from guidewire.
- Activate safety feature of safety scalpel (where provided) once cutaneous puncture site is enlarged, to minimize the risk of cutting the guidewire (refer to Figure 28).

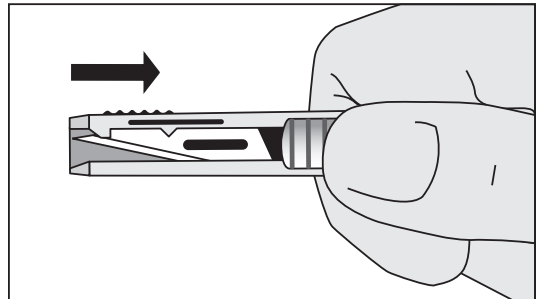


Figure 28

- Use tissue dilator to enlarge puncture site as required.

Warning: Do not leave tissue dilator in place as an indwelling catheter to minimize the risk of possible vessel wall perforation.

Catheter Advancement:

- Thread tip of catheter over SWG. Sufficient SWG length must remain exposed at hub end of catheter to maintain a firm grip on SWG.
- Grasping near skin, advance catheter into vein with slight twisting motion.

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

- Using centimeter marks on catheter as positioning reference points, advance catheter to final indwelling position.

NOTE: Centimeter marking symbology is referenced from catheter tip.

- numerical: 5, 15, 25, etc.
- bands: each band denotes a 10 cm interval, with one band indicating 10 cm, two bands indicating 20 cm, etc.
- dots: each dot denotes a 1 cm interval

- Hold catheter at desired depth and remove SWG.

NOTE: Arrow® catheters are designed to pass freely over SWG.

Caution: If resistance is encountered when attempting to remove guidewire after catheter placement, guidewire may be kinked about tip of catheter within vessel (refer to Figure 29).

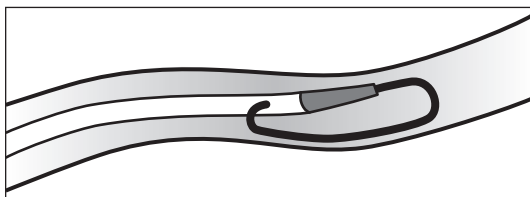


Figure 29

- In this circumstance, pulling back on SWG may result in undue force being applied resulting in SWG breakage.
- If resistance is encountered, withdraw catheter relative to SWG about 2-3 cm and attempt to remove SWG.
- If resistance is again encountered remove SWG and catheter simultaneously.

Warning: Do not apply undue force on guidewire to minimize the risk of possible breakage.

- Verify entire SWG is intact upon removal.

Complete Catheter Insertion:

- Check lumen placement by attaching a syringe to each extension line and aspirate until free flow of venous blood is observed.
- Flush lumen(s) to completely clear blood from catheter.
- Connect all extension line(s) to appropriate Luer-Lock line(s) as required. Unused port(s) may be “locked” through injection cap(s) using standard hospital/institutional protocol.
 - Slide clamps are provided on extension lines to occlude flow through each lumen during line and injection cap changes.

Warning: Open catheter clamp prior to infusion through lumen to minimize the risk of damage to extension line from excessive pressure.

- Secure catheter to patient.
 - Where provided, a catheter clamp, fastener, catheter stabilization device, staples or suture may be used.

- Use triangular junction hub with side wings as primary suture site
- Catheter clamp and fastener should be utilized as a secondary suture site as necessary.

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

See Catheter Clamp and Fastener, Staple Anchoring Device under Accessory Component Instructions section.

- Ensure insertion site is dry before applying dressing. Apply skin protectant as needed.

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

- Assess placement of catheter tip in compliance with hospital/institutional protocol.

Warning: Do not place Central Venous Catheter (CVC) or Peripherally Inserted Central Catheter (PICC) into or allow them to remain in the right atrium or right ventricle. X-ray exam or other method in compliance with hospital/institutional protocol must show catheter tip located in right side of mediastinum in the Superior Vena Cava (SVC) above its junction with right atrium and parallel to vessel wall and its distal tip positioned at a level above either azygos vein or carina of the trachea, whichever is better visualized. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it. Improper advancement of guidewire into the heart has also been implicated in causing cardiac perforation and tamponade. For femoral vein approach, catheter should be advanced into vessel so catheter tip lies parallel to vessel wall and does not enter right atrium.

- If catheter tip is malpositioned, reposition, redress, and re-verify.

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:

- Device specifics:
 - type, brand and lot number
 - length and size of Vascular Access Device (VAD)
 - internal/external catheter length
 - antimicrobial 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
5. Visual confirmation:
 - verification of appropriate tip location prior to initial use
6. Monitor patient for post catheter insertion complications.

Pressure Injection Instructions

Use sterile technique.

Warning: Obtain a visual image to confirm catheter tip position prior to each pressure injection.

1. Remove injection cap from appropriate extension line of catheter.
2. Check for catheter patency:
 - Attach 10 mL syringe filled with sterile normal saline.
 - Aspirate catheter for adequate blood return.
 - Vigorously flush catheter.

Warning: Ensure patency of each lumen of catheter prior to pressure injection to minimize the risk of catheter failure and/or patient complications.

3. Detach syringe.
4. Attach pressure injection administration set tubing to appropriate extension line of catheter according to manufacturer's recommendations.

Caution: Do not exceed ten (10) injections or catheter's maximum recommended flow rate located on product labeling and catheter luer hub to minimize the risk of catheter failure and/or tip displacement.

5. Inject contrast media in accordance with hospital/institutional protocol.

Caution: Warm contrast media to body temperature prior to pressure injection to minimize the risk of catheter failure.

6. Disconnect catheter from pressure injector equipment.

7. Flush catheter using 10 mL syringe or larger filled with sterile normal saline.
8. Disconnect syringe and replace with sterile injection cap on catheter extension line.

NOTE: Do not exceed ten (10) pressure injections.

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.

- Consult manufacturer's recommendations for dressing specifics.
- Transparent semipermeable membrane dressing should be changed every 7 days.
- Gauze and tape should be changed every 48 hours.
- Label dressing with type, size, and length of catheter; date and time; and initials of the clinician performing dressing change.

Maintain Catheter Patency:

Maintaining central venous catheter patency shall be done in accordance with hospital/institutional policies, procedures, and practice guidelines. All personnel who care for patients with central venous catheters must be knowledgeable about effective management to prolong catheter's dwell time and prevent injury.

Perform hand hygiene as required.

1. Solution and frequency of flushing a venous access catheter should be established in hospital/institutional policy.
2. Catheter patency is established and maintained by:
 - flushing intermittently via syringe with heparinized saline or preservative-free 0.9% sodium chloride
 - continuous drip
 - positive pressure device
3. The 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.

4. The 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.

Warning: Open catheter clamp prior to infusion through lumen to minimize the risk of damage to extension line from excessive pressure.

5. When using any central venous catheter for intermittent infusion therapy, proper flushing (heparinization) using a positive-pressure flushing technique will help prevent occlusion.

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

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

Catheter Removal Procedure

1. CVC removal shall be performed:
 - following order of authorized prescriber
 - in accordance with organizational policies, procedures, and practice guidelines
2. A CVC shall be removed 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

Caution: Do not use guidewire techniques to replace catheters in patient suspected of having catheter-related infection.

3. Place patient in supine position, as clinically indicated to minimize the risk of potential air embolism.
4. Remove dressing.

Warning: Do not use scissors to remove dressing, to minimize the risk of cutting catheter.

5. Remove sutures or staples; or open catheter stabilization device retainer wings and remove catheter from catheter stabilization device posts.

6. Place gauze pad over insertion site and catheter.
7. Remove catheter by slowly pulling it parallel to skin. If resistance is met while removing, catheter should not be forcibly removed and physician should be notified.

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

8. Upon removal of catheter:
 - inspect for intact Blue FlexTip® or catheter tip
 - ensure entire catheter length has been removed
9. Apply direct pressure to site until hemostasis is achieved.
10. Apply alcohol swab to catheter stabilization device adhesive and gently lift pad off of skin (if applicable).
11. Dress insertion site. Sterile air occlusive dressing should be applied and site assessed every 24 hours until site is epithelialized.

Warning: Residual catheter track remains an air entry point until completely sealed, occlusive dressing should remain in place for at least 24 - 72 hours dependent upon amount of time catheter was indwelling.

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

Include:

- catheter condition
- 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

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C-45802-101A (9/09)

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