PowerGlide Pro™ midline catheter

INSTRUCTIONS FOR USE

INDICATIONS

The PowerGlide Pro™ Midline Catheter is inserted into a patient's vascular system for short-term use (<30 days) to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The PowerGlide Pro™ Midline Catheter is suitable for use with power injectors.

PRODUCT DESCRIPTION

The PowerGlide Pro™ Midline Catheter is a sterile, single use device designed to provide access to the patient's vascular system. The device is intended for short term use (< 30 days) to sample blood and administer fluids intravenously. The device consists of an introducer needle with a passive safety mechanism, guidewire, and single lumen, radiopaque, body-softening polyurethane catheter rated for power injection.

CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

CONTRAINDICATIONS

The device is contraindicated whenever:

- The presence of device-related infection, bacteremia, or septicemia is known or suspected.
- The patient's body size is insufficient to accommodate the size of the implanted device.
- The patient is known or is suspected to be allergic to materials contained in the device.
- Local tissue factors and/or past treatment will prevent proper device stabilization and/or access.

WARNINGS

- Alcohol should not be used to lock, soak, or declot PowerGlide Pro™ Midline Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Ointments containing acetone and polyethylene glycol should not be used with polyurethane catheters, as these may cause failure of the device.
- Intended for single use only. Do not reuse. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- (Pediatric) Insertion techniques and placement locations are often modified according to the size and developmental age of the child. Only clinicians experienced in proper positioning and placement of venous catheters in pediatric patients should place this catheter in this patient population.
- Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may lead to catheter failure.
- Exceeding the maximum flow rate or the maximum pressure of power injectors of 325 psi (2241 kPa) may result in catheter failure and/or catheter tip displacement.
- If the artery is unintentionally entered, withdraw the needle and apply manual pressure for several minutes. Failure to do so may lead to patient blood loss.
- Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- The fluid level in the catheter will drop if the catheter connector is held above the level of the patient's heart and opened to air. To help prevent a drop in the fluid level and potential air embolism while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.
- Therapies not appropriate for midline catheters include those therapies requiring central venous access. Refer to standards of practice and institutional policies.
- Once the catheter has been advanced, do not re-insert the needle back into the catheter or pull the catheter back onto the needle. If the catheter needs to be repositioned, either do so without the aid of the needle, or remove both the catheter and the needle as a unit to prevent the needle from damaging or shearing the catheter.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.

PRECAUTIONS

- Carefully read and follow all instructions prior to use.
- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, cautions, precautions and instructions for all infusates, including contrast media, as specified by their manufacturer.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only qualified health care practitioners should insert, manipulate and remove these devices.
- Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
- Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
- The catheter must be secured in place to minimize the risk of catheter breakage and embolization.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
- Blood return will slow or stop once the guidewire is fully extended.
- ALWAYS keep the housing stationary while advancing catheter wings. Failure to do so will prevent catheter from entering vein and cause delays in procedure.
- When using room temperature (20°C) contrast with a 26.6 cP viscosity, maximum flow rate may not be achieved.
- Wings will not deploy until guidewire is fully advanced.
- Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use. Solutions should be allowed to completely dry before applying an occlusive dressing.
- PowerGlide Pro™ Midline Catheter's indication for power injection of contrast media implies the catheter's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.
- Consider alternate placement site when there has been:
  - Past irradiation of prospective insertion site.
  - Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.

I. Prior to beginning placement procedure, do the following:

- Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a sterile package and is non-pyrogenic. Do not use if package is damaged, opened or the expiration date has passed. Sterilized using ethylene oxide. Do not resterilize.
- Inspect kit for inclusion of all components.

II. To avert device damage and/or patient injury during placement:

- Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
- Do not perforate, tear, or fracture the catheter with the needle or guidewire during the procedure.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- Do not suture around the catheter as sutures may damage the catheter or compromise catheter patency.

III. After placement, observe the following precautions to avoid device damage and/or patient injury:

- **Warning:** Do not use the device if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation and possible embolism and surgical removal.
- Accessories and components used in conjunction with this device should incorporate luer lock connections.
- **Warning:** If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Do not flush against resistance with a syringe smaller than 10 mL. Prolonged infusion pressure greater than 25 psi (172 kPa) may damage blood vessels or viscus. (INS Standard)
- Once patency has been established with a 10 mL syringe, fluid infusions may be administered using a syringe smaller than 10 mL provided that no resistance is encountered.

SPECIAL PATIENT POPULATION

NOTE: (Pediatric) Insertion of the PowerGlide Pro™ Midline Catheter in pediatric patients may require the use of accessories or components not included in this kit configuration, based on the size and developmental age of the child and facility protocol. Follow manufacturer's recommendations regarding use of any drugs or medications such as chlorhexidine prep solutions, lidocaine injections and heparin.

NOTE: (Pediatric) Catheters inserted via a scalp vein in neonates and pediatric patients should have the tip terminating in the external jugular vein (EJV) [INS, 2011].

NOTE: (Pediatric) Prep the insertion site and surrounding skin per facility policies, procedures, and/or practice guidelines. Chlorhexidine is not recommended for infants under 2 months of age [INS, 2011]. Povidone iodine should be removed from the skin after the procedure to prevent tissue damage, absorption, and thyroid suppression. [NANN, 2007]

For further information or questions, please call 800-443-3385 or 801-522-5000.

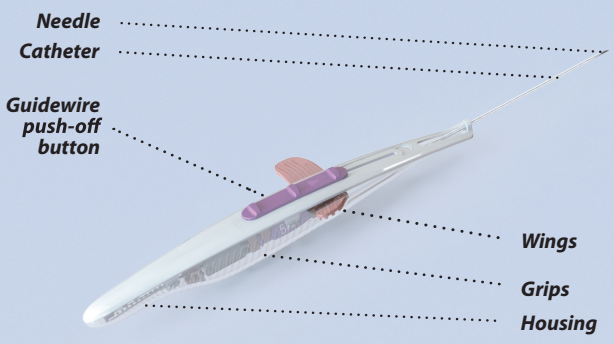
POSSIBLE COMPLICATIONS

The potential exists for serious complications including the following:

- Air Embolism
- Bleeding
- Catheter Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation/Infiltration
- Fibrin Sheath Formation
- Hematoma
- Intolerance Reaction to Implanted Device
- Laceration or Perforation of Vessels or Viscus
- Phlebitis
- Thromboembolism
- Venous Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

INSERTION INSTRUCTIONS

PowerGlide Pro™ Midline Catheter Diagram



1. Identify the vein and insertion site.
   Warning: (Pediatric) Insertion techniques and placement locations are often modified according to the size and developmental age of the child. Only clinicians experienced in proper positioning and placement of venous catheters in pediatric patients should place this catheter in this patient population.
2. Clean and prepare insertion site per your institution's policy.
3. Remove needle sheath from plastic housing.
   Suggestion: To break catheter tip adhesion before inserting the needle, do the following steps:
   A) Fully advance guidewire
   B) Advance and retract catheter wings 1/8 in.
   C) Retract guidewire
4. Insert the needle into the vein and observe for blood return in the catheter.
5. Advance the guidewire using the guidewire push-off button until fully deployed.
   CAUTION: Wings will not deploy until guidewire is fully advanced..
   CAUTION: Blood return will slow or stop once the guidewire is fully extended..
6. Fully advance the catheter using the catheter wings.
   Caution: ALWAYS keep the housing stationary while advancing catheter wings. Failure to do so may prevent catheter from entering vein and cause delays in procedure.
   Warning: If the artery is unintentionally entered, withdraw the needle and apply manual pressure for several minutes. Failure to do so may lead to patient blood loss.
   Warning: Once the catheter has been advanced, do not re-insert the needle back into the catheter or pull the catheter back onto the needle. If the catheter needs to be repositioned, either do so without the aid of the needle, or remove both the catheter and the needle as a unit to prevent the needle from damaging or shearing the catheter.
7. While holding the catheter wings in place, fully remove housing from the catheter.
   Note: Catheter wings remain temporarily connected to catheter hub after housing removal.
   Note: Discard housing and needle per institutional policy.
8. While holding the proximal end of the wing assembly to stabilize the device, lift up and fold back wings.
9. Remove wings from the catheter.
10. Immediately attach primed extension set and/or injection cap to the catheter per your institution's policy.

STATLOCK® STABILIZATION DEVICE AND GUARDIVA® DRESSING PREPARATION

11. Dress site.

- Prepare targeted area for the StatLock® Stabilization Device and GuardIVa® Dressing (if applicable) using alcohol (to remove oil and moisture) and skin prep for skin protection and enhanced adhesion. Allow to dry completely. Ensure all ultrasound gel is removed from skin.
- Place the GuardIVa® Dressing around the catheter with the printed side facing up. Position the GuardIVa® Dressing around the catheter site, so the catheter rests on the slit portion of the GuardIVa® Dressing. The slit edges should come in contact with one another to assure best efficacy.
- **Note:** Refer to the GuardIVa® Dressing IFU for all indications, contraindications, warnings, precautions and safety information.
- **Note:** Leaving about 1 cm of the catheter out at the insertion site may accommodate for the dressing.
- Before applying the StatLock® Stabilization Device pad to skin, press the Statlock® Stabilization Device retainer over the catheter hub to capture the push-tab.
- Peel away the StatLock® Stabilization Device backing, one side at a time and place on skin.
- Place occlusive dressing over the site.
- **Note**: Refer to the StatLock® Pro Stabilization Device IFU for all indications, contraindictions, warnings, precautions and safety information.

SUGGESTED CATHETER MAINTENANCE

The catheter should be maintained in accordance with standard hospital protocols. Suggested catheter maintenance is as follows:

- **Dressing changes**
- Access the dressing in the first 24 hours for accumulation of blood, fluid or moisture beneath the dressing. Periodically confirm catheter placement, patency and security of dressing.
- **Flushing**
- Flush the catheter with 10 mL of sterile saline every 12 hours or after each use or per facility protocol using a 10 mL or larger syringe.
  Note: (Pediatric) When infusion volume is a concern in small or pediatric patients, flush with 3 mL or per facility guidelines.
- **Occluded or partially occluded catheter**
- Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against resistance. If the catheter will neither flush or aspirate and it has been determined that the catheter is occluded with blood, a declotting procedure per institution protocol may be appropriate.
- **When cleaning the exit site**
- **Warning:** Alcohol should not be used to lock, soak, or declot PowerGlide Pro™ Midline Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- **Warning:** Ointments containing acetone and polyethylene glycol should not be used with polyurethane catheters, as these may cause failure of the device.
- Maintain according to hospital protocol.
- Use chlorhexidine gluconate or povidone iodine to clean the exit site around the catheter.
- Allow all cleaning agents/antiseptics to dry completely before applying dressing.

CATHETER PRIMING VOLUME(S):

GAUGE SIZE	LENGTH	PRIMING VOLUME
18 GA	8 cm	0.16 mL
	10 cm	0.17 mL
20 GA	8 cm	0.13 mL
	10 cm	0.15 mL
22 GA	8 cm	0.13 mL

POWER INJECTION PROCEDURE

1. Remove the injection/needleless cap from the PowerGlide Pro™ Midline Catheter.
   Warning: The fluid level in the catheter will drop if the catheter connector is held above the level of the patient's heart and opened to air. To help prevent a drop in the fluid level and potential air embolism while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.
2. Attach a 10 mL or larger syringe filled with sterile saline.
3. Aspirate for adequate blood return and vigorously flush the catheter with the full 10 mL of sterile saline.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
4. Detach syringe.
5. Attach the power injection device to the PowerGlide Pro™ Midline Catheter per manufacturer's recommendations.
6. To achieve maximum flow rate as promoted on the catheter hub, contrast media should be warmed to body temperature prior to power injection.
7. Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum flow rate as printed on the catheter hub.
   Warning: Power injector machine pressure limiting feature may not prevent overpressurization of an occluded catheter, which may lead to catheter failure.
   Warning: Exceeding the maximum flow rate or the maximum pressure of power injectors of 325 psi (2241 kPa) may result in catheter failure and/or catheter tip displacement.
8. Disconnect the power injection device.
9. Attach a new sterile injection/needleless cap on the PowerGlide Pro™ Midline Catheter.
10. Flush the PowerGlide Pro™ Midline Catheter with 10 mL of sterile saline, or per facility protocol.
    NOTE: (Pediatric) When infusion volume is a concern in small or pediatric patients, flush with 3 mL or per facility guidelines.

POWER INJECTIONS

The PowerGlide Pro™ Midline Catheter testing included 5 power injection cycles..

GAUGE SIZE	CONTRAST MEDIA[1] TEMPURATURE	CONTRAST MEDIA[1] VISCOSITY	MAX FLOW (mL/sec)	INJECTOR SAFETY CUT-OFF (PSI)
18 GA	Warmed (37°C)	11.8 cP	7	325 Max
20 GA			5	
22 GA			2	

[1] Visipaque 320

Caution: When using room temperature (20°C) contrast with a 26.6 cP viscosity, maximum flow rate may not be acheived.

STATLOCK® STABILIZATION DEVICE REMOVAL

Carefully remove overlying dressing using stretch technique.

1. Gently lift the StatLock® Pro Stabilization Device pad. Disengage catheter from retainer, and continue to remove pad.
1. If labeled, dissolve adhesive with alcohol swab(s) while gently lifting the StatLock® Pro Stabilization device pad. Disengage catheter from retainer, and continue to remove pad with alcohol.
2. Document the StatLock® Stabilization Device dressing change in the patient chart.
3. Dispose of all equipment in appropriate containers.
   Note: Refer to the StatLock® Pro Stabilization Device IFU for all indications, contraindictions, warnings, precautions and safety information.

GUARDIVA® DRESSING REMOVAL

2. Change the dressing as necessary, according to facility protocol; dressing can be left in place for up to 7 days. More frequent changes may be needed with highly exuding wounds.
3. To remove GuardIVa® Dressing, hold the catheter and pick up the corner of the transparent dressing. In a slow and low motion pull the dressing away from the catheter. The GuardIVa® Dressing will lift off with the transparent dressing.
   Note: Refer to the GuardIVa® Dressing IFU for all indications, contraindications, warnings, precautions and safety information.

POWERGLIDE PRO™ MIDLINE CATHETER REMOVAL

1. Remove dressing, and StatLock® Stabilization Device or tape securement strips.
2. Grasp catheter near insertion site.
3. Remove slowly. Do not use excessive force.
4. If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.
5. Resume removal procedure.

REFERENCES:

Pettit, J and Wycoff, M. (2007). NANN Peripherally Inserted Central Catheters. Guideline for Practice, 2nd Edition. National Association of Neonatal Nurses

Journal of Infusion Nursing (January/February 2011). Infusion Nursing Standards of Practice.

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revised date: August, 2018

Do not use if package is damaged

Lot number

Do not reuse

Quantity

Manufacturer

Do not resterilize

Sterilized using ethylene oxide

Product catalog number

Use by

Non-pyrogenic

Length

Not made with natural rubber latex

Manufacturer:
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, Utah 84116 USA
801-522-5000
www.bardaccess.com

0747882 1808R

BARD

PowerGlide Pro™ midline catheter

BARD

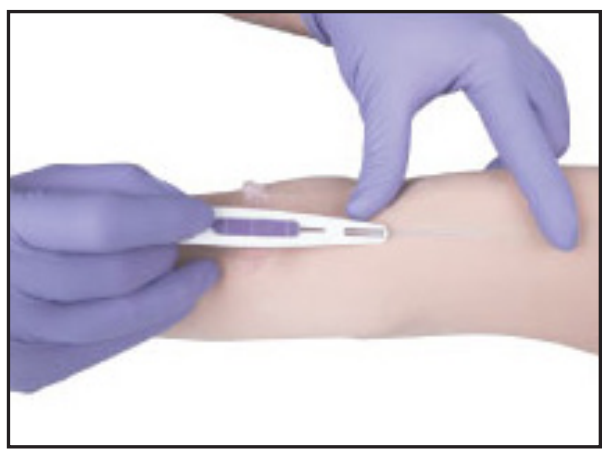
Please see reverse for complete instructions for use.

1 IDENTIFY VEIN AND INSERTION SITE

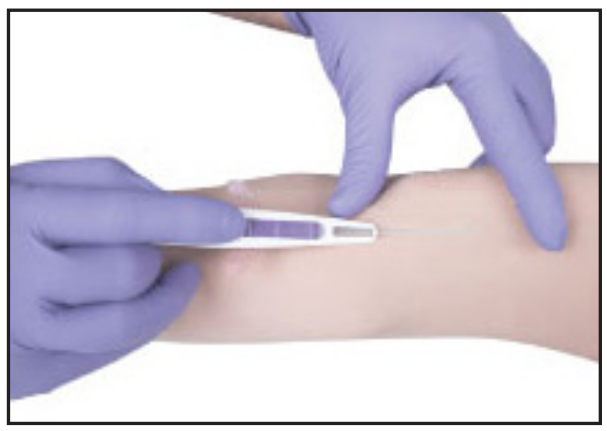
2 CLEAN AND PREPARE INSERTION SITE PER INSTITUTIONAL POLICY

3 REMOVE SHEATH

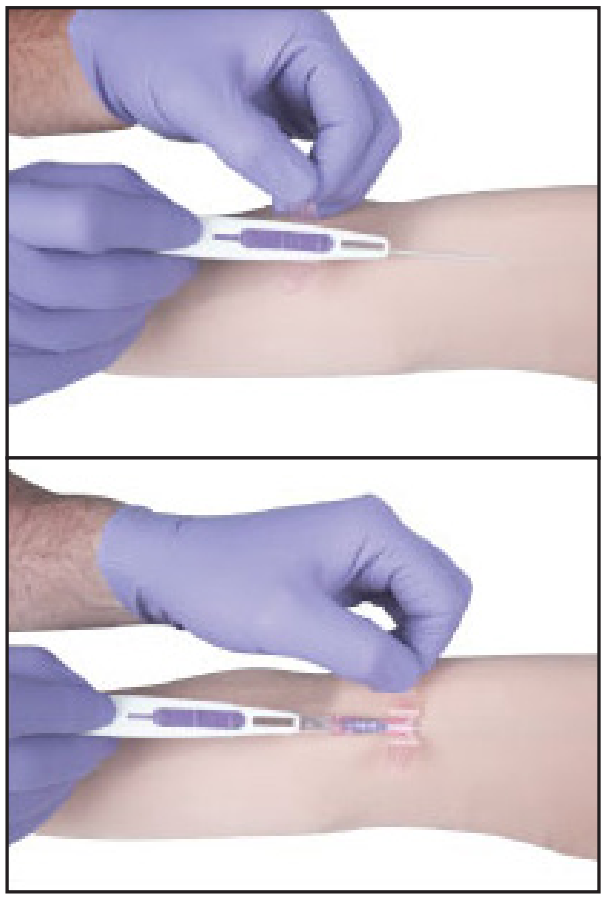
4 INSERT NEEDLE IN VEIN



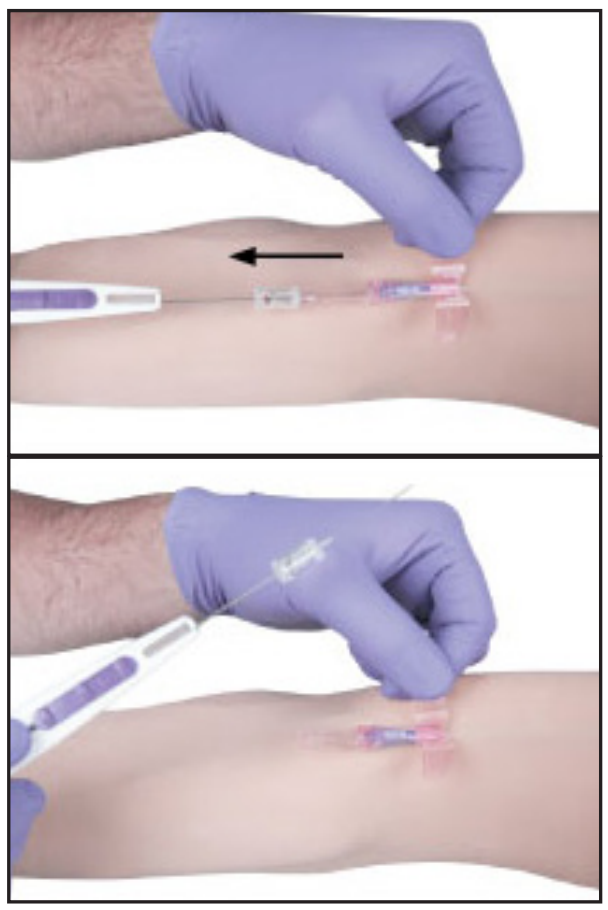
5 ADVANCE GUIDEWIRE



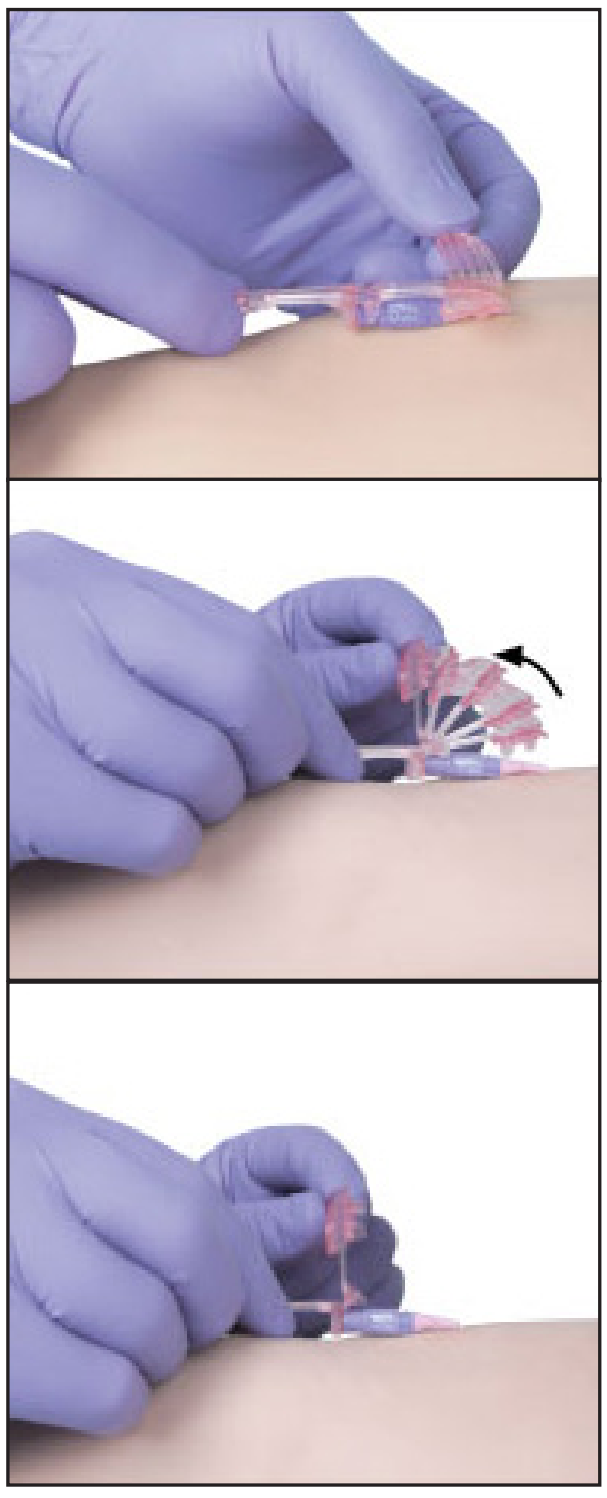
6 ADVANCE CATHETER WINGS



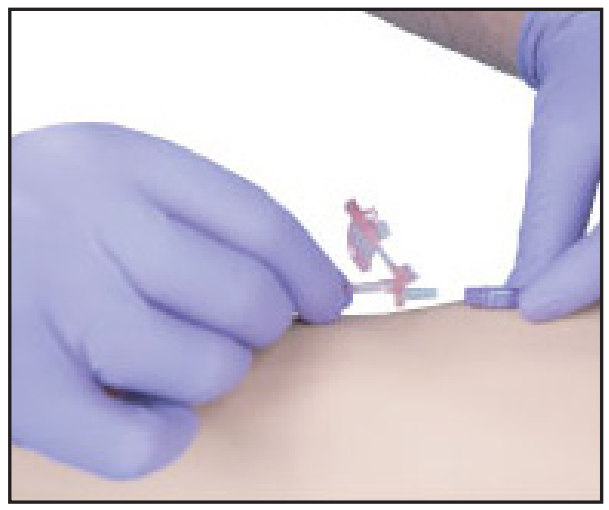
7 FULLY REMOVE HOUSING



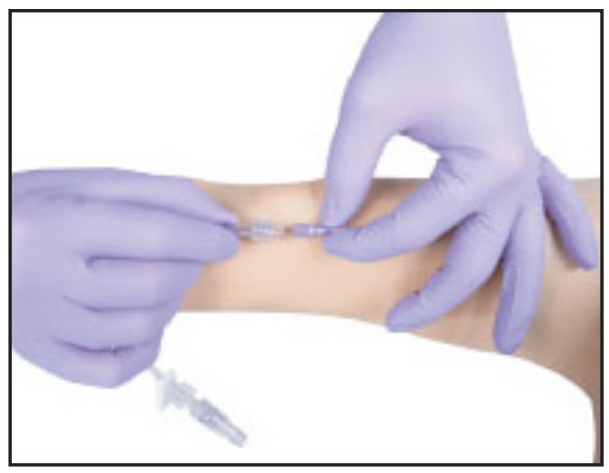
8 LIFT UP CATHETER WINGS



9 REMOVE WINGS



10 ATTACH EXTENSION SET



11 DRESS SITE PER INSTITUTIONAL POLICY