PRODUCT DESCRIPTION

Provena™ Midline Catheters are a family of peripherally placed catheters made from radiopaque body-softening polyurethane materials. Each Provena™ Midline Catheter is designed with kink-resistant, reverse taper design. Catheters are packaged in a tray with accessories for reliable short term (less than 30 days) vascular access. The Provena™ Midline Catheters are suitable for use with power-injectors.

INDICATIONS

The Provena™ Midline Catheters are indicated for short term access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The Provena™ Midline Catheters are suitable for use with power injectors.

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

General Warnings

- When using alcohol or alcohol-containing antiseptics with polyurethane midlines, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.
- Alcohol should not be used to lock, soak or de-clot polyurethane midlines because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Acetone-based solution and polyethylene glycol containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.
- Therapies not appropriate for midline catheters include those therapies requiring central venous access. Refer to standards of practice and institutional policies.
- Do not wipe the catheter with acetone-based solutions, tincture of iodine or polyethylene glycol-containing ointments. These can damage the polyurethane material if used over time.
- (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 midlines in pediatric patients should place this catheter in this patient population.
• Intended for Single Use. 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.

• 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 (allowing air entry) while changing injection caps, hold the connector below the level of the patient’s heart before removing the injection/needleless cap.

• Exceeding the maximum flow rate or the maximum pressure of power injectors of 325 psi may result in catheter failure and/or catheter tip displacement.

• Power injector machine pressure limiting feature may not prevent over-pressurizations of an occluded catheter, which may cause catheter failure.

• Provena™ Midline Catheter 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 suitable trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

• Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.

• Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.

• Use of lumens not marked “Power Injectable” for power injection may result in catheter failure.

Placement Warnings

• If the artery is entered, withdraw the needle and apply manual pressure for several minutes.

• Place a finger over the orifice of the sheath to minimize the blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver until the catheter is inserted into the sheath.

• (Pediatric) This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.

• Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and/or risk of patient injury.
PRECAUTIONS

General Precautions

• Sterilized using ethylene oxide. Do not re-sterilize.
• Carefully read and follow all instructions prior to use.
• Follow all contraindications, warnings, cautions, precautions and instructions for all infusates, as specified by their manufacturer.
• After use, this product may be a potential biohazard. Handle and dispose of in accordance with medical practice and applicable local, state and federal laws and regulations.
• As reported in literature, anaphylactic or anaphylactic-like reactions occur in a small percentage of the population during placement¹, positioning¹, flushing² of catheters, or cleaning of catheter exit site³. These reactions are reported in association with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some patients. Be aware of the potential symptoms or signs of these reactions and take precautionary steps as dictated by institution protocol for their prevention or treatment.
• If CHG allergy is suspected, confirmatory testing is recommended⁴,⁵
• CAUTION: Federal (USA) 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.
• Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
• Secure additional extension sets per hospital protocol. Refrain from having unsupported extension sets that could put stress on the catheter extension legs.

Precautions Related to Device Placement Procedure

• DO NOT USE A SYRINGE SMALLER THAN 10 mL TO FLUSH AND CONFIRM PATENCY. Patency should be assessed with a 10 mL syringe or larger with sterile saline. Upon confirmation of patency, administration of medication should be given in a syringe appropriately sized for the dose. Do not infuse against resistance.
• To reduce potential for blood backflow into the catheter tip, always remove syringes slowly while injecting the last 0.5 mL of sterile saline.
• Do not reininsert needle into IV catheter to minimize the risk of the needle damaging or shearing the IV catheter.
• Do not cut guidewire to alter length.
• The stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet or stiffening wire.
• Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
• Keep sufficient guidewire length exposed at hub to allow for proper handling. A non-controlled guidewire can lead to wire embolism.
• Do not use excessive force when introducing guidewire or microintroducer as this can lead to vessel perforation and bleeding.
• If the guidewire must be withdrawn while the needle is inserted, remove both needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
• Never leave stylet or stiffening wire in place after catheter insertion; injury may occur. Remove stylet or stiffening wire and T-lock (as applicable) after insertion.
• Do not clamp extension leg when stylet or stiffening wire is in catheter to minimize the risk of component or catheter damage.
• Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and reattempt stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into the desired position (zero mark).
• Avoid placement or securement of the catheter where kinking may occur to minimize stress on the catheter, patency problems or patient discomfort.
• Placement of the Provena™ Midline Catheter above antecubital fossa is recommended.
• Do not advance the guidewire past the axilla.
• The midline catheter tip location should be at or near the axillary line [INS, 2016].
• Catheter stylet must be wetted prior to stylet repositioning or withdrawal.
• The catheter must be secured in place to minimize risk of catheter breakage and embolization.
• Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
• Do not bend catheter at sharp angles during implantation. This can compromise catheter patency.
• When using peel-apart introducers:
  - Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apart introducer.
  - Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.
  - Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.
  - Do not withdraw dilator from microintroducer sheath until sheath is within vessel to minimize the risk of damage to sheath tip.
• Do not suture through or around any part of the catheter’s tubing (shaft or extension legs). If using sutures to secure catheter USE THE SUTURE WINGS and make sure they do not occlude, puncture, or cut the catheter.
• Do not use scissors to remove dressing to minimize the risk of cutting catheter.
• Accessories and components used in conjunction with this device should incorporate Luer lock connections. Do not over tighten the Luer connector.
• 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.
SPECIAL PATIENT POPULATION

NOTE: (Pediatric) Insertion of midlines 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 the drug manufacturer’s recommendations regarding use of any drugs or medications such as chlorhexidine prep solutions, lidocaine injections and heparin flush solutions.

NOTE: (Pediatric) “Site selection for vascular access shall include: Assessment of patient’s condition; age; diagnosis; comorbidities; condition of the vasculature at the insertion site and proximal to the intended insertion site; condition of skin at intended insertion site; history of previous venipunctures and access devices; type and duration of infusion therapy; patient preference for VAD site selection.” In addition, facility policies, procedures, and/or practice guidelines can be used to access proper site selection. [INS, 2016]

NOTE: (Pediatric) Midline catheters are peripheral infusion devices with the tips terminated in either the basilic, cephalic, or brachial vein, distal to the shoulder. The basilic vein is preferred due to vein diameter. The tip does not enter the central vasculature. Additional site selections include veins in the leg with the tip below the groin and in the scalp with tip in the neck, above the thorax (EJV) [INS, 2016].

NOTE: (Pediatric) Prep the insertion site and surrounding skin per facility policies, procedures, and/or practice guidelines. The use of chlorhexidine in premature infants and infants under 2 months of age has a potential risk of skin irritation, chemical burns, and possible hypersensitivity including anaphylactic-like reactions. Povidone Iodine should be removed from the skin after the procedure to prevent tissue damage, absorption, and thyroid suppression. [NANN, 2007]

NOTE: (Pediatric) When infusion volume is a concern in small or pediatric patients, flush with 3 mL per lumen or per facility guidelines.

POSSIBLE COMPLICATIONS

The potential exists for serious complications including:

- Air Embolism
- Bleeding
- Catheter Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Exit Site Infection
- Exit Site Necrosis
- Extravasations
- Fibrin Sheath Formation
- Hematoma
- Heparin Induced Thrombocytopenia
- Hypersensitivity, anaphylactic or anaphylactic-like reaction during placement¹, positioning, flushing of catheter or cleaning of catheter exit site.
- Intolerance Reaction to Implanted Device Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Phlebitis
- Spontaneous Catheter Tip Malposition or Retraction
- Thromboembolism
- Venous Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery
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 re-sterilize.

- Inspect kit for inclusion of all components.

**WARNING:** 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.

1. Identify the Vein and Insertion Site
   
   **A.** Apply a tourniquet above the anticipated insertion site.

   **B.** Select a vein based on patient assessment. Recommended veins are basilic, cephalic and median cubital veins.

   **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 midlines in pediatric patients should place this catheter in this patient population.

   **CAUTION:** Placement of the Provena™ Midline Catheter above antecubital fossa is recommended.

   **CAUTION:** Avoid placement or securement of the catheter where kinking may occur to minimize stress on the catheter, patency problems or patient discomfort.

   **NOTE:** These catheters feature a reverse-taper catheter design. Taper length and size should be taken into account when selecting the appropriate vessel and determining catheter length.

   **C.** Release tourniquet.

   **D.** Assess the selected vein to ensure the vessel size is adequate to accommodate the catheter being placed.

2. Patient Position / Catheter Measurement
   
   **A.** Position the arm at a 90° angle.

   **B.** For midline placement, measure to the desired tip location in the proximal portion of the extremity just distal of the shoulder and deltoid muscle.

   **CAUTION:** The midline catheter tip location should be at or near the axillary line [INS, 2016].

   **NOTE:** External measurement can never exactly duplicate the internal venous anatomy.
3. Skin Preparation
   A. Don prep gloves.
   B. Apply underdrape.
   C. Prepare the site according to institutional policy using sterile technique.
      **WARNING:** When using alcohol or alcohol-containing antiseptics with polyurethane midlines, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.
   D. Remove and discard gloves.

4. Sterile Field Preparation
   A. Apply the tourniquet above the intended insertion site to distend the vessel.
   B. Don sterile gloves.
   C. Apply fenestrated drape and complete sterile field preparation.

5. Pre-flush the Catheter
   **CAUTION:** Do not clamp extension leg when stylet or stiffening wire is in catheter to minimize the risk of component or catheter damage.
   **CAUTION:** Catheter stylet must be wetted prior to stylet repositioning or withdrawal.
   A. Attach a prefilled syringe to the Luer attachment on the T-Lock extension set.
   B. Pre-flush all catheter lumens with sterile saline to wet hydrophilic stylet.
   C. Remove the syringe after pre-flushing.

6. Modification of Catheter Length
   **WARNING:** 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.
   **NOTE:** Catheters can be cut to length if a different length is desired due to patient size and desired point of insertion according to hospital protocol. Catheter depth markings are in centimeters.
   A. Measure the distance from the zero mark to the desired tip location.
   B. Disconnect the T-Lock from the catheter Luer connector.
   C. Withdraw the entire T-lock connector/stylet assembly as one unit.
      **CAUTION:** Catheter stylet must be wetted prior to stylet repositioning or withdrawal.
   D. Retract the stylet to well behind the point the catheter is to be cut.
      **CAUTION:** Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
E. Using a sterile scalpel or scissors, carefully cut the catheter according to institutional policy, if necessary.
   **CAUTION:** The stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet or stiffening wire.

F. Inspect cut surface to assure there is no loose material.

G. Re-advance the T-lock connector/stylet assembly. Assure stylet tip is intact.

H. Lock the T-Lock connector to the catheter hub.

I. Gently retract the stylet through the locked T-lock connector until the stylet tip is contained inside the catheter. **WARNING:** Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and/or risk of patient injury.

7. **Perform Venipuncture**

A. Anesthetize with local anesthesia as required.

B. Insert the safety introducer needle into the desired vein.
   **Alternate Technique:** The safety IV catheter may be used as an alternate to the safety introducer needle. Remove the needle from the catheter after the vein is accessed. **WARNING:** If the artery is entered, withdraw the needle and apply manual pressure for several minutes. **CAUTION:** Do not reinsert needle into IV catheter to minimize the risk of the needle damaging or shearing the IV catheter.

C. Release tourniquet.

D. Remove the guidewire tip protector from the guidewire hoop and insert the flexible end of the guidewire into the introducer needle or IV catheter and into the vein. Advance the guidewire to the desired depth. **CAUTION:** Do not cut guidewire to alter length. **CAUTION:** Do not insert stiff end of guidewire into vessel as this may result in vessel damage. **CAUTION:** Keep sufficient guidewire length exposed at hub to allow for proper handling. A non-controlled guidewire can lead to wire embolism. **CAUTION:** Do not use excessive force when introducing guidewire or microintroducer as this can lead to vessel perforation and bleeding. **CAUTION:** Do not advance the guidewire past the axilla.

E. Gently withdraw and remove the safety introducer needle or safety IV catheter, while holding the guidewire in position. **CAUTION:** If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
F. Advance the small sheath and dilator together as a unit over the guidewire, using a slight rotational motion. If necessary, a small incision may be made adjacent to the guidewire to facilitate insertion of the sheath and dilator. Verify institutional guidelines concerning the use of a safety scalpel prior to making incision. **CAUTION:** Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apart introducer. **CAUTION:** Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion. **CAUTION:** Do not withdraw dilator from microintroducer sheath until sheath is within vessel to minimize the risk of damage to sheath tip.

G. Withdraw the dilator and guidewire, leaving the sheath in place. **WARNING:** Place a finger over the orifice of the sheath to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver until the catheter is inserted into the sheath.

8. **Insert and Advance the Catheter**
   
   A. Insert the catheter into the introducer sheath.
   
   B. Advance the catheter slowly.  
      **NOTE:** Resistance may be felt approximately 7 cm distal of catheter hub when introducing the catheter into the sheath due to an increase in outer diameter (O.D.) The introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.

9. **Complete Catheter Insertion**
   
   A. Complete catheter advancement into the desired position.  
      **WARNING:** (Pediatric) This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.  
      **NOTE:** Midlines should be positioned with the catheter tip distal to the shoulder and deltoid muscle.  
      **CAUTION:** The midline catheter tip location should be at or near the axillary line [INS, 2016].
10. Retract and Remove the Introducer Sheath
   A. Stabilize the catheter position by applying pressure to the vein distal to the introducer sheath.
   B. Withdraw the introducer sheath from the vein and away from the site.
   C. Split the introducer sheath and peel it away from the catheter.
      **CAUTION:** Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.

11. Remove the Stylet / T-Lock Assembly
   A. Disconnect the T-Lock from the catheter Luer connector.
   B. Stabilize the catheter position by applying light pressure to the vein distal to the insertion site.
   C. Slowly remove the T-Lock and stylet.
      **CAUTION:** Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and reattempt stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into the desired position (zero mark).
      **CAUTION:** Never leave stylet or stiffening wire in place after catheter insertion; injury may occur. Remove stylet or stiffening wire and T-lock (as applicable) after insertion.

12. Aspirate and Flush each Lumen
   A. Attach primed extension set and/or saline-filled syringe.
   B. Aspirate for adequate blood return and flush each lumen of the catheter with at least 10 mL of sterile saline to ensure patency. In addition, lock each lumen of the catheter with sterile saline.
      **CAUTION:** To reduce potential for blood backflow into the catheter tip, always remove syringes slowly while injecting the last 0.5 mL of sterile saline.
   C. Attach a new sterile injection/needleless cap to each catheter hub.
      **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 (allowing air entry) while changing injection caps, hold the connector below the level of the patient’s heart before removing the injection/needleless cap.

13. Securing the Provena™ Midline Catheter
   The StatLock® Stabilization Device is included in Provena™ Midline Catheter kits. Please refer to Instructions For Use on the proper use and removal. The StatLock® Stabilization Device should be monitored daily and replaced at least every seven days.
   **CAUTION:** The catheter must be secured in place to minimize risk of catheter breakage and embolization.
**WARNING:** When using alcohol or alcohol-containing antiseptics with polyurethane midlines, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

**WARNING:** Alcohol should not be used to lock, soak or de-clot polyurethane midlines because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

**WARNING:** Acetone-based solutions and polyethylene glycol containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.

**WARNING:** Do not wipe the catheter with acetone-based solutions, tincture of iodine or polyethylene glycol-containing ointments. These can damage the polyurethane material if used over time.

**CAUTION:** Do not bend catheter at sharp angles during implantation. This can compromise catheter patency.

**CAUTION:** Do not occlude or cut catheter when using sutures to secure catheter.

**CAUTION:** Do not suture through or around any part of the catheter’s tubing (shaft or extension legs). If using sutures to secure catheter USE THE SUTURE WINGS and make sure they do not occlude, puncture, or cut the catheter.

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**THE STATLOCK® STABILIZATION DEVICE PROCEDURE**

### Single Lumen

2. Cover site and StatLock® Stabilization Device with transparent dressing.
3. Place anchor tape sticky side up, under hub. Wedge tape between hub and wings.
4. Chevron anchor tape on top of transparent dressing.

### Multi Lumen

2. Cover site and StatLock® Stabilization Device with transparent dressing.
3. Place first anchor tape sticky side up, under one extension leg. Wedge tape between hub and wings. Chevron anchor tape on top of transparent dressing.
4. Place additional anchor tape sticky side up under remaining hubs. Wedge tape between hubs and wings. Chevron anchor tape on top of transparent dressing.
**TAPE STRIP SECUREMENT PROCEDURE**

**Single Lumen**

1. Place first anchor tape over wings or bifurcation.
2. Cover site and first anchor tape with transparent dressing up to hub, but not over hub.
3. Place second anchor tape sticky side up under hub and close to transparent dressing. Wedge tape between hub and wings.
4. Chevron second anchor tape on top of transparent dressing and place third anchor tape over hub.

**Multi Lumen**

1. Place first anchor tape over wings or bifurcation.
2. Cover site and first anchor tape with transparent dressing up to hub, but not over hub.
3. Place second anchor tape sticky side up under hub and close to transparent dressing. Wedge tape between hub and wings. Anchor only one hub of multi lumen catheter.
4. Place additional anchor tape sticky side up under remaining hubs. Wedge tape between hubs and wings. Chevron anchor tape on top of transparent dressing.

**14. Power Injection Procedure**

**WARNING:** Provena™ Midline Catheter 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.

A. Remove the injection/needleless cap from the Provena™ Midline Catheter.
B. Attach a 10 mL or larger syringe filled with sterile saline.
C. Aspirate for adequate blood return and vigorously flush the catheter with the full 10 mL of sterile saline. This will ensure the patency of the Provena™ Midline Catheter and prevent damage to the catheter. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed with power injection study until occlusion has been cleared.

**WARNING:** Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.

D. Detach syringe.
E. Attach the power injection device to the Provena™ Midline Catheter per manufacturer’s recommendations.
F. Contrast media should be warmed to body temperature prior to power injection.

**WARNING:** Failure to warm contrast media to the body temperature prior to power injection may result in catheter failure.

Warning: Use of lumens not marked “Power Injectable” for power injection may result in catheter failure.
G. Complete power injection study taking care not to exceed the flow rate limits. **WARNING:** Power injector machine pressure limiting feature may not prevent over-pressurizations of an occluded catheter, which may cause catheter failure.  
**WARNING:** Exceeding the maximum flow rate or the maximum pressure of power injectors of 325 psi may result in catheter failure and/or catheter tip displacement.

H. Disconnect the power injection device.

I. Attach a new sterile injection / needleless cap to the Provena™ Midline Catheter.

J. Flush the Provena™ Midline Catheter with 10 mL of sterile saline, using a 10 mL or larger syringe. In addition, lock each lumen of the catheter with sterile saline.

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**Provena™ Midline Catheters Maximum Flow Rate**

| Flow Rate | 6mL/sec |

The Provena™ Midline Catheter testing included 10 power injection cycles.

15. Suggested Catheter Maintenance

**CAUTION:** As reported in literature, anaphylactic or anaphylactic-like reactions occur in a small percentage of the population during placement¹, positioning¹, flushing of catheters or cleaning of catheter exit site². These reactions are reported in association with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some patients. Be aware of the potential symptoms or signs of these reactions and take precautionary steps as dictated by institution protocol for their prevention or treatment.

**CAUTION:** If CHG allergy is suspected, confirmatory testing is recommended⁴,⁵

A. Dressing Changes

- Assess the dressing in the first 24 hours for accumulation of blood, fluid or moisture beneath the dressing. During all dressing changes, assess the external length of the catheter to determine if migration of the catheter has occurred. Periodically confirm catheter placement, tip location, patency and security of dressing.

**CAUTION:** Do not use scissors to remove dressing to minimize the risk of cutting catheter.

**CAUTION:** Accessories and components used in conjunction with this device should incorporate Luer lock connections. Do not overtighten the Luer connector.

B. Flushing

- Flush each lumen of the catheter with 10 mL of sterile saline every 12 hours or after each use. In addition, lock each lumen of the catheter with sterile saline.

**NOTE:** Flush with 20 mL of sterile saline after blood therapy.

**CAUTION:** DO NOT USE A SYRINGE SMALLER THAN 10 mL TO FLUSH AND CONFIRM PATENCY. Patency should be assessed with a 10 mL or larger syringe with sterile saline. Upon confirmation of patency, administration of medication should be given in a syringe appropriately sized for the dose. Do not infuse against resistance.

**WARNING:** If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
C. 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 lumen will neither flush nor aspirate and it has been determined that the catheter is occluded with blood, a de-clotting procedure per institution protocol may be appropriate.

D. When Cleaning the Exit Site
- Maintain according to hospital protocol.
- Use chlorhexidine gluconate, povidone iodine, or other antiseptic solution per facility protocol to clean the exit site around the catheter.
- Allow all cleaning agents / antiseptics to dry completely before applying dressing.

**WARNING:** Acetone-based solutions and polyethylene glycol containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.

16. Catheter Removal
A. Remove dressing, and StatLock® Stabilization Device or tape securement strips.
B. Grasp catheter near insertion site.
C. Remove slowly. Do not use excessive force.
D. If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.
E. Resume removal procedure.
F. Inspect the end of the catheter and the catheter length to ensure complete removal.

**CAUTION:** After use, this product may be a potential biohazard. Handle and dispose of in accordance with medical practice and applicable local, state and federal laws and regulations.

**WARNING:** Intended for Single Use. 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.

**CAUTION:** Do not use scissors to remove dressing to minimize the risk of cutting catheter.

REFERENCES

Manufacturer:
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 USA
800-545-0890, 801-522-5000
www.bardaccess.com

Clinical Information:
1-800-443-3385 (USA)
Email:
medical.services@crbard.com

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