Indications
The PowerGlide™ 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 procedure. The PowerGlide™ Midline Catheter is suitable for use with power injectors.

Product Description
The PowerGlide™ 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 catheter rated for power injection.

Contents are supplied sterile. Sterilized using ethylene oxide. DO NOT RESTERILIZE.

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.
• Past irradiation of prospective insertion site.
• Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
• Local tissue factors will prevent proper device stabilization and/or access.

Warnings
• When using alcohol or alcohol containing antiseptics with PowerGlide™ Midline Catheters, 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 declot PowerGlide™ Midline Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
• Acetone and polyethylene glycol containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.
• Do not wipe the catheter with acetone based solutions or polyethylene glycol containing ointments. These can damage the polyurethane material if used over time.
• 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.
• Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
• Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may cause catheter failure.
• Exceeding the maximum flow rate as printed on the catheter hub, or the maximum pressure of power injectors of 325 psi (2241 kPa), may result in catheter failure and/or catheter tip displacement.
• PowerGlide™ 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.
• If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
• 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 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. This may result in damage to the catheter. 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.
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.
- Rx Only: 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.
- Caution: Blood return will slow or stop once the guidewire is fully extended.
- Caution: ALWAYS keep the housing stationary while advancing catheter handles. Do NOT hold the catheter handle stationary and retract the housing.
- Caution: Failure to keep housing stationary will prevent catheter from entering vein and cause delays in procedure.
- Caution: Failure to warm contrast media prior to power injection may result in flow rates less than promoted on the catheter hub.
- Caution: Make sure guidewire is fully extended before moving on to the next step.

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.
- Fluid infusions may be administered using a syringe smaller than 10 mL provided that no resistance is encountered.

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
- Fibrin Sheath Formation
- Hematoma
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- 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™ Midline Catheter Diagram

1. Identify the vein and insertion site.
   NOTE: (Pediatric) Insertion of the PowerGlide™ 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) "Site selection for vascular access shall include assessment of the 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." In addition, facility policies, procedures, and/or practice guidelines can be used to assess proper site selection. [INS, 2011]
   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].

2. Clean and prepare insertion site per your institution's policy.
   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]

Remove needle sheath from plastic housing.
3. To break catheter tip adhesion, hold back grips while advancing catheter approximately 1/8" (3 mm) off the needle using the catheter handle and return to original position.

4. Insert the needle into the vein. When venous access is achieved, blood return can be seen along the catheter tubing. **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.

5. While holding the needle in place using the front grips, advance the guidewire using the guidewire push-off until guidewire is fully extended and locks into place. Guidewire should advance smoothly and without resistance.

**Caution:** Make sure guidewire is fully extended before moving on to the next step. **Caution:** Blood return will slow or stop once the guidewire is fully extended.
6. Grip the plastic housing by holding the back grips and fully advance the catheter using the catheter handle. This inserts the catheter into the vein.

**Caution:** ALWAYS keep the housing stationary while advancing catheter handle. Do NOT hold the catheter handle stationary and retract the housing.

**Caution:** Failure to keep housing stationary will prevent catheter from entering vein and cause delays in procedure.

**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. This may result in damage to the catheter. 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. Hold catheter in place using catheter handle and fully remove housing. The needle safety mechanism activates upon removal from handle. Blood flow will be restricted by a plug located in the handle.

**Note:** Catheter handle remains temporarily connected to catheter hub after housing removal.

**Note:** Discard housing and needle into puncture resistant, leak proof sharps container.

8. Hold catheter hub and twist and remove catheter handle. Immediately attach primed extension set and/or injection cap to the catheter per your institution's policy.
StatLock® Stabilization Device and GuardIVa® Dressing Preparation

9. 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.

10. 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.


13. Place: Place the StatLock® Stabilization Device on targeted skin one side at a time.

Suggested Catheter Maintenance

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

- **Dressing changes**
  Assess 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 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 nor 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: Do not wipe the catheter with acetone-based solutions or polyethylene glycol containing ointments. These can damage the polyurethane material if used over time.

  - Maintain according to hospital protocol. Avoid using acetone based solutions or ointment. These substances are known to degrade polyurethane.
  - 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):

<table>
<thead>
<tr>
<th>Gauge Size</th>
<th>8 cm</th>
<th>10 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 GA</td>
<td>0.16 mL</td>
<td>0.17 mL</td>
</tr>
<tr>
<td>20 GA</td>
<td>0.13 mL</td>
<td>0.15 mL</td>
</tr>
<tr>
<td>22 GA</td>
<td>0.13 mL</td>
<td></td>
</tr>
</tbody>
</table>

StatLock® Stabilization Device Removal
Carefully remove overlying dressing using stretch technique.
1. **Dissolve** adhesive with alcohol swab while gently lifting the StatLock® Stabilization Device pad.
2. **Disengage** catheter from the StatLock® Stabilization Device retainer.
3. **Document** the StatLock® Stabilization Device dressing change in the patient chart.
4. **Dispose** of all equipment in appropriate containers.

GuardIVa® Dressing Removal
1. 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.
2. 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™ 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.

Power Injection Procedure
1. Remove the injection/needleless cap from the PowerGlide™ Midline Catheter.
2. Attach a 10 mL or larger syringe filled with sterile normal saline.
3. Aspirate for adequate blood return and vigorously flush the catheter with the full 10 mL of sterile normal 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™ 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.
   **Caution:** Failure to warm contrast media prior to power injection may result in flow rates less than printed on the catheter hub.
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 over-pressurization 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. Replace the injection/needleless cap on the PowerGlide™ Midline Catheter.
10. Flush the PowerGlide™ Midline Catheter with 10 mL of 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™ Midline Catheter testing included 5 power injection cycles.

<table>
<thead>
<tr>
<th>Gauge Size</th>
<th>Contrast Media(^1) Temperature</th>
<th>Contrast Media(^1) Viscosity</th>
<th>Max Flow (mL/sec)</th>
<th>Injector Safety Cut-Off (psi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 GA</td>
<td>Warm  (37°C)</td>
<td>11.8 cP</td>
<td>7</td>
<td>325 Max</td>
</tr>
<tr>
<td>20 GA</td>
<td></td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>22 GA</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\)Visipaque 320

**Note:** When using room temperature (20°C) contrast with a 26.6 cP viscosity, maximum flow rate may not be achieved.
StatLock® Stabilization Device Specific Information

Catheter Stabilization Device with Power Injector Extension Set

Read carefully before use:

Do not alter the StatLock® Stabilization Device or components. Procedure must be performed by trained personnel with knowledge of anatomical landmarks, safe technique and potential complications.

**Contraindications:**

Known tape or adhesive allergies.

**Warnings and Precautions:**

1. Do not use the StatLock® Stabilization Device where loss of adherence could occur, such as with a confused patient, diaphoretic or non-adherent skin or when the access device is not monitored daily.
2. Needle-free valve (if present) contraindicated for blunt cannula systems.
3. May be used with low pressure power injectors up to 325 psi and maximum flow rates up to 10 mL/second.
4. For Power Injector use: The extension set and needle-free valve (if present) must be secured to other devices with a luer lock connection; other devices must also be rated for up to 325 psi.
5. The extension set's slide clamp should not be used to stop or restrict the flow of fluid when connected to a power injector or infusion pump.
6. Observe universal blood and body fluid precautions and infection control procedures, during application and removal of the StatLock® Stabilization Device.
7. Avoid the contact with alcohol or acetone, both can weaken bonding of components and the StatLock® Stabilization Device pad adherence.
9. Remove oil and moisturizer from targeted skin area.
10. The StatLock® Stabilization Device pad adherence and catheter/tube position should be routinely inspected.
11. Orient the StatLock® Stabilization Device so arrow points toward catheter tip.
12. The StatLock® Stabilization Device should be replaced at least every 7 days.
13. 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.
14. Do not re-sterilize. The sterility of the single use device is not guaranteed following re-sterilization because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Re-sterilization may compromise the structural integrity, essential material and/or design characteristics and may lead to an unpredictable loss of functionality and/or device failure.

**Extension Set**

**Intended/Indications for Use:**
The Intravenous Power Injector Extension Set is intended to allow for the aspiration, injection or gravity/pump flow of fluids and may be used with low pressure power injectors having a maximum pressure setting of 325 psi and maximum flow rate of 10 mL/second. When used with a low pressure power injector, the Intravenous Power Injector Extension Set must be secured with other devices rated for pressures up to 325 psi with a luer lock connection.

**Directions for Use:**
Use aseptic technique.

1. Tighten all connections.
2. Remove Protector Caps (A) as required.
3. Connect Female Port (B) to fluid delivery line or device and prime/flush.
4. Connect Male Port (C) to catheter hub.
5. Open Slide Clamp (D) for unimpeded flow.

**General Precautions:**

1. Avoid air trapped in set. Puncturing tube can cause air embolism or leakage.
2. Avoid contact with alcohol, it can alter the structure of plastic components.

**NOTES:**

1. Replace extension set and needleless connectors per CDC guidelines.
2. Dispose of all equipment, including the extension set, in appropriate containers. 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.
Extension Set Priming Volume(s):

Macro Bore (0.40cmOD x 0.22cmID)

6" P Extension Set 0.32 mL

Symbols Legend:

- Do not use if package is damaged
- Do not reuse
- Manufacturer
- Length
- Sterile
- Sterilized using ethylene oxide
- Lot number
- Quantity
- Use by
- Product catalog number
- Non Pyrogenic

This product and packaging is not made with natural rubber latex

This product and packaging do not contain DEHP

References:


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: November, 2014

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