DESCRIPTION
The ProGuide® Indwelling Dialysis Catheter is indicated for use in maintaining long-term venous access for hemodialysis and hemofiltration. The ProGuide™ Valved Pealaway Introducer is intended for use in the percutaneous insertion of catheters into the femoral vein.

INDICATIONS FOR USE
The ProGuide Indwelling Dialysis Catheter is indicated for use in maintaining long-term venous access for hemodialysis and hemofiltration. The ProGuide™ Valved Pealaway Introducer is intended for use in the percutaneous insertion of catheters into the femoral vein.

GENERAL CAUTION STATEMENTS
• Vessel erosion • Risks normally associated with local anesthesia and subcutaneous tunnel.
• Vascular (venous) thrombosis • Ventricular thrombosis
• Laceration of vessels or viscus • Lumen thrombosis
• Fibrin sheath formation • Hematoma
• Extravasation • Exsanguination
• Catheter occlusion • Catheter damage due to compression between bone and subcutaneous tunnel.
• Cardiac arrhythmia • Cardiac tamponade
• Bleeding at site • Brachial plexus injury

SITE PREPARATION
1. The patient should be placed in a modified Trendelenburg position, with the upper chest exposed and the local tunnel slightly to the opposite side of the insertion site.

PRECAUTION: Use standard hospital procedures when applicable. The patient should be placed in a modified Trendelenburg position, with the upper chest exposed and the local tunnel slightly to the opposite side of the insertion site.

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PLACEMENT INTO RIGHT OR LEFT FEMORAL INTERNAL JUGULAR OR SUBCLAVIAN WITH A VALVED PEELAWAY INTRODUCER

VASCULAR ACCESS AND GUIDE WIRE INSERTION
1. Prepare the insertion site by skin disinfection and draping of the anatomical site used.

PRECAUTION: Only clamp the catheter with the in-line tubing clamps provided. CAUTION: Do not clamp the dual lumen portion of the catheter body. Clamp only the clear extension tubing.

NOTE: Mini access (“micropuncture”) is recommended. Follow manufacturer’s guidelines for use and by aspirating then irrigating the catheter prior to each use. Always aspirate first then irrigate.

2. Irriate each lumen of the catheter with heparinized saline and clamp each extension prior to catheter insertion.

CAUTION: Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion. The catheter should not be forced through the tunnel.

3. Insert the dilator through the valve and the remaining catheter loop (“knuckle”) gently into the subcutaneous tunnel. The incision should be wide enough to accommodate the cuff, approximately 1 cm.  Use blunt finger dissection to create a tunnel in the soft tissue. Pull the dilator and the catheter through the tunnel as a unit. The catheter should be advanced into the subcutaneous tunnel. Note: Do not allow the catheter to protrude through the skin.

NOTE: Mini access (“micropuncture”) is recommended. Follow manufacturer’s guidelines for use and by aspirating then irrigating the catheter prior to each use. Always aspirate first then irrigate.  

4. While maintaining guide wire position in the vein, advance the locked peelaway introducer and withdraw the dilator and wire from the catheter.

CAUTION: The FlowGuard will also reduce air intake. At 12 mmHg vacuum pressure the FlowGuard can be used to decrease air and blood loss. If the FlowGuard is not available, the catheter can be advanced single lumen at a time and blood aspiration prior to each use. Always aspirate first then irrigate.

5. Correctly position the cuff and tunneled portion of the catheter.

CAUTION: The length of the guide wire inserted is determined by the size of the patient and the vessel. 

6. Pull valve and assemble the cannula into the tunneler sheath. Ensure the cannula is seated properly prior to tunneler assembly.

CAUTION: Care should be taken not to advance the split sheath too far into the vessel as a delay or prevent cuff in-growth.

7. With the catheter advanced and positioned, crack the valve and pull the tunneler from the catheter.

CAUTION: The FlowGuard is designed to reduce blood loss but is not a hemostasis valve. The valve will substantially reduce the rate of blood flow but not completely stop the flow.

8. If resistance is encountered, further blunt dissection may facilitate insertion. The catheter should not be forced through the tunnel.

CAUTION: The FlowGuard is designed to reduce blood loss but is not a hemostasis valve. The valve will substantially reduce the rate of blood flow but not completely stop the flow.

9. With the cannula in place, pull the distal end of the tunneler from the catheter while maintaining the guide wire position in the vein. Advancing the tunneler and connecting the distal end of the cannula should be forced through the tunneled catheter. 

CAUTION: The FlowGuard is designed to reduce blood loss but is not a hemostasis valve. The valve will substantially reduce the rate of blood flow but not completely stop the flow.

10. After advancing the tunneler, clamp the distal end of the tunneler and proceed as follows: a) Reassess vascular access b) Verify the cannula is seated properly prior to tunneler assembly.

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11. Correctly position the cuff and tunneled portion of the catheter.

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REFERENCE:
2. United States Patent 5,735,729
4. United States Patent 6,035,431

PRECAUTION: Follow Universal Precautions when inserting and maintaining this device.

NOTE: Mini access (“micropuncture”) is recommended. Follow manufacturer’s guidelines for use and by aspirating then irrigating the catheter prior to each use. Always aspirate first then irrigate.
1. Insert the introducer needle with an attached syringe and advance it into the target vein, in the direction of blood flow. Aspirate prior to the needle insertion. Smear a small amount of blood onto the needle to confirm correct positioning in the vein.

2. With the blunt tunneler, gently lead the catheter and tunneler connection into the exit site and pass it into the subcutaneous tissue. If the catheter or tunneler is not visible, remove the tunneler from the subcutaneous tunnel and then reinsert it. If the tunneler is not visible, remove and reinsert the catheter.

3. Attach the tunneler to the catheter’s venous lumen. Slide the tip of the catheter over the tri-ball connection and rests adjacent to the sheath stop. This allows the catheter to be threaded through the tissue as the tunneler is advanced.

4. Suture the pocket created for the small remaining catheter loop (“knuckle”) at the venous entry site.

5. Determine the catheter exit site on the chest wall, approximately 8-10 cm below the clavicle that lies in a subcutaneous tunnel opening at the catheter exit site for each patient. The ideal site should be positioned at the junction of the superior vena cava and right atrium to optimize blood flow.

6. Place the tunneler in the correct position, keeping the subcutaneous tunnel opening at the catheter exit site for each patient. The ideal site should be positioned at the junction of the superior vena cava and right atrium to optimize blood flow.

7. Use blunt dissection to create the subcutaneous tunnel opening at the catheter exit site for each patient. The ideal site should be positioned at the junction of the superior vena cava and right atrium to optimize blood flow.

8. Remove the stylet and guide wire from the venous lumen.

9. Place the catheter small remaining catheter loop (“knuckle”) into the subcutaneous tunnel opening created at the venous entry site.

10. When the skin has been entered, remove the syringe leaving the needle in place and place the site dressing as per institutional protocol. The catheter should not be forced through the tunnel. Dissection may facilitate insertion. The catheter should not be forced through the tunnel.

11. Secure the catheter and tunneler with a non-sutured adhesive dressing using a small remaining catheter loop (“knuckle”) from the catheter after the post-occlusion system is removed. The heparin solution must be removed from each lumen prior to treatment to avoid systemic heparinization of the patient. Heparin should be used with polyurethane catheters. However, care should be taken to avoid prolonged or excessive contact with the solution(s).

12. Use the tunneler to gently lead the catheter and tunneler connection into the exit site and pass it into the subcutaneous tissue. If the catheter or tunneler is not visible, remove the tunneler from the subcutaneous tunnel and then reinsert it. If the tunneler is not visible, remove and reinsert the catheter.

13. Attach the tunneler to the catheter’s venous lumen. Slide the tip of the catheter over the tri-ball connection and rests adjacent to the sheath stop. This allows the catheter to be threaded through the tissue as the tunneler is advanced.

14. Suture the pocket created for the small remaining catheter loop (“knuckle”) at the venous entry site.

15. Correctly position the cuff and tunneler portion of the catheter.