DuoGlide* Short-Term Dialysis Catheter

Dual Lumen Catheter
Instructions For Use

DESCRIPTION
The catheter is divided into two separate round lumens permitting continuous blood flow with one puncture.

All **DuoGlide*** catheters are made of thermosensitive polyurethane, which softens when exposed to body temperature.

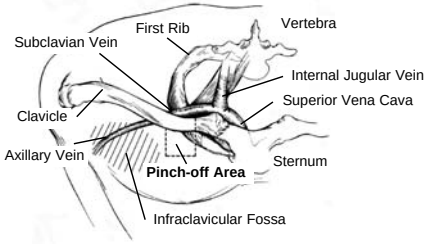
STERILE EO

INDICATIONS FOR USE
DuoGlide* Dual Lumen catheters are indicated for use in attaining short term **(less than 30 days)** vascular access for hemodialysis, hemoperfusion and apheresis therapy via the jugular, subclavian or femoral vein.

CONTRAINDICATIONS
- The catheter is intended for short-term vascular access only and is not to be used for any purpose other than indicated in these instructions.

ChloraPrep* Solution One-Step Applicator Contraindications
USA Only
- Do not use in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption.
- Do not use on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol.
- Do not use for lumbar puncture or allow contact with meninges.
- Do not use on open skin wounds or as a general skin cleanser.

WARNINGS
- **SUBCLAVIAN ONLY. Pinch-off Prevention: Percutaneous insertion of the catheter must be made into the axillary-subclavian vein at the junction of the outer and mid-third of the clavicle lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle and can lead to damage or fracture and embolization of the catheter. [1] Fluoroscopic or radiographic confirmation of catheter tip placement should be helpful in demonstrating that the catheter is not being pinched by the first rib and clavicle.[1]**



Signs of Pinch-off

Clinical:
- Difficulty with blood withdrawal.
- Resistance to infusion of fluids.
- Patient position changes required for infusion of fluids or blood withdrawal.

Radiologic: (see table)
- Grade 1 or 2 distortion on chest X-ray. **Pinch-off** should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows: [2,3]

Radiologic Signs of Pinch-Off

Grade	Severity	Recommended Action
Grade 0	No Distortion	No action.
Grade 1	Distortion present **without** luminal narrowing	Chest x-ray should be taken to monitor progression of pinch-off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.
Grade 2	Distortion present **with** luminal narrowing	Removal of the catheter should be considered.
Grade 3	Catheter transection or fracture	Prompt removal of the catheter.

- **The catheter must not be left in the femoral vein longer than three days. To maintain peak performance it is recommended that subclavian and jugular catheters be replaced after four weeks.**
- **Alcohol or alcohol-containing antiseptics (such as chlorhexidine) may be used to clean the catheter/skin site; however, care should be taken to avoid prolonged or excessive contact of the catheter with the solution(s). Solutions should be allowed to completely dry before applying occlusive dressing.**
- **Acetone and Polyethylene Glycol (PEG)-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments (e.g., Polysporin* ointment) are the preferred alternative.**
- **Do not resterilize the catheter or components by any method. The manufacturer will not be liable for any damages caused by re-use of the catheter or accessories.**
- **Place all clamps near the center of the polyurethane extension pieces. Polyurethane may develop cuts or tears if subjected to excessive pulling or contact with rough edges. Repeated clamping near or on the Luer-lock connectors may cause tubing fatigue and possible disconnection.**
- **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.**
- **Repeated over-tightening of bloodlines, syringes and caps will reduce connector life and may lead to connector failure.**
- **Enzymes in blood and heparin may cause temporary sticking of the extensions when clamped for extended periods of time. To release, open clamp and slide away, gently rotating the tubing between fingers and thumb until the tubing separates.**
- **To avoid damage to vessels and viscus, infusion pressures must not exceed 25 psi (172 kPa). The use of a 10 ml or larger syringe is recommended because smaller syringes generate more pressure than larger syringes. NOTE: A three pound (13.3 Newton) force on the plunger of a 3 ml syringe generates pressure in excess of 30 psi (206 kPa) whereas the same three pound (13.3 Newton) force on the plunger of a 10 ml syringe generates less than 15 psi (103 kPa) of pressure.**
- **Accessories and components used in conjunction with this catheter must incorporate Luer-lock adapters in order to avoid inadvertent disconnection.**
- **Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the opening of the catheter lumens.**

- **Before dialysis begins, all connections to the extracorporeal circuit must be checked carefully. During all dialysis procedures frequent visual inspection must be conducted to detect leaks and prevent blood loss or entry of air into the extracorporeal circuit. Excess blood leakage may lead to patient shock.**
- **In the rare event of a leak, the catheter must be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis procedure.**
- **If the catheter is not used immediately for treatment, follow the suggested Catheter Patency Guidelines.**
- **Failure to clamp extensions when not in use may lead to air embolism.**
- **Verification of the catheter tip location must be confirmed by x-ray to ensure proper placement.**
- **For optimal product performance and to avoid complications, do not insert any portion of the curve into the vein.**
- **To prevent systemic heparinization of the patient, the heparin solution must be aspirated out of both lumens immediately prior to using the catheter.**
- **For jugular and subclavian insertion, the patient must be placed on a cardiac monitor during this procedure. Cardiac arrhythmia may result if the guidewire is allowed to pass into the right atrium. The guidewire must be held securely during the procedure.[8]**
- **The risk of infection is increased with femoral vein insertion.**
- **Recirculation in femoral catheters was reportedly significantly greater than in internal jugular catheters.**
- **Before attempting the insertion of the catheter, ensure that you are familiar with the possible complications listed below and their emergency treatment should they occur.**
- **Cannulation of the left internal jugular vein was reportedly associated with higher incidence of complications compared to catheter placement in the right internal jugular vein.[4]**
- **After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and all applicable local, state and federal laws and regulations.**

CHLORAPREP* SOLUTION ONE-STEP APPLICATOR WARNINGS

- **Flammable, keep away from fire or flames.**
- **Do not use with electrocautery procedures.**
- **For external use only.**
- **When using this product keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a physician.**
- **Stop use and ask doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.**
- **Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.**

PRECAUTIONS:

- **Rx Only - Federal (USA) law restricts this device to sale by or on the order of a physician.**
- **⚠ Carefully read and follow all instructions prior to use.**
- **Only qualified health care practitioners should insert, manipulate and remove these devices.**
- **Strict aseptic technique must be used during the insertion, maintenance and catheter removal procedures.**
- **Do not pull back guidewire over needle bevel as this may sever the end of the guidewire. The introducer needle must be removed first. Also, if unusual resistance is met during manipulation of the guidewire, discontinue the procedure and determine the cause of resistance before proceeding. Withdraw needle and guidewire if cause of resistance cannot be determined.**
- **Do not allow the guidewire to inadvertently advance totally into the vessel.**
- **For jugular and subclavian insertion, the catheter tip should not be located in the right atrium.**
- **Left sided placement in particular, may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC.[5,6]**

POSSIBLE COMPLICATIONS

The use of an indwelling central venous catheter provides an important means of venous access for critically ill patients; however, the potential exists for serious complications including the following:

- Air Embolism
- Arterial Puncture
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Cuff Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage Due to Compression Between the Clavicle and First Rib
- Catheter-Related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemomediastinum
- Hemothorax
- Hydrothorax
- Inflammation, Necrosis or Scarring of Skin Over Implant Area
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Perforation of Vessel or Viscus
- Phlebitis
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Venous Stenosis
- Venous Thrombosis
- Ventricular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-operative Recovery

These and other complications are well documented in medical literature and must be carefully considered before placing the catheter. Placement and care of the catheters must be performed only by persons knowledgeable of the risks involved and qualified in the procedures.

INSTRUCTIONS FOR CATHETER INSERTION

1. The catheter must be inserted only under strict aseptic conditions. For **Jugular** or **Subclavian** insertion, the patient must be in a modified Trendelenburg position, with the head turned to the side opposite that of the insertion site. A small rolled towel may be inserted between the shoulder blades. For **Femoral** insertion, place patient in supine position to expose the side of the groin to be accessed.
2. Prepare the access site using standard surgical technique and drape the prepped area. If hair removal is necessary, use clippers or depilatories. Next, scrub the entire area preferably with chlorhexidine gluconate unless contraindicated in which case povidone–iodine may be used. If using the ChloraPrep* Solution One-Step Applicator perform skin preparation using the following steps:
   - Prepare the site with the ChloraPrep* Solution One-Step Applicator or according to institution protocol using sterile technique.
   - Pinch the wings of the ChloraPrep* Solution One-Step Applicator to break the ampule and release the antiseptic. Do not touch the sponge.
   - Wet the sponge by repeatedly pressing and releasing the sponge against the treatment area until fluid is visible on the skin.
   - Use repeated back-and-forth strokes of the sponge for at least 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to dry for approximately 30 seconds. Do not blot or wipe away.
   - Maximum treatment area for one applicator is approximately 130 cm^2 (approximately 4 x 5 in.). Discard the applicator after a single use.
   - Remove and discard gloves.

CHLORAPREP* SOLUTION ONE-STEP APPLICATOR WARNINGS

- Flammable, keep away from fire or flames.
- Do not use with electrocautery procedures.
- For external use only.
- When using this product keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a physician.
- Stop use and ask doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.
- Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

3. Prepare a sterile field throughout the procedure. The operator should wear a cap, mask, sterile gown, sterile gloves, and use a large sterile drape to cover the patient.
4. The insertion site is identified. A local anesthetic is injected over the site.
5. A syringe is attached to an introducer needle that will permit passage of a 0.035 inch (0.89 mm) guidewire.
6. The introducer needle is inserted into the identified vein.
7. The syringe is removed leaving the introducer needle in place.
   WARNING: For jugular and subclavian insertion, the patient must be placed on a cardiac monitor during this procedure. Cardiac arrhythmia may result if the guidewire is allowed to pass into the right atrium. The guidewire must be held securely during the procedure.

8. The flexible end of a guidewire is inserted through the introducer needle into the vein.
   CAUTION: Do not pull back guidewire over needle bevel as this may sever the end of the guidewire. The introducer needle must be removed first. Also, if unusual resistance is met during manipulation of the guidewire, discontinue the procedure and determine the cause of resistance before proceeding. Withdraw needle and guidewire if cause of resistance cannot be determined.
9. Holding the guidewire securely in place, remove the introducer needle. **CAUTION:** Do not allow the guidewire to inadvertently advance totally into the vessel.
10. The introducer needle tract is widened by creating a small surgical incision at the skin exit site. The incision should be slightly larger than the wide/flat side of the catheter.
11. Use the **Dualator*** vessel dilator(s) to dilate the subcutaneous tissues. Dilate 2-3 times with slow, gradual advancements. The larger portion of the **Dualator*** dilator device must enter the vein prior to catheter insertion.
12. Flush each lumen with heparinized saline prior to insertion and clamp the arterial (red) lumen.
13. The venous clamp must be in the open position to allow the catheter to pass completely over the wire and into the vein.
14. The dual lumen catheter is passed over the proximal end of the guidewire by inserting the guidewire tip into the tapered end of the catheter. Insert the catheter flat side to the skin.
15. Pinch guidewire and the catheter together, advance together in 5 to 10 cm increments (retract wire as needed). Do not twist the catheter during over-the-guidewire insertion.
16. The depth markings in one cm increments may be used to determine insertion depth.
17. The catheter tip should be in the lower superior vena cava for optimal performance. If placed femorally, the catheter tip should be placed in the inferior vena cava to minimize recirculation.[8]
    CAUTION: For jugular and subclavian insertion, the catheter tip must be located above the junction of the superior vena cava and right atrium. **WARNING:** Verification of the catheter tip location must be confirmed by x-ray.
18. The guidewire is removed, and the venous clamp is closed. Both lumens are irrigated again with heparinized saline filled syringes. (It is necessary to open the extension clamps during the irrigation procedure). Both the arterial and venous clamps are now closed and the injection caps are placed over the ends of each Luer-lock connector on the extension pieces.
19. The rotatable, pre-attached suture wing is oriented to the skin surface and the catheter is attached using suture.
20. When placing the catheter, use the removable suture wing to minimize movement at the exit site. I.) Using your fingers, squeeze the suture wing together so that it splits open and place the wing around the catheter near the venipuncture site. II.) Secure the wing onto the catheter by tying sutures around the wing using the suture grooves. III.) Secure the removable wing in place by suturing through the holes or by using adhesive wound closures. **WARNING:** For optimal product performance and to avoid complications, do not insert any portion of the curve into the vein.
21. A sterile adhesive transparent dressing is used to cover the skin exit site.
22. The catheter is now ready for use. For hemodialysis, hemoperfusion, or apheresis the arterial lumen of the catheter is connected to the arterial side of the extracorporeal circuit. The venous lumen of the catheter is connected to the venous side of the extracorporeal circuit.

CATHETER PATENCY GUIDELINES

1. Flush arterial and venous lumens with a minimum of 10 mL of sterile saline using a 10 mL or larger syringe.
   WARNING: To avoid damage to vessels and viscus, infusion pressures whould not exceed 25 psi (172 kPA). The use of a 10 mL or larger syring is recommended because smaller syringes generate more pressure than larger syringes.
2. Inject heparin solution into each lumen in amounts equal to the priming volumes as printed on the catheter clamps. Be sure to clamp each lumen immediately and attach end caps. **WARNING:** Failure to clamp extensions when not in use may lead to air embolism.
3. For additional security, suture the entry site to anchor the catheter.
4. Follow your hospital protocal for dressing change and exit site care. Allow alcohol-containing agents (e.g., Chrolaprep[1] solution) to air dry completely before dressing the catheter.
   WARNING: Acetone and Polyethylene Glycol (PEG) - containing ointments can cause failure of this device and should not be used on polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments (e.g., Polysporin* ointment) are the preferred alternative.
5. Verify the catheter tip location with x-ray or fluoroscopy.

PERFORMANCE GUIDELINES: Flow rate vs venous pressures†

Flow Rate vs Lumen Pressure (400 mL/min Flow Rate)		
	30 cm Straight	**24 cm Curved Extension**
Venous (mm Hg)	**226**	**193**
Arterial (mm Hg)	**-231**	**-195**

† As suggested by *In vitro data*, using a blood simulate approximating the viscosity of whole blood.

CARE AND MAINTENANCE

The care and and maintenance of the catheter requires well trained, skilled personnel following a detailed protocol. The protocol should include a directive that the catheter is not to be used for any purpose other than the prescribed therapy.

Accessing Catheter, Cap Changes, Dressing Changes[6]

- Experienced personnel
- Use aseptic technique
  - Proper hand hygiene
  - Clean gloves to access catheter and remove dressing and sterile gloves for dressing changes
  - Surgical mask (1 for the patient and 1 for the healthcare professional)
- Catheter exit site should be examined for signs of infection and dressings should be changed at each dialysis treatment or per hospital policy.
- Catheter Luer-lock connectors with end caps attached should be soaked for 3 to 5 minutes in povidone iodine and then allowed to dry before separation.
- Carefully remove the dressing and inspect the exit site for inflammation, swelling and tenderness. Notify physician immediately if signs of infection are present.

Exit Site Cleaning[6]

- Use aseptic technique (as outlined above).
- Clean the exit site at each dialysis treatment with chlorhexidine gluconate unless contraindicated. Apply antiseptic per manufacturer's recommendations. Allow to air dry completely.
- Cover the exit site with sterile, transparent, semipermeable dressing or per hospital protocol.

Recommended Cleaning Solutions

Catheter Luer-lock Connectors/End Caps:

- Povidone iodine (allow connectors/end caps to soak for 3 to 5 minutes) [6]

WARNING: Alcohol should not be used to lock, soak or declot polyurethane Dialysis Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

Hand cleaner solutions are not intended to be used for disinfecting our dialysis catheter Luer-lock connectors.

Exit Site:

- Chlorhexidine gluconate 2% solution (preferred) [7, 8, 9, 10, 11]
- Chlorhexidine gluconate 4% solution
- Dilute aqueous sodium hypochlorite
- 0.55% sodium hypochlorite solution
- Povidone iodine
- Hydrogen peroxide
- Chlorhexidine patches
- Bacitracin zinc ointments in petrolatum bases

WARNING: Acetone and Polyethylene Glycol (PEG)-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments (e.g., Polysporin* ointment) are the preferred alternative.

POST DIALYSIS

Use aseptic technique (as outlined above).

1. Flush arterial and venous lumens with a minimum of 10 mL of sterile saline.
   WARNING: To avoid damage to vessels and viscus, infusion pressures must not exceed 25 psi (172 kPa). The use of a 10 mL or larger syringe is recommended because smaller syringes generate more pressure than larger syringes.

2. Inject heparin solution into both the arterial and venous lumens of the catheter. The appropriate heparin solution concentration and flushing frequency should be based on hospital protocol. Heparin solution of 1,000 to 5,000 units/mL has been found to be effective for maintaining the patency of hemodialysis and apheresis catheters. When injecting heparin solution, inject quickly and clamp extension while under positive pressure. Heparin solution volume to lock each lumen must be equal to the priming volume of each lumen. Priming volumes are marked on each lumen.

3. Clean catheter Luer-lock connectors per hospital protocol. Attach sterile end caps to both the arterial and the venous clamping extension pieces.
   WARNING: To prevent systemic heparinization of the patient, the heparin solution must be aspirated out of both lumens immediately prior to using the catheter. In most instances, no further heparin solution injection is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.

CATHETER REMOVAL

After removing the catheter, apply manual pressure to the puncture site for 10-15 minutes until no signs of bledding are present. Then apply dressing for 8 hours.

DISPOSAL

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

TROUBLESHOOTING

PATIENT WITH FEVER

Patient with fever and chills following the procedure may be indicative of catheter-related bacteremia. If bacteremia is present, removal of the catheter may be indicated.

INSUFFICIENT FLOW

Excessive force must not be used to flush an obstructed lumen. Insufficient blood flow may be caused by an occluded tip resulting from a clot or by contacting the wall of the vein. If manipulation of the catheter or reversing arterial and venous lines does not help, then the physician may attempt to dissolve the clot with a thrombolytic agent (e.g., TPA, Cathflo* Activase* thrombolytic). Physician discretion advised.

CATHETER EXCHANGE

Do not routinely replace dialysis catheters to prevent catheter-related infections[11]. It may become necessary to exchange the indwelling catheter due to a persistent rise in pressures or decrease of flow rates which cannot be rectified through troubleshooting. Catheter exchanges should be performed under strict aseptic conditions in which the physician should wear a cap, mask, sterile gown, sterile gloves, and use a large sterile drape to cover the patient.

REFERENCES

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Other references available upon request.

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